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# Diabetes Guidelines Implementation Toolkit

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# "Diabetes Guidelines Implementation Toolkit"

# **Grady North Fulton Health Center**

Capstone Project Institute of Public Health, Georgia State University Gustavo Arguello Lacayo April 2011

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# **Section I: Introduction**

# 1) Definition of the Program

"Diabetes Guidelines Implementation Toolkit" is a capstone project aimed to help the Grady North Fulton Health Center implement the American Diabetes Association (ADA) "Standards in Medical Care in Diabetes, 2011" guidelines. In addition, this toolkit can be used to implement the ADA diabetes guidelines in any other primary or community healthcare facility to improve diabetes care.

Grady North Fulton Health Center is one of eight Neighborhood Health Centers of Grady Health System in Georgia. The center is located in North Fulton County on Roswell Road, Sandy Springs. Primary care services provided by the center include family medicine, pediatrics, and women's health (OB/GYN). It also provides laboratory services, translation services, and financial counseling. In 2010, there were 8,682 patient visits to Grady North Fulton Health Center, and that accounts for 6.3% of the clinic visit in all neighborhood clinics.

Grady Health System is aiming to implement the Patient Centered Medical Home (PCMH) model in its Neighborhood Health Centers, and Grady North Fulton Health Center is now going through the process of being certified by the National Committee of Quality Assurance (NCQA) as a Patient Centered Medical Home.

To become PCMH certified the health center is required to implement evidence-based guidelines for three of the most common diseases treated at the facility. This implementation toolkit will help to fulfill this standard and achieve the PCMH certification.

A toolkit is defined as a collection of information, resources, and recommendations for a specific subject area or activity; or as a set of tools designed to be used together or for a particular purpose. A toolkit is used, intended or design to train, implement, assess, evaluate and survey the individuals using it.

Once the decision is made to put the evidence-based diabetes guidelines into practice, this implementation toolkit will serve as a guide to help to direct the process of implementation. The toolkit will suggest practical ways to implement the use of the guidelines, and it will provide resources and template materials such as information handouts, flow sheets, referral forms, sample patient letters, etc.

The American Diabetes Association (ADA) annually publishes the "Standards in Medical Care in Diabetes" in its magazine *Diabetes Care*. This document is intended to guide physicians in the evidence-based best practices to care for diabetic patients. The clinical team at Grady North Fulton Health Center selected these guidelines because they are well accepted as standards by the national medical community for diabetes care.

# 2) Program Objectives

The objective of this program is to help the Grady North Fulton Health Center or any other community healthcare facility implement the evidence-based diabetes guidelines. The ultimate goal of implementation is to improve the delivery of effective preventive health care services and promote diabetes preventive behaviors in order to prevent diabetes, its complications and disabilities, and the burden associated with the disease.

Diabetes can affect many parts of the body and can lead to serious complications such as blindness, kidney damage, and lower-limb amputations. Working together, people with diabetes, their support network, and their health care providers can reduce the occurrence of these and other diabetes complications. Proven methods for reducing diabetes complications include by controlling the levels of blood glucose, blood pressure, and blood lipids, and receiving other preventive care practices in a timely manner.

# 3) Program Rationale

# A. The Importance of Diabetes

The World Health Organization (WHO) estimates that there are more than 220 million people worldwide living with diabetes. WHO projects diabetes deaths will double between 2005 and 2030. (WHO, 2011)

According to the Center for Disease Control and Prevention (CDC), diabetes affects 25.8 million people in the U.S. This accounts for 8.3% of the U.S. population. Only 18.8 million affected persons have a diabetes diagnosis and the remaining 7 million are undiagnosed. In 2010 there were 1.9 million people aged 20 or older newly diagnosed. Among people aged 65 or older 26.9% had diabetes in 2010. (CDC, 2011)

Diabetes is the leading cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults in the United States. Diabetes is also a major cause of heart disease and stroke, and it is the seventh leading cause of death in the United States, appearing in 71,382 death certificates as the underlying cause of death and in 160,022 as contributing cause of death in 2007. It is also important note that diabetes is likely to be underreported as a cause of death. Overall, the risk for death among people with diabetes is about twice that of people of similar age without diabetes. (CDC, 2011)

Pre-diabetes is a condition in which individuals have blood glucose or glycosylated hemoglobin (Hb A1C) levels higher than normal but not high enough to be classified as diabetes. People with pre-diabetes have an increased risk of developing type 2 diabetes, heart disease, and stroke. Estimates based on fasting glucose or hemoglobin A1C levels yields that 35% of U.S. adults aged 20 years or older had pre-diabetes (50% of adults aged 65 years or older) between 2005 and 2008. (CDC, 2011)

The 2007–2009 national survey data for people aged 20 years or older indicate that 7.1% of non-Hispanic whites, 8.4% of Asian Americans, 11.8% of Hispanics, and 12.6% of non-Hispanic blacks had diagnosed diabetes. Among Hispanics, rates were 7.6% for both Cubans and for Central and South Americans, 13.3% for Mexican Americans, and 13.8% for Puerto Ricans. (CDC, 2011)

Adults with diabetes have heart disease death rates about 2 to 4 times higher than adults without diabetes. The risk for stroke is 2 to 4 times higher among people with diabetes. In 2005–2008, of adults aged 20 years or older with self-reported diabetes, 67% had blood pressure greater than or equal to 140/90 millimeters of mercury (mmHg) or used prescription medications for hypertension. In the same frame period, 28.5% people with diabetes aged 40 years or older had diabetic retinopathy, and of these 4.4% had advanced diabetic retinopathy that could lead to severe vision loss. (CDC, 2011)

Patients with diabetes account for 44% of all new cases of kidney failure in 2008. About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage. The results of such damage include impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, erectile dysfunction, or other nerve problems. Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations. More than 60% of non-traumatic lower-limb amputations occur in people with diabetes, and in 2006, about 65,700 non-traumatic lower-limb amputations were performed in people with diabetes. (CDC, 2011)

The estimated cost (direct and indirect) of diabetes in the U. S. in 2007 was \$174 billion. The direct medical cost was \$116 billion and the indirect cost (disabilities, work loss, premature mortality) was \$58 billion. The medical expenses for people with diabetes are more than two times (2.3) higher than for people without diabetes. (CDC, 2011) In the United Kingdom (UK), around 10% of National Health Service spending goes on diabetes and its complications. (The Lancet, 2010)

The goal of medical care for people with diabetes is to optimize glycemic control and minimize complications. To achieve optimal glucose control, the person with diabetes should be able to access health care providers who have expertise in the field of diabetes. Treatment plans must also include self-management training and tools, regular and timely laboratory evaluations, medical nutrition therapy, appropriately prescribed medications, and regular self-monitoring of blood glucose levels. (ADA, 2010)

#### **B.** Clinical Practice Guidelines

Disease-specific standards for directing patient management are becoming increasingly important. These standards, however, are often not followed because they are not sufficiently integrated into the clinical care setting. Medical organizations have shown a growing interest in the establishment and dissemination of clinical policies for different practice areas in order to improve quality of care. Government agencies have seen practice guidelines as a potentially useful tool in promoting a more cost-effective use of resources in health care, and in reducing variations in practice styles. (Nilasena & Lincoln, 1995)

Clinical Practice Guidelines (CPGs) have been developed as one tool to help reduce unexplained variation in clinical practice, control cost, and produce better patient outcomes. CPGs are statements developed systematically to assist practitioners and patients in choosing appropriate health care for specific clinical circumstances. They incorporate available evidence on health outcomes into sets of recommendations concerning appropriate management strategies for patient with specific conditions. (Chodoff & Crowley, 1995)

The purposes of CPGs are limiting variations in practice that may signal problems in the quality of service; eliminating or reducing unnecessary costs associated with variations in practice; influencing health care practice in a scientific direction by providing concise guides to practice based on the consensus of experts; providing up-to-date summaries of evidence-based "best practices" accessible to practitioners in a format they find usable; and providing a basis for educating the public on the value, risks and benefits of diagnostic and therapeutic procedures. (Lewis, 1995)

As defined by the Institute of Medicine (IOM), CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances". (Field & Lohr, 1990) The primary objective of CPGs is to recommend minimum standards of care for a specific patient population based on scientific evidence and expert opinion. (Clark et al., 2000)

CPGs can improve the quality of management of diabetes. The use of structured consultation prompts for the recording of clinical information recommended by the guidelines improves implementation of the guidelines in practice. (Feder et al., 1995) Diabetes is a common disease and its diagnosis is quantitative and relatively unambiguous. Chronic management of diabetes requires monitoring of several laboratory parameters and serial physical examinations common to all patients. (Lobach & Hammond, 1994)

An analysis by researchers at the CDC suggested that less than 5% of patients with diabetes receive care that follows the American Diabetes Association (ADA) guidelines. (Beckles et al., 1998) Poor adherence to guidelines may occur because physicians are not aware of or do not understand the rationale behind the guideline or because patients refuse to undergo

recommended interventions. More commonly, however, lack of adherence stems from "system" factors, including physicians not remembering screening guidelines in the midst of a busy primary care clinic, lack of time to carry out recommended procedures, lack of reimbursement, and lack of resources. (Kirkman et al., 2002)

One study in 1994 demonstrated that the use of Computer Assisted Management Protocol (CAMP) resulted in improvement of compliance with diabetes care standards. This demonstrates that CAMP is one effective tool by which practice guidelines can be integrated into the clinical setting and it also has a potentially important role in the evaluation of the care standards themselves. (Lobach & Hammond, 1994)

In another study the author found that the computer generated reminder system can improve physician compliance with established guidelines for diabetes preventive care. This improvement may result from the ability of the system to facilitate physician documentation of important care items. (Nilasena & Lincoln, 1995)

Another study showed that reminders programmed into a computerized medical record system improved rates of ophthalmology referral, hemoglobin A1C measurement, and nephropathy screening in an academic primary care clinic. (Kirkman et al., 1999)

Similarly, another study showed striking improvements in physiologic measures such as blood pressure, lipids, and hemoglobin A1C, process measures, and satisfaction with care in a managed care system through use of a multifaceted intervention that included an enhanced data management system, use of non-physician providers to perform some examinations, and use of protocols and standing orders. (Clark et al., 2001)

The American Diabetes Association (ADA) has proposed guidelines for the care of diabetic patients. The 2011 recommendations were recently published in their journal Diabetes Care as "Standards in Medical Care in Diabetes, 2011". Adherence to these guidelines could potentially reduce the complications of the disease by a significant degree. Thus, the successful implementation of these guidelines into medical practice could dramatically decrease the burden of suffering and the cost of health care for diabetic complications.

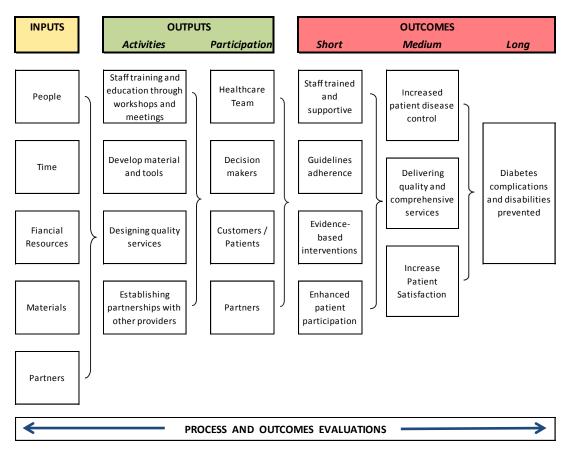
The ADA guidelines address items that should be included in the initial assessment of a patient with diabetes and define specific aspects of the initial medical history, physical examination, and laboratory assessment. Health care providers may wish to use items from the guideline in the initial assessment of their patients. (Clark et al., 2000)

# Section II: Program Design

# 1) Logic Model

A logic model is a simplified picture of a program, initiative, or intervention that shows the logical relationships among the resources that are invested, the activities that take place and the benefits or changes that result. The logic model is the "big picture" of the program that allows people to better understand the program activities, processes and desired outcomes. Logic models provide in a graphic display of boxes and arrows the relationships and linkages of the various components of the program. (McKenzie et. al., 2009)

Creating a logic model is an important part of the program planning process. It should be created in the early stage of planning to increase the effectiveness of the program. It should be revised frequently to ensure goals are being achieving. In this project a Logic Model was developed to guide in the implementation of the diabetes guidelines. The long term goal is to improve the delivery of effective preventive health care services in order to prevent diabetes, its complications and disabilities, and the burden associated with the disease.



