Montana Geriatric Education Center

Instructions on Completing the Module
Screening for Diabetes in Older Adults

**The results of the assessments and evaluations are confidential, and the data is used to meet requirements of our federally funded grant.*

Please make sure to turn in Pre-Test, Post-Test, and Module Evaluation.

1. ***Before*** reading the module, and without looking at it, complete the Pre-Test.

   Record your answers on the examination form marked Pre-Test. *(Found at the start of the module.)* Keep the completed answer form to turn in at the completion of the module.

2. Complete the module as outlined in the syllabus.

3. ***After*** reading the module, please complete the Post-Test.

   Use the questions in Appendix **C** and record your answers on the examination form marked Post-Test. *(Found at the end of Appendix C.)* Keep the completed answer form to turn in with the pre-test at the completion of the module.

   Complete the Module Evaluation. *(Found after the post-test.)* Keep the completed module evaluation form to turn in with the pre-test and post-test at the completion of the module.

4. **To obtain credit for the module you must:**

   a. Complete and turn in MTGEC Participant Profile

   b. Turn in the Pre-Test, Post-Test, and Module Evaluation

   c. Obtain a score of 70% or better on the Post-Test

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Pre-test: *Screening for Diabetes in Older Persons*

Record responses on examination form.

1) **Chronic exposure to elevated glucose levels may have detrimental effects on which of the following organ systems?**
   a) Heart & blood vessels
   b) Kidney
   c) Eye
   d) All of the above

2) **According to 2007 medical expenditures, diabetes is : the 3rd most costly disease in the United States.**
   a) the most costly disease in the United States.
   b) the 2nd most costly disease in the United States.
   c) the 3rd most costly disease in the United States.
   d) the 5th most costly disease in the United States.

3) **Which of the following diseases is the leading cause of death among patients with diabetes?**
   a) Kidney failure
   b) Cancer
   c) Heart disease
   d) Pneumonia

4) **Older patients with diabetes have higher rates of premature death and greater functional disability compared to younger patients with diabetes.**
   a) True
   b) False

5) **Which of the following geriatric conditions would NOT be exacerbated by diabetes?**
   a) Depression
   b) Cancer
   c) Persistent pain
   d) Polypharmacy

6) **Native Americans are how many times more likely to be diagnosed with diabetes compared to Caucasians of similar age?**
   a) Similar diagnosis rate to Caucasians
   b) Over twice as likely
   c) Three times as likely
   d) Four times as likely

7) Which of the following characteristics is NOT commonly associated with type 2 diabetes?

a) Obesity
b) Insulin resistance
c) Onset before age 40
d) Varying degrees of endogenous in insulin production

8) Patients with glucose values higher than normal but less than the diagnostic cut-off for diabetes are said to have:

a) Gestational diabetes
b) Pre-diabetes
c) Adult onset diabetes
d) Insulin resistance

9) Which of the following is NOT considered to be a risk factor for developing type 2 diabetes?

a) Body mass index ≥ 25 kg/m2
b) Chronic inactivity
c) Female sex
d) Hypertension (≥140/90 mmHg)

10) Diabetic patients are at increased risk of heart attack and stroke compared to non-diabetic patients. As such, which of the following statements best represents treatment recommendations for patients with both dyslipidemia and hypertension?

I. LDL-cholesterol goal < 100 mg/dL
II. LDL-cholesterol goal < 130 mg/dL
III. HDL-cholesterol goal > 40 mg/dL (men) & > 50 mg/dL (women)
IV. Blood pressure <140/<80 mmHg
V. Blood pressure <130/<90 mmHg

a) I, III, V
b) II, III, IV
c) II, III, V
d) I, III, IV

11) The American Diabetes Association recommends daily low dose aspirin therapy to prevent thrombosis in which subset of patients:

a) Adults with type 2 diabetes who have at least a 10% risk of a cardiovascular event in the next 10 years.
b) All adults over 30 years of age with type 2 diabetes
c) ONLY adults with type 2 diabetes who have already had a heart attack or stroke
d) ONLY adults with type 2 diabetes who have an allergy to clopidogrel.

12) Type 2 diabetes accounts for what percentage of all end-stage renal dysfunction patients?

a) 22%
b) 41%
c) 55%
d) 66%

13) Which of the following statements is TRUE regarding the relationship of albumin in diabetic nephropathy?

a) The degree of nephropathy is associated with the degree of albuminuria.
b) As renal function diminishes, the renal excretion of albumin also decreases.
c) Macroalbuminuria is classified as albumin content in the urine between 30-299 mcg/mg of creatinine.
d) Macroalbuminuria takes approximately 12 months to develop in diabetic nephropathy.

14) Which of the following neuropathies would NOT be considered to be autonomic in origin?

a) Neurogenic bladder
b) Erectile dysfunction
c) Inability to detect cold or heat
d) Gastroparesis

15) The American Diabetes Association recommends patients with diabetes be vaccinated annually with the influenza vaccine.

a) True
b) False

16) Diabetes is the leading cause of non-traumatic lower-limb amputations in the United States. Which of the following risk factors would NOT increase the likelihood of incurring an amputation?

a) Peripheral neuropathy
b) Peripheral vascular disease
c) Severe nail pathology
d) Well controlled blood sugars

17) Which of the following statements is TRUE regarding screening recommendations for diabetes in the general population?

a) Everyone should be tested annually after the age of 35.
b) Patients with a body mass index ≥ 25 kg/m^2 should be screened at least every 3 years starting at age 45.
c) Patients with a body mass index ≥ 25 kg/m^2 should be screened annually starting at age 45.
d) Multiple clinical trials have demonstrated the cost-effectiveness of early detection for diabetes in the general population.

18) A 67 year old female, American Indian patient who is obese and taking antihypertensive medications is being screened for diabetes using the Afinion™ HbA1c test. Her HbA1c result is 5.7%. What action would you recommend?

a) This patient clearly has diabetes and should be referred for follow-up care.
b) This patient does not have diabetes and should not be referred for follow-up care.
c) This patient has multiple risk factors for diabetes, and given the A1c result, should be referred to her primary care provider at the patient's earliest convenience to discuss the results.
d) Counsel the patient to watch how much sugar she is eating.

19) A 72 year old male patient, who appears to be in good health, is screened for diabetes using the Afinion™ test. His HbA1c result is 7.5%. What action would you recommend?

a) This patient has very few risk factors and should not be referred for follow-up care.
b) This patient should be referred to his primary care provider for follow-up care, as the A1cNow® result suggests chronic hyperglycemia.
c) Counsel this patient on the importance of risk factor reduction.
d) Both b & c

20) Which of the following non-pharmacologic therapies is NOT recommended by the American Diabetes Association?

a) Lose weight
b) Sucrose should be completely removed from the diet
c) Aerobic exercise for 20-30 minutes at least 3 days per week
d) Stop smoking

PRE-TEST: Examination Form

Screening for Diabetes in Older Adults

Participant Information

1. Name: _____

2. Mailing address: _____

_____

_____

_____

3. Date exam completed _____

Questions: (Please circle one response per question)				
1	A	B	C	D
2	**A**	**B**	**C**	**D**
3	A	B	C	D
4	**A**	**B**	**C**	**D**
5	A	B	C	D
6	**A**	**B**	**C**	**D**
7	A	B	C	D
8	**A**	**B**	**C**	**D**
9	A	B	C	D
10	**A**	**B**	**C**	**D**
11	A	B	C	D
12	**A**	**B**	**C**	**D**
13	A	B	C	D
14	**A**	**B**	**C**	**D**
15	A	B	C	D
16	**A**	**B**	**C**