#### **Diabetes Guidelines Implementation Logic Model**

# 2) Recommendations for the Implementation

Since medical knowledge and technological development rapidly advance, it is extremely important to keep the guidelines updated annually. Keeping the guidelines in accordance with ADA publications is essential to preserve the validity of the toolkit.

There are two main dimensions that need to be considered for successful implementation of the guidelines and promoting changes in practices: built local ownership from the staff responsible for the implementation of the new guideline and ensure that clinical and administrative systems are in place to facilitate staff adherence to the guideline. (Farley et al., 2005)

In the Army Medical Department (AMEDD) implementation of the Diabetes Practice Guidelines, six critical factors were identified that strongly influence how successful new practices were integrated into a clinical and administrative process. (Farley et al., 2005)

These factors are:

- Visible and consistent commitment by command leadership
- Ongoing monitoring of progress in carrying out an implementation plan
- Provision of implementation guidance and support, including toolkits of support materials and ready access to staff support and other resources
- Identification of a physician who is respected local opinion leader to serve as guideline champion and lead the implementation activities
- Provision of adequate dedicated time and resources support for the guideline champion to enable them to perform their task effectively
- Institutionalization of new practices as part of a clinic's normal routine procedures within a finite period.

It is important for the successful compliance of the guidelines to establish professional partnerships with other providers that will complement the services needed for the diabetic patient comprehensive care. Important partners to consider would be a Certified Diabetes Educator, a Medical Nutrition Therapist, an Ophthalmologist or Optometrist, and a Podiatry. The administrative team must contact them and establish proper channels of communication and flow to make the provision of services more suitable for the patient.

# 3) Timeline

In order for the program to be implemented smaller tasks were identified and prioritized, and a timeline table was created. Planning timelines can assist in defining the tasks and activities needed; the laying out of plans over the life of the project; and the monitoring of progress so that midcourse correction can be made if needed. (McKenzie et. al., 2009) The timeline

recommendations for program planning, implementation, and evaluation are provided in the table below.

It is important to provide some notice in advance to the staff, stakeholders, and clients about the implementation of the program. It is necessary to start with an announcement and the appointment of a leadership team who will lead program implementation. After this step it is necessary to assign responsibilities and roles that healthcare team members will take. Preparation of tools, materials, and data input into the diabetes patient registry can be started in the first four months of the planning process. Prior to the program "Kick Off" the staff and personnel should be trained on all tools that are available. This is the appropriate time to collect baseline data for future program evaluation and comparison.

Celebrating the "Kick Off" on "World Diabetes Day," November 14<sup>th</sup>, will bring awareness to the global response to diabetes. Six months is enough time for successful implementation and adoption of the guidelines. The first process evaluation can be done at the 6th month of the full implementation process.

TASKS			MONTHS										
YEAR 1	J	J	Α	S	0	Ν	D	J	F	Μ	А	Μ	
Announce the program and leadership	V												
Assign responsibilities	V												
Prepare the materials and tools	V	V	V	V									
Start the patient registry	V	V	٧	V	V								
Train staff and personnel					V								
Baseline data collection					V								
Celebration of World Diabetes Day						V							
Program "Kick Off"						V							
Full implementation						V	V	V	V	٧	٧	٧	
Process evaluation											٧	V	

**Timeline Table** 

# 4) Program Evaluation

Any program regardless of the size, nature, and duration must have an appropriate and adequate evaluation. The most critical purposes of the program evaluations are to assess and improve quality, and determine effectiveness. During the evaluation process, three different types of evaluation take place: process evaluation, impact evaluation, and outcome evaluation. (McKenzie et. al., 2009)

The process evaluation is any combination of measurements obtained during the implementation of program activities to control, assure, or improve the quality of the program.

Impact evaluation focuses on the immediate observable effects of a program, leading to the intended outcome of a program. Outcome evaluation focuses on an ultimate goal or product of a program or treatment, generally measured in the health field by mortality or morbidity data in a population, vital measures, symptoms, signs, or physiological indicators on individuals; this evaluation is long term in nature. (McKenzie et. al., 2009)

The data will need to be collected in three different time periods in the first year of implementation: baseline, mid-term evaluation and final evaluation. Since this is a program that will be implemented and ongoing, the evaluation must take place periodically. It is appropriate for the mid-term evaluation to take place six months after the program is implemented and for the final evaluation to occur twelve months after implementation. Later on the program can be evaluated every six or twelve months. The data collection at the baseline, mid-term and final evaluation will be used to perform both a process and outcome evaluation.

The baseline data might already be available through the organization or it may have to be collected prior to program implementation. The objective of collecting baseline data is to allow comparison to determine changes that have occurred since implementation.

The mid-term evaluation should be performed six months after the implementation of the program. The mid-term evaluation is important to determine what is going well and what is not going well during the first six months. Conducting a process evaluation at this point will allow the organization to make changes in how the program is being run and to address any concerns or issues that have appeared.

The final evaluation should take place twelve months after implementation to determine the effectiveness of the program. An outcome evaluation is data dependent and looks at numbers and facts in order to determine results.

To perform the evaluation of this program chart audits of all encounters with diabetic patients have to be done. The measurements will be documented and followed from the electronic medical records system used in the health center. Some important indicators and variables that need to be monitored to perform the evaluation of the program are listed below:

- Percentage of diabetic patients with Hb A1C less than 6 months old.
- Percentage of diabetic patients with lipid profile less than 12 months old.
- Percentage of diabetic patient with nephropathy tests less than 12 months old.
- Percentage of diabetic patients with an eye dilated exam less than 12 months old.
- Percentage of diabetic patients with a comprehensive foot exam less than 12 months old.
- Percentage of diabetic patients that has received the influenza vaccine in the last 12 months.
- Percentage of diabetic patients that has received pneumococcal vaccine.
- Percentage of the Diabetes Flow Sheets up-to-dated.

- Provider compliance: calculated as the number of required guidelines followed over the total number of required guidelines, and expressed as percent compliance.
- Percentage of diabetic patients with blood pressure controlled.
- Percentage of diabetic patient with glucose blood level under control.

# Section III: Program Implementation

This section includes the most relevant information for preventive diabetes care from the American Diabetes Association's "Standards in Medical Care in Diabetes, 2011" and the tools designed for the implementation of the guidelines. This toolkit is focused on preventive measures and interventions to encourage and empower the entire health care team and promote adherence to the guidelines. All the interventions can be collectively performed by the health care team, not only by physicians. However, in order to focus on the therapeutic guidelines it is necessary to develop a standardized treatment protocol targeted to physicians.

# 1) Educational Information for Diabetes Care by Healthcare Personnel

Diabetes is a chronic illness that requires continuing medical care and ongoing patient selfmanagement education and support to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and requires that many issues, beyond glycemic control, be addressed. A large body of evidence exists that supports a range of interventions to improve diabetes outcomes. (ADA, 2011)

These standards of care are intended to provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude clinical judgment or more extensive evaluation and management of the patient by other specialists as needed. The recommendations included are screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes. (ADA, 2011)

## A. Classification of Diabetes

The classification of diabetes includes four clinical classes:

- Type 1 diabetes (results from  $\beta$ -cell destruction, usually leading to absolute insulin deficiency)
- Type 2 diabetes (results from a progressive insulin secretory defect on the background of insulin resistance)
- Other specific types of diabetes due to other causes, e.g., genetic defects in β-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug or chemical-induced (such as in the treatment of HIV/AIDS or after organ transplantation)
- Gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy that is not clearly overt diabetes)

#### **B. Diagnosis of Diabetes**

For decades, the diagnosis of diabetes was based on plasma glucose criteria, either the fasting plasma glucose (FPG) or the 2-h value in the 75-g oral glucose tolerance test (OGTT). In 2009, the International Expert Committee that included representatives of the ADA, the International Diabetes Federation (IDF), and the European Association for the Study of Diabetes (EASD) recommended the use of the hemoglobin A1C test to diagnose diabetes, with a threshold of  $\geq$ 6.5%, and ADA adopted this criterion in 2010. The diagnostic test should be performed using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay.

The A1C has several advantages to the FPG and OGTT, including greater convenience, since fasting is not required; evidence to suggest greater pre-analytical stability; and less day-to-day perturbations during periods of stress and illness. These advantages must be balanced by greater cost, the limited availability of A1C testing in certain regions of the developing world, and the incomplete correlation between A1C and average glucose in certain individuals. The established glucose criteria for the diagnosis of diabetes (FPG and 2-h PG) remain valid as well (See Table 1).

Table 1: Criteria for the diagnosis of diabetes
A1C ≥ 6.5%. The test should be performed in a laboratory using a method that is NGSP
certified and standardized to the DCCT assay.*
OR
FPG ≥ 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*
OR
2-h plasma glucose ≥ 200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random
plasma glucose ≥ 200 mg/dl (11.1 mmol/l).
*In the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.
Source: ADA, 2011.

#### C. Categories of Increased Risk for Diabetes (Pre-Diabetes)

In 1997 and 2003, the Expert Committee on Diagnosis and Classification of Diabetes Mellitus recognized an intermediate group of individuals whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. These persons were defined as having impaired fasting glucose (IFG) (FPG levels 100–125 mg/dl [5.6–6.9 mmol/l]) or impaired glucose tolerance (IGT) (2-h PG values in the OGTT of 140 –199 mg/dl [7.8 –11.0

mmol/l]). It should be noted that the World Health Organization (WHO) and a number of other diabetes organizations define the cutoff for IFG at 110 mg/dl (6.1 mmol/l). In addition, it is it is reasonable to consider an A1C range of 5.7–6.4% as identifying individuals with high risk for future diabetes. (See Table 2)

Individuals with IFG and/or IGT have been referred to as having pre-diabetes, indicating the relatively high risk for the future development of diabetes. IFG and IGT should not be viewed as clinical entities in their own right but rather risk factors for diabetes as well as cardiovascular disease (CVD). IFG and IGT are associated with obesity (especially abdominal or visceral obesity), dyslipidemia with high triglycerides and/or low HDL cholesterol, and hypertension.

Table 2: Categories of increased risk for diabetes (pre-diabetes)*
FPG 100–125 mg/dl (5.6–6.9 mmol/l): IFG
OR
2-h plasma glucose in the 75-g OGTT 140–199 mg/dl (7.8–11.0 mmol/l): IGT
OR
A1C 5.7–6.4%
*For all three tests, risk is continuous, extending below the lower limit of the range
and becoming disproportionately greater at higher ends of the range.
Source: ADA, 2011.

#### D. Testing for Diabetes in Asymptomatic Patients

Testing for diabetes in asymptomatic patient should be considered in adults of any age with body mass index (BMI)  $\geq$ 25 kg/m2 and one or more of the known risk factors for diabetes. Because age is a major risk factor for diabetes, testing of those without other risk factors should begin no later than age 45 years. Either Hb A1C, FPG, or the 2-h OGTT is appropriate for testing. The 2-h OGTT identifies people with either IFG or IGT and thus more people at increased risk for the development of diabetes and CVD. It should be noted that the two tests do not necessarily detect the same individuals. If tests are normal, repeat testing carried out at least at 3-year intervals is reasonable. The appropriate interval between tests is not known. The rationale for the 3-year interval is that false negatives will be repeated before substantial time elapses, and there is little likelihood that an individual will develop significant complications of diabetes within 3 years of a negative test result. (See Table 3)

#### Table 3: Criteria for testing for diabetes in asymptomatic adult individuals

1. Testing should be considered in all adults who are overweight (BMI  $\ge$  25 kg/m2<sup>\*</sup>) and have additional risk factors:

- physical inactivity
- first-degree relative with diabetes
- high-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
- women who delivered a baby weighing > 9 lb or were diagnosed with GDM
- hypertension (≥140/90 mmHg or on therapy for hypertension)
- HDL cholesterol level <35 mg/dl (0.90 mmol/l) and/or a triglyceride level > 250 mg/dl (2.82 mmol/l)
- women with polycystic ovarian syndrome (PCOS)
- A1C  $\geq$  5.7%, IGT, or IFG on previous testing
- other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
  history of CVD
- 2. In the absence of the above criteria, testing for diabetes should begin at age 45 years.

3. If results are normal, testing should be repeated at least at 3-year intervals, with consideration of more frequent testing depending on initial results and risk status.

\*At-risk BMI may be lower in some ethnic groups. Source: ADA, 2011.

#### E. Initial Evaluation

A complete medical evaluation should be performed to classify the diabetes, detect the presence of diabetes complications, review previous treatment and glycemic control in patients with established diabetes, assist in formulating a management plan, and provide a basis for continuing care. Laboratory tests appropriate to the evaluation of each patient's medical condition should be performed. A focus on the components of comprehensive care will assist the health care team to ensure optimal management of the patient with diabetes. (See Table 4)

	Components of the comprehensive diabetes evaluation
Medical h	
	• Age and characteristics of onset of diabetes (e.g., diabetic ketoacidosis [DKA], asymptomatic laboratory finding)
	<ul> <li>Eating patterns, physical activity habits, nutritional status, and weight history; growth</li> </ul>
	and development in children and adolescents
	Diabetes education history
	<ul> <li>Review of previous treatment regimens and response to therapy (A1C records)</li> </ul>
	<ul> <li>Current treatment of diabetes, including medications, meal plan, physical activity</li> </ul>
	patterns, and results of glucose monitoring and patient's use of data
	<ul> <li>DKA frequency, severity, and cause</li> </ul>
	Hypoglycemic episodes
	<ul> <li>Hypoglycemia awareness</li> </ul>
	Any severe hypoglycemia: frequency and cause
	History of diabetes-related complications
	<ul> <li>Micro-vascular: retinopathy, nephropathy, neuropathy (sensory, including history of foot lesions; autonomic, including sexual dysfunction and gastroparesis)</li> </ul>
	<ul> <li>Macro-vascular: coronary heart disease (CHD), cerebrovascular disease, peripheral artery disease (PAD)</li> </ul>
	Other: psychosocial problems, dental disease
Physical e	xamination
	<ul> <li>Height, weight, body mass index (BMI)</li> </ul>
	<ul> <li>Blood pressure determination, including orthostatic measurements when indicated</li> </ul>
	Fundoscopic examination
	Thyroid palpation
	<ul> <li>Skin examination (for acanthosis nigricans and insulin injection sites)</li> </ul>
	Comprehensive foot examination:
	Inspection
	<ul> <li>Palpation of dorsalis pedis and posterior tibial pulses</li> </ul>
	<ul> <li>Presence/absence of patellar and Achilles reflexes</li> </ul>
	<ul> <li>Determination of proprioception, vibration, and monofilament sensation</li> </ul>
Laborato	ry evaluation
	<ul> <li>A1C, if results not available within past 2–3 months</li> </ul>
	<ul> <li>If not performed/available within past year:</li> </ul>
	<ul> <li>Fasting lipid profile, including total, LDL and HDL cholesterol and triglycerides</li> </ul>
	Liver function tests
	<ul> <li>Test for urine albumin excretion with spot urine albumin-to-creatinine ratio</li> </ul>
	<ul> <li>Serum creatinine and calculated glomerular filtration rate (GFR)</li> </ul>
	Thyroid- stimulating hormone in type 1 diabetes, dyslipidemia, or women over age 50 years
Referrals	
	Annual dilated eye exam
	<ul> <li>Family planning for women of reproductive age</li> </ul>
	<ul> <li>Registered dietitian for medical nutrition therapy (MNT)</li> </ul>
	<ul> <li>Diabetes self-management education (DSME)</li> </ul>
	Dental examination
	Mental health professional, if needed

Source: ADA, 2011.

#### F. Glycosylated Hemoglobin (A1C)

Because A1C is thought to reflect average glycemia over several months, and has strong predictive value for diabetes complications, A1C testing should be performed routinely in all patients with diabetes, at initial assessment and then as part of continuing care. Measurement approximately every 3 months determines whether a patient's glycemic targets have been reached and maintained. For any individual patient, the frequency of A1C testing should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician. Some patients with stable glycemia well within target may do well with testing only twice per year, while unstable or highly intensively managed patients (e.g., pregnant type 1

women) may be tested more frequently than every 3 months. The availability of the A1C result at the time that the patient is seen (point-of-care testing) has been reported to result in increased intensification of therapy and improvement in glycemic control. (See Table 5)

#### Table 5: Recommendation for A1C testing

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals.
- Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed.

Source: ADA, 2011.

#### G. Glycemic Goals in Adults

Glycemic control is fundamental to the management of diabetes. Lowering A1C to below or around 7% has been shown to reduce micro-vascular and neuropathic complications of diabetes and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macro-vascular disease. Therefore, a reasonable A1C goal for many non-pregnant adults is <7%. (See Table 6)

Because additional analyses from several randomized trials suggest a small but incremental benefit in micro-vascular outcomes with A1C values closer to normal, providers might reasonably suggest more stringent A1C goals for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes, long life expectancy, and no significant cardiovascular disease (CVD). Conversely, less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macro-vascular complications, extensive comorbid conditions, and those with longstanding diabetes in whom the general goal is difficult to attain despite diabetes self-management education (DSME), appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin.

Table 6: Glycemic recommendations for non-pregnant adults with diabetes						
A1C	< 7.0%					
Pre-prandial capillary plasma glucose	70–130 mg/dl (3.9–7.2					
Peak post-prandial capillary plasma glucose	mmol/l)					
<ul> <li>Goals should be individualized based on:</li> </ul>	< 180 mg/dl* (<10.0 mmol/l)					
<ul> <li>duration of diabetes</li> </ul>						
<ul> <li>age/life expectancy</li> </ul>						
<ul> <li>comorbid conditions</li> </ul>						
<ul> <li>known CVD or advanced micro-vascular</li> </ul>						
complications						
<ul> <li>hypoglycemia unawareness</li> </ul>						
<ul> <li>individual patient considerations</li> </ul>						
<ul> <li>More or less stringent glycemic goals may be</li> </ul>						
appropriate for individual patients.						
<ul> <li>Post-prandial glucose may be targeted if A1C</li> </ul>						
goals are not met despite reaching pre-prandial						
glucose goals.						
*Post-prandial glucose measurements should be made 1–2 h after the beginning of the meal,						
generally peak levels in patients with diabetes.						
Source: ADA 2011						

Source: ADA, 2011.

#### H. Hypertension/Blood Pressure Control

Cardiovascular disease (CVD) is the major cause of morbidity and mortality for individuals with diabetes, and the largest contributor to the direct and indirect costs of diabetes. The common conditions coexisting with type 2 diabetes (e.g., hypertension and dyslipidemia) are clear risk factors for CVD, and diabetes itself confers independent risk. Hypertension is a common comorbidity of diabetes, affecting the majority of patients, with prevalence depending on type of diabetes, age, obesity, and ethnicity. Hypertension is a major risk factor for both CVD and micro-vascular complications. In type 1 diabetes, hypertension is often the result of underlying nephropathy, while in type 2 diabetes it usually coexists with other cardio-metabolic risk factors.

The recommendation for screening and diagnosis of hypertension is that blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure  $\geq$ 130 mmHg or diastolic blood pressure  $\geq$ 80 mmHg should have blood pressure confirmed on a separate day. Repeat systolic blood pressure  $\geq$ 130 mmHg or diastolic blood pressure  $\geq$ 80 mmHg confirms a diagnosis of hypertension.

The recommended goals for a blood pressure control are: a systolic blood pressure <130 mmHg is appropriate for most patients with diabetes; based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate; patients with diabetes should be treated to a diastolic blood pressure <80 mmHg.

Measurement of blood pressure in the office should be done by a trained individual and should follow the guidelines established for non-diabetic individuals: measurement in the seated position, with feet on the floor and arm supported at heart level, after 5 min of rest. Cuff size

should be appropriate for the upper arm circumference. Elevated values should be confirmed on a separate day. Because of the clear synergistic risks of hypertension and diabetes, the diagnostic cut-off for a diagnosis of hypertension is lower in people with diabetes (blood pressure  $\geq$ 130/80) than those without diabetes (blood pressure 140/90 mmHg).

## I. Dyslipidemia/Lipid Management

Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of CVD. For the past decade or more, multiple clinical trials demonstrated significant effects of pharmacologic (primarily statin) therapy on CVD outcomes in subjects with CHD and for primary CVD prevention. Low levels of HDL cholesterol, often associated with elevated triglyceride levels, are the most prevalent pattern of dyslipidemia in persons with type 2 diabetes.

The recommendations for screening of dyslipidemia in diabetic patients are: in most adult patients, measure fasting lipid profile at least annually; in adults with low-risk lipid values (LDL cholesterol <100 mg/dl, HDL cholesterol >50 mg/dl, and triglycerides <150 mg/dl), lipid assessments may be repeated every 2 years.

## J. Nephropathy Screening

Diabetic nephropathy occurs in 20–40% of patients with diabetes and is the single leading cause of end-stage renal disease (ESRD). Persistent albuminuria in the range of 30–299 mg/24 h (micro-albuminuria) has been shown to be the earliest stage of diabetic nephropathy in type 1 diabetes and a marker for development of nephropathy in type 2 diabetes. Micro-albuminuria is also a well-established marker of increased CVD risk. Patients with micro-albuminuria who progress to macro-albuminuria (300 mg/24 h) are likely to progress to ESRD. Intensive diabetes management with the goal of achieving near-normoglycemia has been shown to delay the onset of micro-albuminuria and the progression of micro- to macro-albuminuria in patients with type 1 and type 2 diabetes.

As general recommendations to reduce the risk or slow the progression of nephropathy, optimize glucose control and blood pressure control. The recommendation for screening are: perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of 5 years and in all type 2 diabetic patients starting at diagnosis; and measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD), if present.

## K. Retinopathy Screening

Diabetic retinopathy is a highly specific vascular complication of both type 1 and type 2 diabetes, with prevalence strongly related to the duration of diabetes. Diabetic retinopathy is

the most frequent cause of new cases of blindness among adults aged 20–74 years. Glaucoma, cataracts, and other disorders of the eye occur earlier and more frequently in people with diabetes. In addition to duration of diabetes, other factors that increase the risk of, or are associated with, retinopathy include chronic hyperglycemia, the presence of nephropathy, and hypertension.

As general recommendations to reduce the risk or slow the progression of retinopathy, optimize glycemic control and blood pressure control.

The recommendation for screening of retinopathy are: adults and children aged 10 years or older with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes; patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes; subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist; less frequent exams (every 2–3 years) may be considered following one or more normal eye exams; and examinations will be required more frequently if retinopathy is progressing.

## L. Neuropathy Screening

The diabetic neuropathies are heterogeneous with diverse clinical manifestations. They may be focal or diffuse. Most common among the neuropathies are chronic sensor-motor diabetic peripheral neuropathy (DPN) and autonomic neuropathy. Although DPN is a diagnosis of exclusion, complex investigations to exclude other conditions are rarely needed.

The early recognition and appropriate management of neuropathy in the patient with diabetes is important for a number of reasons: 1) non-diabetic neuropathies may be present in patients with diabetes and may be treatable, 2) a number of treatment options exist for symptomatic diabetic neuropathy, 3) up to 50% of DPN may be asymptomatic and patients are at risk of insensate injury to their feet, and 4) autonomic neuropathy and particularly cardiovascular autonomic neuropathy is associated with substantial morbidity and even mortality.

The recommendations for neuropathy screening are: all patients should be screened for distal symmetric polyneuropathy at diagnosis and at least annually thereafter, using simple clinical tests; and screening for signs and symptoms of autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes.

## M. Foot Care

Amputation and foot ulceration, consequences of diabetic neuropathy and/or peripheral arterial disease (PAD), are common and major causes of morbidity and disability in people with diabetes. Early recognition and management of risk factors can prevent or delay adverse

outcomes. The risk of ulcers or amputations is increased in people who have the following risk factors: previous amputation, past foot ulcer history, peripheral neuropathy, foot deformity, peripheral vascular disease, visual impairment, diabetic nephropathy (especially patients on dialysis), poor glycemic control, and cigarette smoking.

For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold).

Provide general foot self-care education to all patients with diabetes. A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. Refer patients who smoke, have loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long surveillance.

Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options.

## N. Immunization

Influenza and pneumonia are common, preventable infectious diseases associated with high mortality and morbidity in the elderly and in people with chronic diseases. People with diabetes may be at increased risk of the bacteremic form of pneumococcal infection and have been reported to have a high risk of nosocomial bacteremia, which has a mortality rate as high as 50%. Safe and effective vaccines are available that can greatly reduce the risk of serious complications from these diseases.

The recommendations are annually provide an influenza vaccine to all diabetic patients at least 6 months of age; and administer pneumococcal polysaccharide vaccine to all diabetic patient  $\geq$ 2 years of age. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immune-compromised states, such as after transplantation.

## **O. Diabetes Self-Management Education**

Diabetes self-management education (DSME) is an essential element of diabetes care, and national standards for DSME are based on evidence for its benefits. Education helps people

with diabetes initiate effective self-management and cope with diabetes when they are first diagnosed. Ongoing DSME and support also help people with diabetes maintain effective self-management throughout a lifetime of diabetes as they face new challenges and treatment advances become available. DSME helps patients optimize metabolic control, prevent and manage complications, and maximize quality of life in a cost-effective manner.

DSME is the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes. The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving, and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life in a cost-effective manner.

The recommendations are: people with diabetes should receive DSME according to national standards when their diabetes is diagnosed and as needed thereafter; effective self-management and quality of life are the key outcomes of DSME and should be measured and monitored as part of care; DSME should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes.

## P. Medical Nutrition Therapy

Medical nutrition therapy (MNT) is an integral component of diabetes prevention, management, and self-management education. In addition to its role in preventing and controlling diabetes, ADA recognizes the importance of nutrition as an essential component of an overall healthy lifestyle. Achieving nutrition-related goals requires a coordinated team effort that includes the active involvement of the person with pre-diabetes or diabetes. Because of the complexity of nutrition issues, it is recommended that a registered dietitian who is knowledgeable and skilled in implementing nutrition therapy into diabetes management and education be the team member who provides MNT.

As general recommendations individuals who have pre-diabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT.

# Q. Physical Activity

Exercise is an important part of the diabetes management plan. Regular exercise has been shown to improve blood glucose control, reduce cardiovascular risk factors, contribute to weight loss, and improve well-being. Furthermore, regular exercise may prevent type 2 diabetes in high-risk individuals.

The recommendations are: people with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate); and

in the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week.

#### **R. Smoking Cessation**

A large body of evidence from epidemiological, case-control, and cohort studies provides convincing documentation of the causal link between cigarette smoking and health risks. Much of the work documenting the impact of smoking on health did not separately discuss results on subsets of individuals with diabetes, but suggests that the identified risks are at least equivalent to those found in the general population. Other studies of individuals with diabetes consistently demonstrate that smokers have a heightened risk of CVD, premature death, and increased rate of micro-vascular complications of diabetes. Smoking may have a role in the development of type 2 diabetes.

The recommendations are: advise all patients not to smoke; and include smoking cessation counseling and other forms of treatment as a routine component of diabetes care.

## S. Antiplatelet Agents

Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous myocardial infarction or stroke (secondary prevention). Its net benefit in primary prevention among patients with no previous cardiovascular events is more controversial, both for patients with and without a history of diabetes.

Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%, such as in men <50 and women <60 years of age with no major additional CVD risk factors), since the potential adverse effects from bleeding likely offset the potential benefits. For patients with CVD and documented aspirin allergy, clopidogrel (75mg/day) should be used.

# 2) Tools for the Implementation

## A. Diabetes Flow Sheet

A flow sheet is simply a one page form that gathers all the patient information regarding a condition, in this program the condition addressed is diabetes. The flow sheet would be stored in the patient chart and serves as a reminder of care and a record of whether goals have been met. While flow sheets can be easy and effective tools on paper, they become infinitely more valuable when combined with computerized data. Computerized programs offer automatic reminders when patients need certain service and provide an easy way to track patient data overtime. (White, 2000)

Diabetes flow sheets can be used to promote better adherence to guidelines when it comes to assessing and treating diabetes. In one study in 54 family practice offices in New Jersey and Pennsylvania, it was found that diabetes flow sheets were used in 23% of medical records of patients with diabetes. The use of flow sheets was associated with better mean guideline adherence scores for the assessment and the treatment of diabetes. (Hahn, 2008)

The Canadian Diabetes Association (CDA) designed a Diabetes Flow Sheet (using the CDA clinical practice guidelines) to assist primary care practitioners in treating their patients and to provide ongoing feedback. This feedback helps primary care practitioners to attain and maintain compliance with their CPGs. Using this tool primary care practitioners have access to care guidelines and directed assistance to achieve targets. They have a tool that is practical and easy to use. Patients' treatment plans are continuously audited improving outcome and reducing morbidity and mortality. Overall, the participating physicians did improve standards of care and guideline compliance in their respective practices as a result of this project. (Patasi & Conway, 2008)

In this toolkit a Diabetes Flow Sheet was developed according to the ADA "Standards in medical care in diabetes, 2011" to facilitate the implementation and adherence to the diabetes guidelines at Grady North Fulton Health Center. This flow sheet is intended to be part of each diabetic patient's medical chart. It is strongly suggested to design and use the flow sheet in an electronic format integrated with the electronic health information system used in the facility. (See Appendix C)

The Diabetes Flow Sheet will hold the patient information and the measures of the standards. Every column will represent the date of an assessment and will contain the measures by date. Thus, in a single page the physician will have all the information relevant to diabetes care and can determine what needs to be done afterwards. If the flow sheet is integrated with the electronic medical records it can be filled automatically, if not, anyone from healthcare team can do it before or during the patient-physician encounter.

#### **B.** Patient Registry

A patient registry is an organized system that collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. (Gliklich & Dreyer, 2010)

The World Health Organization (WHO) defined registries in health information systems as "a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose." (Brooke, 1974)

A disease registry is one type of clinical information system that is effective in supporting new models for delivering chronic care. By tracking patient information, a disease registry helps physician and other members of the care team to identify and reach out to patients with gaps in care. It also prompts them to ensure that appropriate and timely care is provided during patient visits. (Metzger, 2004)

Electronic patient registries can help to reduce barriers to comprehensive care by improving record-keeping and targeted care. It has been suggested that diabetes management programs are successful in improving diabetes outcomes only when a registry is in place. (Hummel, et al. 2003)

Patient registries identify relevant sub-populations of patients for proactive care, which includes timely preventive and chronic care reminders and prompts to ensure that patients receive care at appropriate intervals. Registries are vital for providing high-quality care. (AAFP, 2007)

The patient registry is an important tool that will help to implement the diabetes guidelines and keep track of diabetic patients of the clinic. This tool is intended to keep patient's information up-to-date, defining goals and services they need to improve outcomes. Having a registry with the list of all diabetic patients and their important clinical measures would help the healthcare team to quickly identify which patients needs a reminder phone call, a new test or a referral to the specialist. Many of the data management and scheduling task can be performed by a clerical person supervised by a nurse or a physician.

Using a commercially available spreadsheet program, such as Microsoft Excel, a list (or registry) of the patients with a given chronic disease can be easily created. The registry can be used to track key measures and remind staff automatically when patients need certain labs and preventive services. Such lists can be accessed and managed by anyone on the staff (including nurses, medical assistants and administrative staff) with minimal training. The most difficult part of creating this spreadsheet is the initial data entry. This can be done over several months by assigning the job to a specific staff member or by hiring a part-time data-entry clerk to

perform the job. Once the initial worksheet has been created, any staff member can be assigned to the maintenance aspects. (Ortiz, 2006)

In this toolkit a Diabetes Registry spreadsheet was developed according to the ADA "Standards in medical care in diabetes, 2011" to facilitate the implementation and adherence to the diabetes guidelines at Grady North Fulton Health Center. This registry is intended to be used as a complement in the delivery of care of diabetic patients, using information from individual medical records and the Diabetes Flow Sheet. The database will need a person to provide maintenance and keep all the patient information up-dated. In addition this person will be responsible for effective communication with patients when it is needed. In this toolkit a Diabetes Reminded Letter is also provided to use it with the registry.

Ten diabetes target values were selected for monitoring according to the ADA standards: blood pressure, hemoglobin A1C, lipids profile (LDL, HDL, and triglycerides), kidney function tests (micro-albuminuria and creatinine), eye exam, foot exam, and influenza vaccination. The spreadsheet is programmed to change the color of cells to indicate values or services that need to be addressed for each patient. Red is present when the services are overdue or when any value is out of the standard. Yellow is present one month prior to the service being overdue. In the hemoglobin A1C column, yellow means that the patients are in the pre-diabetes range. The spreadsheet developed can be found in the appendixes with one example. (See Appendix D & E)

## C. Diabetes Reminder Letter

A Diabetes Reminder Letter can be used as a complement to the Diabetes Registry. When a patient is not in compliance with standards, a reminder letter can be sent to let them know what needs to be done before the next visit. The letter will basically remind the patient to schedule an appointment and to take the tests needed in the lab. A template diabetes reminder letter was developed and is included in this toolkit. (See Appendix F)

The Diabetes Reminder Letter was adapted from the one developed by Family Care Network, Copyright © 2000 American Academy of Family Physicians, and can be downloaded at: http://www.aafp.org/fpm/20000900/diabetesreminderletter.pdf

#### D. Eye Referral Form

Early detection and treatment of diabetic eye disease can prevent blindness, yet many persons with diabetes lack regular eye care. In addition, laser therapy applied to advanced diabetic proliferative retinopathy reduces the risk of severe vision loss by 50% or more. However, about a third of people with diabetes have never had ophthalmologic examinations and more than half of these individuals have eye disease. (Will, 1994)

A Retinal Eye Exam Communication Form was designed and it was already in use by Grady North Fulton Health Center. The patients take it to their eye doctors to fill it and they bring it back to the clinic to be storage in their medical charts. The fulfillment of the form guarantees the performance of a dilated eye exam by a specialist and promotes the patient participation and responsibility in their own diabetes care.

This form is included in this toolkit to be part of the implementation of the diabetes guidelines. It starts with the patient instruction. It has two sections; the section one is to be filled by the patient and the section two is to be filled by the eye care provider. (See Appendix G)

# E. Annual Comprehensive Diabetes Foot Exam Form

The comprehensive diabetes foot exam is a detailed, annual physical examination of feet, combined with an educational and counseling session, performed on people with diabetes. Nerve damage, poor circulation and trouble fighting infections, can make foot problems very serious for people with diabetes. The goal of the examination is to identify any changes in the feet, prevent problems and reduce the risk of amputations. The exam should only take about 15-20 minutes and will not include the treatment of corns, calluses or nails.

The Annual Comprehensive Diabetes Foot Exam Form is a tool that documents the inspection of the skin, hair, and nails, examination of musculoskeletal structures, pedal pulses, and protective sensation, assessment of risk for foot problems, assessment of footwear, and completing a management plan. (National Diabetes Education Program, 2000)

A physician or any other trained health care provider should conduct the foot exam. This form is very easy to fill and can be filled by the physician or the nurse. Every diabetic patient must have one of this forms in their medical record chart, the exam must be performed annually or in every visit if the patient have complication. If any complication is founded the patient must has to be referred to a podiatry provider. (See Appendix H)

This form is provided by the National Diabetes Education Program and it is available without cost to any provider and can be downloaded at:

http://www.chronicconditions.org/clearinghouse/doc/foot\_exam\_form.pdf

# F. 10-g Monofilament Test

The neurological evaluation of the foot is an important part of the comprehensive diabetic foot exam. The clinical exam recommended, however, is designed to identify loss of protective sensation (LOPS) rather than early neuropathy. The clinical examination to identify LOPS is simple and requires no expensive equipment. Five simple clinical tests are considered useful in the diagnosis of LOPS in the diabetic foot: the 10-g monofilament, vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, and vibration perception threshold testing (VPT). Ideally

two of these should be regularly performed during the screening exam. Normally the 10-g monofilament and one other test are performed. (Boulton, et al. 2008)

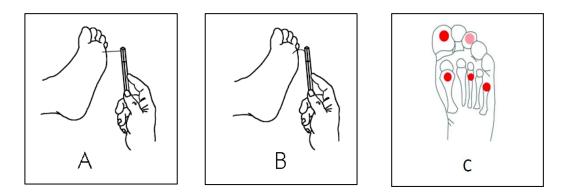
Many prospective studies have confirmed that loss of pressure sensation using the 10-g monofilament is highly predictive of subsequent ulceration. Nylon monofilaments are constructed to buckle when a 10-g force is applied; loss of the ability to detect this pressure at one or more anatomic sites on the plantar surface of the foot has been associated with loss of large-fiber nerve function. (Boulton, et al. 2008)

The nylon monofilament test is a simply performed office test to diagnose patients at risk for ulcer formation due to peripheral sensory neuropathy. The test is abnormal if the patient cannot sense the touch of the monofilament when it is pressed against the foot with just enough pressure to bend the filament.

The sensory testing device is a 5.07 (10-gram) Semmes-Weinstein nylon monofilament mounted on a holder that has been standardized to deliver a 10-gram force when properly applied. Research has shown that a person who can feel the 10-gram filament in the selected sites is at reduced risk for developing ulcers. Because sensory deficits appear first in the most distal portions of the foot and progress proximally in a "stocking" distribution, the toes are the first areas to lose protective sensation. (National Diabetes Education Program, 2000)

The technique for testing pressure perception with the 10-g monofilament is:

- The sensory exam should be done in a quiet and relaxed setting.
- The patient must not watch while the examiner applies the filament.
- Test the monofilament on the patient's hand so he/she knows what to anticipate.
- The five sites to be tested are indicated on the examination form. (See Diagram C)
- Apply the monofilament perpendicular to the skin's surface. (See Diagram A)
- Apply sufficient force to cause the filament to bend or buckle, using a smooth, not a jabbing motion. (See Diagram B)
- The total duration of the approach, skin contact, and departure of the filament at each site should be approximately 1 to 2 seconds.
- Apply the filament along the perimeter and NOT on an ulcer site, callus, scar or necrotic tissue.
- Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- Press the filament to the skin such that it buckles at one of two times as you say "time one" or "time two." Have patients identify at which time they were touched.
- Randomize the sequence of applying the filament throughout the examination.



To document the findings of the 10-gr monofilament test the foot diagram on the Annual Comprehensive Diabetes Foot Exam Form should be used.

#### **G.** Group Visits

Group visits are one way to broaden the doctor-patient relationship and incorporate system approaches to education, monitoring, process improvement, behavior modification, and social capital. (Gaynor, et. al., 2007) The group visit is a new treatment modality originating in managed care for efficient service delivery to patients with chronic health problems. Group visits offer promise for delivering care to diabetic patients, as visits are lengthier and can be more frequent, more organized, and more educational. Group visits can be a strategy to address adherence to guidelines. (Clancy, 2007)

One of the advantages of group visits is that providers can deliver consistent messages to multiple patients simultaneously in group visits, rather than repeating them individually to multiple patients. With open general discussions in group visits, patients potentially educate each other about referrals and tests experienced; perhaps hearing information from their peers resulted in higher acceptance of suggestions from the physicians. Incorporating motivational and behavioral strategies emphasizing patients' daily responsibilities and skill building for healthy lifestyles compatible with diabetes may affect improvements in clinical outcomes. (Clancy, 2007)

Group visits offer a cost-effective solution. In contrast to the typical 15-minute office visit, a two-hour group visit with 20 patients permits ample time for education and discussion. The benefits are wide-ranging: reduced health care expenses, improved patient and provider satisfaction, higher immunization rates, fewer repeat hospital admissions and fewer visits to the emergency department and subspecialists. (Masley, 2000)

A group visit can be performed following the next suggestions on the three important moments of a group visit: before, during, and after. Allow about two hours to plan and two hours to conduct a group visit with 20 patients. (Masley, 2000) Before the group visit allow 60 minutes for preparing or obtaining discussion material and/or scheduling guest speakers; and 60 minutes for chart review and documentation.

During the group visit give 30 minutes for collection of subjective and objective data, discussion of potential changes in therapy with patients, signing of chart notes and completion of billing slips; 15 minutes for group members to introduce themselves and for you to share your agenda and time schedule on a flip chart; 45 minutes for didactic information sharing; 15 minutes for questions and answers specific to your educational message and to plan the next group visit.

After the group visit allow 15 minutes for one-on-one meetings with patients to discuss urgent or unrelated problems they may bring to your attention during the group session. In our experience, one or two patients, at most, have needed attention for minor complaints.

## H. Patient Information Handouts

Patient information handouts are tools very useful in providing essential information to patient that helps them to improve their understanding about the diabetes and engage them in their self-care. There is a great amount of websites and organization that provide free or paid handouts. In this toolkit it is proposed to use the materials and handouts provided by the organization Learning About Diabetes, Inc. This organization is a non-profit, charitable, educational corporation dedicated to provide patients, caregivers, and health care professionals, easy-to-read highly illustrated, low literacy, and culturally sensitive health care information.

In the Learning About Diabetes website there are multiple types of handouts, booklets, picture histories, and comic books. All the information is about diabetes care and it is available for free in English and Spanish. In the toolkit we will include the most comprehensive handout to be used in the clinic, but at the website there are more available by specific topic. (See Appendix I)

The webpage is: <u>http://www.learningaboutdiabetes.org</u>

# 3) Other Resources and Organizations

#### American Diabetes Association

The American Diabetes Association (ADA) is a United States-based association working to fight diabetes and to help those affected by diabetes. The association funds research to manage, cure and prevent diabetes (including type 1 diabetes, type 2 diabetes, gestational diabetes, and pre-diabetes); delivers services to hundreds of communities; provides information for both patients and health care professionals; and gives voice to those denied their rights because of diabetes.

The ADA website provides comprehensive information for patients about the disease, care and prevention. It has a section for professional providing links to their journals, professional education opportunities, and resources. There is also included a series of diabetes animations for use in presentations for patients.

More information can be found at: <u>http://www.diabetes.org</u>

#### American Association of Diabetes Educators

The American Association of Diabetes Educators (AADE) is a multidisciplinary membership organization for healthcare professionals who specialize in teaching patients about diabetes and how to self-manage the disease. Founded in 1973, AADE works to define the practice of diabetes education, increase patients' access to the services of diabetes educators, and provide members with the support and tools to become leaders in the field of diabetes care. On its website they provide some resources to patients and physicians. They provide free handouts, videos and other resources.

More information can be found at: <u>http://www.diabeteseducator.org</u>

## **National Diabetes Education Program**

The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health, the Centers for Disease Control and Prevention, and more than 200 public and private organizations. The NDEP has developed a huge library of copyright free diabetes education materials targeting providers, patients, the media, and ethnic populations. Materials may be viewed on the NDEP Web site and many may be downloaded and reproduced.

More information can be found at: <u>http://www.ndep.nih.gov</u>

#### **MedlinePlus**

MedlinePlus is a website that brings together authoritative information from National Library of Medicine (NLM), the National Institutes of Health (NIH), and other government agencies and health-related organizations. Pre-formulated MEDLINE searches are included in MedlinePlus and give easy access to medical journal articles. MedlinePlus also has extensive information about drugs, an illustrated medical encyclopedia, interactive patient tutorials, and latest health news. In the diabetes section they have many links with information, pictures, tutorials and other resources very useful for patient.

More information can be found at: http://www.nlm.nih.gov/medlineplus/diabetes.html

#### **International Diabetes Federations**

The International Diabetes Federation (IDF) is an umbrella organization of over 200 national diabetes associations in over 160 countries. It represents the interests of the growing number of people with diabetes and those at risk. IDF's mission is to promote diabetes care, prevention and a cure worldwide. Led by the International Diabetes Federation, the Unite for Diabetes campaign secured a United Nations (UN) Resolution on diabetes in December 2006. The Resolution encourages UN Member States to develop national policies for the prevention, treatment and care of diabetes in line with the sustainable development of their health-care systems, taking into account the internationally agreed development goals, including the Millennium Development Goals (MDG). The IDF has developed a global guideline for type 2 diabetes.

More information can be found at: <u>http://www.idf.org</u>

#### **World Diabetes Day**

World Diabetes Day is celebrated every year on November the 14th. The World Diabetes Day campaign is led by the International Diabetes Federation (IDF) and its member associations. Created by the Federation and the World Health Organization in 1991, World Diabetes Day is an official United Nation's World Day. The campaign draws attention to issues of paramount importance to the diabetes world and keeps diabetes firmly in the public spotlight. You can access to the materials available at their webpage and celebrate the date with your patients.

More information can be found at: <u>http://www.worlddiabetesday.org</u>

## **Diabetes Recognition Program**

In 1997, the National Committee for Quality Assurance (NCQA) and the American Diabetes Association (ADA) developed and launched the Diabetes Physician Recognition Program (DPRP)

to help identify physicians providing quality diabetes care. Recognition is contingent on a physician or medical group demonstrating provision of care consistent with performance measures based on practice guidelines for managing diabetes. The DPRP-recognized physicians and groups are publicized through health plan provider directories and on the NCQA's Web site.

More information can be found at: <u>http://www.ncqa.org/tabid/139/Default.aspx</u>

#### **Bridges to Excellence Initiative: Diabetes Care Link**

Bridges to Excellence is a multistate, multiemployer coalition developed by employers, physicians, healthcare service researchers, and other industry experts to identify and reward quality across the healthcare system. Diabetes and BP control are a significant part of the pay-for-performance quality measurements, because this effort is built around the NCQA's recognition programs. The specific initiative that is part of the Bridges to Excellence program is called Diabetes Care Link. Physicians who demonstrate they are top performers in diabetes care can earn up to \$80 per year for each person with diabetes covered by a participating employer. To participate, physicians must demonstrate that their performance with diabetes management is consistent with the standards set by the NCQA/ADA's DPRP.

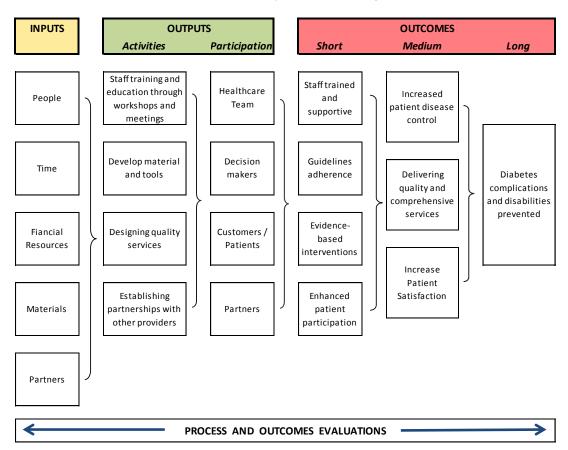
More information can be found at: <u>http://www.bridgestoexcellence.org</u>

# **Section IV: Appendix**

Appendix A: Logic Model Appendix B: Summary Table: ADA Standard of Medical Care in Diabetes, 2011 Appendix C: Diabetes Flow Sheet Appendix D: Diabetes Registry Spreadsheet Appendix E: Diabetes Registry Spreadsheet Example Appendix F: Diabetes Reminder Letter Appendix G: Retinal Eye Exam Communication Form Appendix H: Annual Comprehensive Diabetes Foot Exam Form Appendix I: Patient Information Handouts Appendix J: Sample Posters to Celebrate the World Diabetes Day Appendix K: Executive Summary: Standards of Medical Care in Diabetes, 2011

### **Appendix A: Logic Model**

The Logic model includes basically three components: inputs (or resources), outputs (or activities), and outcomes (or results or effects). The inputs or resources include the human, financial, organizational, and community resources a program has available to direct toward doing the work. The outputs or the program activities are what the program does with the resources. Activities are the processes, tools, events, technology, and actions that are an intentional part of the program implementation. These interventions are used to bring about the intended program changes or results. The outputs or results are the direct products of program activities and may include types, levels and targets of services to be delivered by the program. Outcomes are the specific changes in program participants' behavior, knowledge, skills, status and level of functioning. Short-term outcomes should be attainable within 1 to 3 years, while longer-term outcomes should be achievable within a 4 to 6 year timeframe. (Kellogg Foundation, 2004)



### **Diabetes Guidelines Implementation Logic Model**

# Appendix B: Summary Table: ADA Standard of Medical Care in Diabetes, 2011

	Assessment	Frequency of monitoring	Goal	Comments
Glycemic	control			
	Glycosylated hemoglobin (A1C)	2 times a year; quarterly in uncontrolled patients	≤7%	
	Pre-prandial capillary plasma glucose	As necessary for glycemic control	70–130 mg/dl (3.9–7.2 mmol/l)	
	Peak post-prandial capillary plasma glucose	As necessary for glycemic control	< 180 mg/dl* (<10.0 mmol/l)	Post-prandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes.
Blood pre Lipid prof		Each visit Annually; if low risk values every 2 years	< 130/80 mmHg	
	LDL cholesterol	CVCIY Z YEAIS	<100 mg/dl	
	HDL cholesterol		>50 mg/dl	
	Triglycerides		<150 mg/dl	
Nephropa			0.	
	Test for micro- albuminuria	Annually	<30 mg/24 h	
	Serum creatinine	Annually	<1.5 mg/dl	Should be used to estimate GFR and stage the level of chronic kidney disease (CKD), if present
Retinopat				
	Dilated eye examination by an ophthalmologist or optometrist.	Annually	Normal	Refer to ophthalmologist
Neuropat				
Immuniza	Foot examination	Annually	No complication	Refer to podiatrist
	Influenza vaccine	Annually	N/A	Recommended for all patient ≥6 months old
	Pneumococcal vaccine	One-time. Revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago	N/A	Recommended to all patients ≥2 years of age
Diabetes : educatior	self-management	At diagnosis and as needed thereafter	Healthy diabetes management with metabolic control	Refer to diabetes educator
Medical n	utrition therapy	As needed	Healthy eating and weight control	Refer to a dietitian familiar with the components of diabetes MNT
Physical a	ctivity	Each visit	150 minutes per week of moderate-intensity aerobic physical activity and resistance training three times per week	Exercise counseling related to type, frequency, duration, and intensity
Smoking	cessation	Each visit	No smoking	Refer to smoking cessation counseling

Source: ADA, 2011.

## **Appendix C: Diabetes Flow Sheet**

### DIABETES FLOW SHEET Grady North Fulton Health Center, Grady Health System

PATIENT	 HEIGHT
PROVIDER	DATE OF BIRTH
MR#	DATE OF DX.

\_\_\_\_\_

CTANDADD	6041	EDEOLIENIOV	DATE	DATE	DATE	DATE
STANDARD	GOAL	FREQUENCY				
Weight	N/A	each visit				
BMI	<25	each visit				
Blood pressure	<130/80mmhg	each visit				
Hb A1C	≤ 7%	q 4 - 6 month*				
LDL Cholesterol	<100mg/dl	annually				
HDL Cholesterol	>50mg/dl	annually				
Triglycerides	<150mg/dl	annually				
Microalbunimuria	<30mg/24 h	annually				
Creatinine	<1.5mg/dl	annually				
Eye examination**	Normal	annually				
Foot examination	Normal	annually				
Influenza vaccine	Received	annually				
Pneumococcal vaccine	Received	one-time***				
Review dietary pattern	Appropriate	each visit				
Review physical activity	Appropriate	each visit				
Review smoking status	No smoking	each visit				

\* 2 times a year in controlled patients; quarterly in uncontrolled patients.

\*\* Dilated eye examination by an ophthalmologist or optometrist.

\*\*\* Revaccination is recommended in >64 years of age previously immunized when they were <65 years if the vaccine was administered >5 years ago

	DATE LAST FLU VACCINATI ON	T																7
	DATELAST FOOTEXAM VAC					 				 		1		_				_
		+				 					_	+		_				_
	IT DATE LAST VE EYE EXAM					 												
	DATE LAST CREATININE																	
	CREATININE DATE LAST (MG/DL) CREATININE																	
	DATE LAST MICROALB UMINURIA																	
	MICROABU MINURIA (MG/24HR)																	
System	DATE LAST LIPID PROFILE																	
DIABETES REGISTRY Grady North Fulton Health Center, Grady Health System	TRYGLICERI DES (MG/DL)																	
EGISTRY nter, Grad	(NG/DL) HDL																	
DIABETES REGISTRY In Health Center, Gra	(NG/DL) LDL																	
DI th Fulton I	DATE LAST A1C																	
irady Nor	A1C (%)																	
0	DIASTOLIC BLOOD PRESSURE																	
	SYSTOLIC BLOOD PRESSURE																	
	DATE LAST VISIT																	
	PROVIDER																	
	MR#																	
	NAME																	

# Appendix D: Diabetes Registry Spreadsheet

DATELAST FLU VACCINATI ON	09/18/10	09/22/10	11/05/10	09/24/10	08/15/10	10/20/10	09/05/09	09/18/10												
DATE LAST FOOT EXAM	08/15/10	06/05/10	09/05/10	05/12/10	12/12/08	10/22/10	08/01/09	06/20/10												
DATE LAST EYE EXAM	06/05/10	08/05/10	12/30/10 04/09/10	06/12/10	01/10/09	01/81/60	0.8/15/09	06/25/10												
CREATININE DATE LAST (MG/DL) CREATININE	12/28/10	11/22/11	12/30/10	11/09/10		01/23/11	07/05/10	05/01/10												
CREATININE (MG/DL)	1.2	1.4	1.2	1.2	1.4	1.2	1.3	1.3												
DATE LAST MICROALB UMINURIA	12/28/10	11/25/10	12/30/10	12/01/10	03/10/10	01/23/11	07/05/10	05/01/10												
MICROABU MINURIA (MG/24HR)	23	29	25	24	28	18	22	28												
DATE LAST LIPID PROFILE	12/28/10	03/30/10	12/30/10	12/01/10	03/10/10	01/23/11	07/05/10	05/01/10												
TRYGLICERI DES (MG/DL)	125	112	149	139	1.90	115	140	125												
(NG/DL) HDL	54	50	52	56	49	20	52	53												
(ng/bit) IDL	98	66	66	88	110	66	95	67												
DATELAST A1C	12/28/10	11/25/10	12/30/10	12/01/10	03/10/10	11/82/10	07/05/10													
A1C (%)	6.4	6.5	6.3	5.5	1.1	8.0	6.0	5.6												
DIASTOLIC BLOOD PRESSURE	80	16	60	80	20	100	80	80												
SYSTOLIC BLOOD PRESSURE	130	1.40	110	120	130		130	120												
DATELAST VISIT	01/10/11	02/05/11	11/05/10	09/24/10	08/15/10	11/81/20	08/05/10	05/01/10												
PROVIDER	Dr. Provider 1	Dr. Provider 1	Dr. Provider 2	Dr. Provider 2	Dr. Provider 3	Dr. Provider 3	Dr. Provider 4	Dr. Provider 4												
MR#	111111111						TTTTTTTT	8888888888												
NAME	Sample Patient 1	Sample Patient 2 2222222	Sample Patient 3 3333333	Sample Patient 4 4444444	Sample Patient 5 55555555	Sample Patient 6 66666666	Sample Patient 7	Sample Patient 8												

# Appendix E: Diabetes Registry Spreadsheet Example

DIABETES REGISTRY Grady North Fulton Health Center, Grady Health System

## Appendix F: Diabetes Reminder Letter

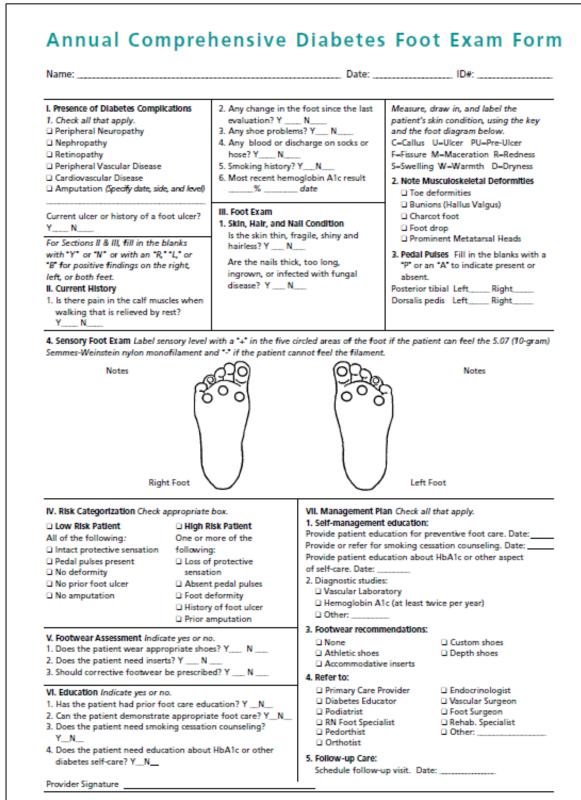
	Date://
Dear	:
t is time fo preparing fo	or your diabetes check-up. For the visit to be as beneficial as possible, we need your help in or it.
Please phor	ne the office at 404-612-6372 to schedule your appointment with:
	t results will be available for discussion at the time of your visit, please obtain the following oproximately one week prior to your scheduled appointment.
0	Hemoglobin A1C
0	Lipids (Fast for 12 hours)
0	Microalbuminuria test
0	Creatinine - blood
0	Other:
0	No lab work is needed
o.m.to 4:30 t is to you accomplish Your partici	ment is necessary for your lab work. The lab hours are 8:00 a.m.to 12:30 p.m. and 1:30 p.m., Monday through Friday. Ir benefit for you to think about your self-management goals and what you would like to at your diabetes visit. ipation is vital for good care of your diabetes. Thanks for taking care of yourself and helping for your visit.
	nportant that you bring this letter with you to the laboratory. Also, please bring your curren s list to your check-up.

## Appendix G: Retinal Eye Exam Communication Form

Retinal Eye Exam Comm	nunication Form
Patient Instructions:	
<ol> <li>Schedule an eye exam with an Ophthalmologist (</li> <li>Fill in Section 1 with your name, date of birth information of your primary care doctor.</li> <li>Take this form back to an eye doctor and have the</li> <li>Bring this form back to your primary care doct primary care doctor: <i>Grady North Fulton Clinic</i></li> </ol>	, and phone number and the name and contact em complete Section 2. tor or ask the eye doctor to send/fax it to your
Section 1 (To be completed by patient)	
NameDate of Birth:	/ / Phone
Physician:Dr. Ann Hoos-YoungDr. Hu	
Physician Address: Grady North Fulton Clinic, 7741 R	oswell Road, Sandy Springs, GA 30350
Physician Phone: 404 612-2273	
Section 2 (To be completed by Ophthalmologist)	
Eye Exam Date//	
Were eyes dilated for this exam? Yes () No ()	
Exam Results:	
	Ophthalmologist
No diabetic retinopathy	Name
Diabetic retinopathy requiring no treatment	
	Address
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease	
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment	Address
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease Follow-up Eye Exam recommendations:	Address
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease Follow-up Eye Exam recommendations: 3 Months6 Months1 YearOther	Address Phone
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease Follow-up Eye Exam recommendations: 3 Months6 Months1 YearOther	Address
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease Follow-up Eye Exam recommendations: 3 Months6 Months1 YearOther	Address
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease	Address Phone
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease Follow-up Eye Exam recommendations:	Address Phone Fax
Diabetic retinopathy requiring no treatment Diabetic retinopathy requiring treatment Other eye disease	Address         Phone         Fax         Fax         n in the patient's medical records

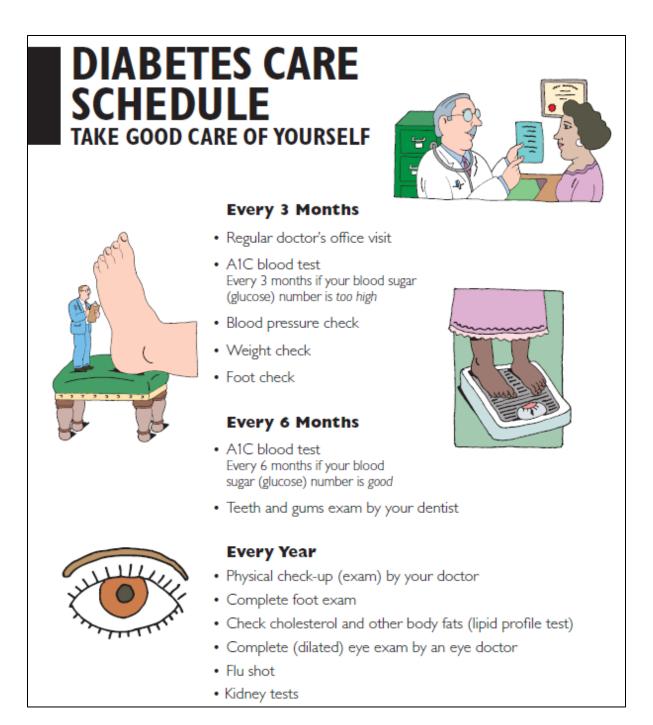
Source: Grady North Fulton Health Center

### **Appendix H: Annual Comprehensive Diabetes Foot Exam Form**

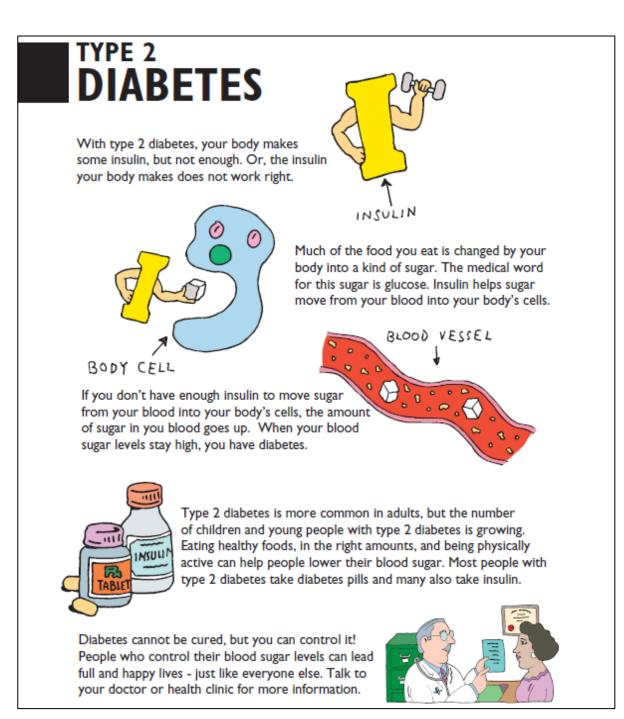


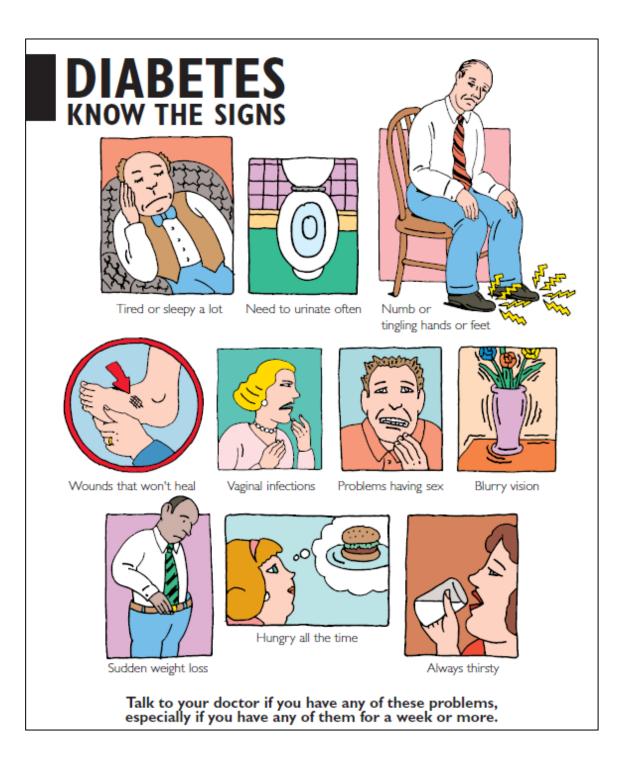
Available at: http://www.chronicconditions.org/clearinghouse/doc/foot exam form.pdf

### **Appendix I: Patient Information Handouts**









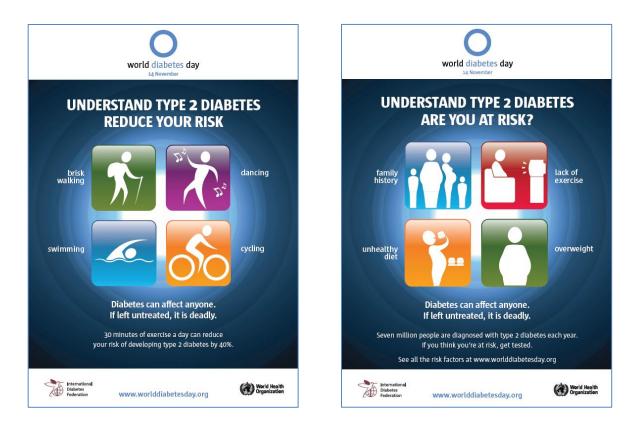
### Appendix J: Sample Posters to Celebrate the World Diabetes Day







Available in English and Spanish at: http://www.worlddiabetesday.org/en/materials/campaign-posters-0





Available in English and Spanish at: <u>http://www.worlddiabetesday.org/en/materials/campaign-posters-0</u>

# Appendix K: Executive Summary: Standards of Medical Care in Diabetes, 2011 Executive Summary: Standards of Medical Care in Diabetes—2011

#### Current criteria for the diagnosis of diabetes

- AlC ≥6.5%. The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP)-certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay
- fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h, or
- 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water
- in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l)
- in the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.

#### Testing for diabetes in asymptomatic patients

- Testing to detect type 2 diabetes and assess risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25 kg/m<sup>2</sup>) and who have one or more additional risk factors for diabetes (see Table 4 of the "Standards of Medical Care in Diabetes—2011"). In those without these risk factors, testing should begin at age 45 years. (B)
- If tests are normal, repeat testing carried out at least at 3-year intervals is reasonable. (E)
- To test for diabetes or to assess risk of future diabetes, A1C, FPG, or 2-h 75-g OGTT are appropriate. (B)
- In those identified with increased risk for future diabetes, identify and, if ap-

propriate, treat other cardiovascular disease (CVD) risk factors. (B)

#### Detection and diagnosis of gestational diabetes mellitus (GDM) • Screen for undiagnosed type 2 diabetes

- Screen for undiagnosed type 2 diabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria. (B)
- In pregnant women not known to have diabetes, screen for GDM at 24–28 weeks of gestation, using a 75-g 2-h OGTT and the diagnostic cut points in Table 6 of the "Standards of Medical Care in Diabetes—2011". (B)
- Screen women with GDM for persistent diabetes 6–12 weeks postpartum. (E)
- Women with a history of GDM should have lifelong screening for the development of diabetes or prediabetes at least every 3 years. (E)

#### Prevention/delay of type 2 diabetes

- Patients with impaired glucose tolerance (IGT) (A), impaired fasting glucose (IFG) (E), or an A1C of 5.7–6.4% (E) should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 min/week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on potential cost-savings of diabetes prevention, such programs should be covered by third-party payors. (E)
- Metformin therapy for prevention of type 2 diabetes may be considered in those at highest risk for developing diabetes, such as those with multiple risk factors, especially if they demonstrate progression of hyperglycemia (e.g. A1C ≥6%) despite lifestyle interventions.
- Monitoring for the development of di-

# DOI: 10.2337/dc11-5004

© 2011 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. See http://creativecommons. org/licenses/by-nc-nd/3.0/ for details. abetes in those with prediabetes should be performed every year. (E)

#### Glucose monitoring

- Self-monitoring of blood glucose (SMBG) should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (A)
- For patients using less-frequent insulin injections, non-insulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to the success of therapy. (E)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy. (E)
- Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age ≥25 years) with type 1 diabetes. (A)
- Although the evidence for AlClowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)

#### AIC

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
- Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed. (E)

#### Glycemic goals in adults

 Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of

### Available at: <a href="http://care.diabetesjournals.org/content/34/Supplement\_1">http://care.diabetesjournals.org/content/34/Supplement\_1</a>

diabetes and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1C goal for many nonpregnant adults is <7%. (B)

- Because additional analyses from several randomized trials suggest a small but incremental benefit in microvascular outcomes with AIC values closer to normal, providers might reasonably suggest more stringent AIC goals for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes, long life expectancy, and no significant cardiovascular disease. (B)
- Conversely, less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, and those with longstanding diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucoselowering agents including insulin. (C)

#### Diabetes self-management education (DSME)

- People with diabetes should receive DSME according to national standards when their diabetes is diagnosed and as needed thereafter. (B)
- Effective self-management and quality of life are the key outcomes of DSME and should be measured and monitored as part of care. (C)
- DSME should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)
- Because DSME can result in costsavings and improved outcomes (B), DSME should be adequately reimbursed by third-party payors. (E)

#### Medical nutrition therapy (MNT) General recommendations

- Individuals who have prediabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT. (A)
- Because MNT can result in cost-savings and improved outcomes (B), MNT

should be adequately covered by insurance and other payors. (E)

## Energy balance, overweight, and obesity

- In overweight and obese insulinresistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate, low-fat calorie-restricted, or Mediterranean diets may be effective in the short term (up to 2 years). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)
- Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)

#### Recommendations for primary prevention of diabetes

- Among individuals at high risk for developing type 2 diabetes, structured programs that emphasize lifestyle changes that include moderate weight loss (7% of body weight) and regular physical activity (150 min/week), with dietary strategies including reduced calories and reduced intake of dietary fat, can reduce the risk for developing diabetes and are therefore recommended. (A)
- Individuals at high risk for type 2 diabetes should be encouraged to achieve the U.S. Department of Agriculture (USDA) recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B)

#### Recommendations for management of diabetes: macronutrients in diabetes management

- The best mix of carbohydrate, protein, and fat may be adjusted to meet the metabolic goals and individual preferences of the person with diabetes. (E)
- Monitoring carbohydrate, whether by carbohydrate counting, choices, or experience-based estimation, remains a key strategy in achieving glycemic control. (A)
- For individuals with diabetes, the use of the glycemic index and glycemic load

may provide a modest additional benefit for glycemic control over that observed when total carbohydrate is considered alone. (B)

- Saturated fat intake should be <7% of total calories. (A)
- Reducing intake of *trans* fat lowers LDL cholesterol and increases HDL cholesterol (A); therefore, intake of *trans* fat should be minimized. (E)

#### Other nutrition recommendations

- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men).
   (E)
- Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)
- Individualized meal planning should include optimization of food choices to meet recommended daily allowance (RDA)/dietary reference intake (DRI) for all micronutrients. (E)

#### Physical activity

- People with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate). (A)
- In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week. (A)

#### Psychosocial assessment and care

- Assessment of psychological and social situation should be included as an ongoing part of the medical management of diabetes. (E)
- Psychosocial screening and follow-up should include, but is not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)
   Screen for psychosocial problems such
- Screen for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when selfmanagement is poor. (C)

#### Hypoglycemia

 Glucose (15–20 g) is the preferred treatment for the conscious individual

with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. (E)

- Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals should be instructed in its administration. Glucagon administration is not limited to health care professionals. (E)
- Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness and reduce the risk of future episodes. (B)

#### **Bariatric surgery**

- Bariatric surgery may be considered for adults with BMI >35 kg/m<sup>2</sup> and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacologic therapy. (B)
- Patients with type 2 diabetes who have undergone bariatric surgery need lifelong lifestyle support and medical monitoring. (E)
- Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI of 30–35 kg/m<sup>2</sup>, there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m<sup>2</sup> outside of a research protocol. (E)
- The long-term benefits, costeffectiveness, and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well-designed controlled trials with optimal medical and lifestyle therapy as the comparator. (E)

#### Immunization

- Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)
- Administer pneumococcal polysaccharide vaccine to all diabetic patients ≥2 years of age. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the</li>

vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as after transplantation. (C)

#### Hypertension/blood pressure control Screening and diagnosis

 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. Repeat systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg confirms a diagnosis of hypertension. (C)

#### Goals

- A goal systolic blood pressure <130 mmHg is appropriate for most patients with diabetes. (C)
- Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate. (B)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

#### Treatment

- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months and then, if targets are not achieved, be treated with the addition of pharmacological agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)
- Lifestyle therapy for hypertension consists of: weight loss, if overweight; DASH (Dietary Approaches to Stop Hypertension)-style dietary pattern, including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity. (B)
- Pharmacologic therapy for patients with diabetes and hypertension should be with a regimen that includes either an ACE inhibitor or an ARB. If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added to those with an esti-

mated glomerular filtration rate (GFR) ≥30 ml/min/1.73 m<sup>2</sup> and a loop diuretic for those with an estimated GFR <30 ml/min/1.73 m<sup>2</sup>. (C)

- Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be monitored. (E)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of longterm maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)

#### Dyslipidemia/lipid management Screening

- In most adult patients, measure fasting lipid profile at least annually. In adults with low-risk lipid values (LDL cholesterol <100 mg/dl, HDL cholesterol</li>
- >50 mg/dl, and triglycerides <150 mg/dl), lipid assessments may be repeated every 2 years. (E)
- Treatment recommendations and goals
- Lifestyle modification focusing on the reduction of saturated fat, trans fat, and cholesterol intake; the increase of omega-3 fatty acids, viscous fiber, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:
- with overt CVD (A)
- without CVD who are over the age of 40 years and have one or more other CVD risk factors (A)
- For patients at lower risk than above (e.g. without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains >100 mg/dl or in those with multiple CVD risk factors. (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)</li>
- In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option. (B)
- · If drug-treated patients do not reach the

above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of  $\sim$  30–40% from baseline is an alternative therapeutic goal. (A)

- Triglyceride levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable. However, LDL cholesterol-targeted statin therapy remains the preferred strategy. (C)
- If targets are not reached on maximally tolerated doses of statins, combination therapy using statins and other lipidlowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

#### Antiplatelet agents

- Consider aspirin therapy (75–162 mg/ day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)
- Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%, such as in men <50 years of age and women <60 years of age with no major additional CVD risk factors), since the potential adverse effects from bleeding likely offset the potential benefits. (C)
- In patients in these age-groups with multiple other risk factors (e.g. 10-year risk 5–10%), clinical judgment is required. (E)
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)
- Combination therapy with ASA (75– 162 mg/day) and clopidogrel (75 mg/ day) is reasonable for up to a year after an acute coronary syndrome. (B)

#### Smoking cessation

- Advise all patients not to smoke. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

#### Coronary heart disease (CHD) screening and treatment Screening

 In asymptomatic patients, routine screening for CAD is not recommended, as it does not improve outcomes as long as CVD risk factors are treated. (A)

#### Treatment

- In patients with known CVD, ACE inhibitor (C) and aspirin and statin therapy (A) (if not contraindicated) should be used to reduce the risk of cardiovascular events.
- In patients with a prior myocardial infarction, β-blockers should be continued for at least 2 years after the event.
   (B)
- Longer-term use of β-blockers in the absence of hypertension is reasonable if well tolerated, but data are lacking. (E)
- Avoid thiazolidinedione (TZD) treatment in patients with symptomatic heart failure. (C)
- Metformin may be used in patients with stable congestive heart failure (CHF) if renal function is normal. It should be avoided in unstable or hospitalized patients with CHF. (C)

#### Nephropathy screening and treatment

- General recommendations
- To reduce the risk or slow the progression of nephropathy, optimize glucose control. (A)
- To reduce the risk or slow the progression of nephropathy, optimize blood pressure control. (A)

#### Screening

- Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at diagnosis. (E)
- Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate GFR and stage the level of chronic kidney disease (CKD), if present. (E)

#### Treatment

- In the treatment of the nonpregnant patient with micro- or macroalbuminuria, either ACE inhibitors or ARBs should be used. (A)
- While there are no adequate head-tohead comparisons of ACE inhibitors

and ARBs, there is clinical trial support for each of the following statements:

- In patients with type I diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
- In patients with type 2 diabetes, hypertension, and microalbuminuria, both ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
- In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy. (A)
- If one class is not tolerated, the other should be substituted. (E)
- Reduction of protein intake to 0.8–1.0 g • kg body wt<sup>-1</sup> • day<sup>-1</sup> in individuals with diabetes and the earlier stages of CKD and to 0.8 g • kg body wt<sup>-1</sup> • day<sup>-1</sup> in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (B)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of acute kidney disease and hyperkalemia. (E)
- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is recommended. (E)
- When estimated GFR (eGFR) is <60 ml.min/1.73 m<sup>2</sup>, evaluate and manage potential complications of CKD. (E)
- Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (heavy proteinuria, active urine sediment, absence of retinopathy, rapid decline in GFR), difficult management issues, or advanced kidney disease. (B)

#### Retinopathy screening and treatment General recommendations

- To reduce the risk or slow the progression of retinopathy, optimize glycemic control. (A)
- To reduce the risk or slow the progression of retinopathy, optimize blood pressure control. (A)

#### Screening

 Adults and children aged 10 years or older with type 1 diabetes should have an initial dilated and comprehensive

eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)

- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less-frequent exams (every 2-3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing. (B)
- High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)
- Women with pre-existing diabetes who are planning a pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B)

#### Treatment

- Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (PDR) to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)
- Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk PDR, clinically significant macular edema, and some cases of severe NPDR. (A)
- The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as this therapy does not increase the risk of retinal hemorrhage. (A)

#### Neuropathy screening and treatment

- All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis and at least annually thereafter, using simple clinical tests. (B)
- Electrophysiological testing is rarely needed, except in situations where the clinical features are atypical. (E)
- Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcomes. (E)
- Medications for the relief of specific symptoms related to DPN and autonomic neuropathy are recommended, as they improve the quality of life of the patient. (E)

#### Foot care

- For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). (B)
- Provide general foot self-care education to all patients with diabetes. (B)
- A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B)
- Refer patients who smoke, have loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)

#### Children and adolescents

#### Glycemic control

 Consider age when setting glycemic goals in children and adolescents with type 1 diabetes. (E)

#### Screening and management of chronic complications in children and adolescents with type 1 diabetes

#### Nephropathy

- Annual screening for microalbuminuria, with a random spot urine sample for albumin-to-creatinine ratio (ACR), should be considered once the child is 10 years of age and has had diabetes for 5 years. (E)
- Confirmed, persistently elevated ACR on two additional urine specimens from different days should be treated with an ACE inhibitor, titrated to normalization of albumin excretion if possible. (E)

#### Hypertension

- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacologic treatment should be considered. (E)
- Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently >130/80 mmHg, if 95% exceeds that value) should be initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension, following appropriate reproductive counseling due to its potential teratogenic effects. (E)
- The goal of treatment is a blood pressure consistently <130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)

#### Dyslipidemia

### Screening

If there is a family history of hypercholesterolemia (total cholesterol >240 mg/dl) or a cardiovascular event before age 55 years, or if family history is unknown, then a fasting lipid profile should be performed on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then the first lipid screening should be considered at puberty (≥10 years). All children diagnosed with diabetes at or after

puberty should have a fasting lipid profile performed soon after diagnosis (after glucose control has been established). (E)

For both age-groups, if lipids are abnormal, annual monitoring is recommended. If LDL cholesterol values are within the accepted risk levels (<100 mg/dl [2.6 mmol/l]), a lipid profile should be repeated every 5 years. (E)</li>

#### Treatment

- Initial therapy should consist of optimization of glucose control and MNT using a Step 2 American Heart Association diet aimed at a decrease in the amount of saturated fat in the diet.
- After the age of 10 years, the addition of a statin in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dl (4.1 mmol/l), or LDL cholesterol >130 mg/dl (3.4 mmol/l) and one or more CVD risk factors, is reasonable. (E)
- The goal of therapy is an LDL cholesterol value <100 mg/dl (2.6 mmol/l). (E)

#### Retinopathy

- The first ophthalmologic examination should be obtained once the child is ≥10 years of age and has had diabetes for 3–5 years. (E)
- After the initial examination, annual routine follow-up is generally recommended. Less frequent examinations may be acceptable on the advice of an eye care professional. (E)

#### Celiac disease

- Children with type 1 diabetes should be screened for celiac disease by measuring tissue transglutaminase or antiendomysial antibodies, with documentation of normal total serum IgA levels, soon after the diagnosis of diabetes. (E)
- Testing should be repeated in children with growth failure, failure to gain weight, weight loss, diarrhea, flatulence, abdominal pain, or signs of malabsorption or in children with frequent unexplained hypoglycemia or deterioration in glycemic control. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation with endoscopy and biopsy. (E)
- Children with biopsy-confirmed celiac disease should be placed on a glutenfree diet and have consultation with a

dietitian experienced in managing both diabetes and celiac disease. (E)

#### Hypothyroidism

- Children with type 1 diabetes should be screened for thyroid peroxidase and thyroglobulin antibodies at diagnosis.
   (E)
- TSH concentrations should be measured after metabolic control has been established. If normal, they should be rechecked every 1–2 years, or if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. (E)

#### Preconception care

- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- Starting at puberty, preconception counseling should be incorporated in the routine diabetes clinic visit for all women of child-bearing potential. (C)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most non-insulin therapies. (E)
- Since many pregnancies are unplanned, consider the potential risks and benefits of medications that are contraindicated in pregnancy in all women of child-bearing potential, and counsel women using such medications accordingly. (E)

#### Older adults

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care using goals developed for younger adults. (E)
- Glycemic goals for older adults not meeting the above criteria may be relaxed using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of ben-

efit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)

 Screening for diabetes complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

#### Diabetes care in the hospital

- All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record.
   (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- · Goals for blood glucose levels:
  - Critically ill patients: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dl (10 mmol/l). Once insulin therapy is started, a glucose range of 140–180 mg/dl (7.8 to 10 mmol/l) is recommended for the majority of critically ill patients. (A)
  - More stringent goals, such as 110– 140 mg/dl (6.1–7.8 mmol/l) may be appropriate for selected patients, as long as this can be achieved without significant hypoglycemia. (C)
  - Critically ill patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (E)
  - Non-critically ill patients: There is no clear evidence for specific blood glucose goals. If treated with insulin, the pre-meal blood glucose target should generally be <140 mg/dl (7.8 mmol/l) with random blood glucose <180 mg/dl (10.0 mmol/l), provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidites. (E)
- Scheduled subcutaneous insulin with basal, nutritional, and correction components is the preferred method for achieving and maintaining glucose control in non-critically ill patients. (C) Using correction dose or "supple-

mental" insulin to correct pre-meal hyperglycemia in addition to scheduled prandial and basal insulin is recommended. (E)

 Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive medications. (B) If hyperglycemia is documented and persistent, treatment is necessary. Such patients should be treated to the same glycemic goals as patients with known diabetes. (E)

 A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be documented in the medial record and tracked. (E)

- All patients with diabetes admitted to the hospital should have an A1C obtained if the result of testing in the previous 2–3 months is not available.
   (E)
- Patients with hyperglycemia in the hospital who do not have a diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

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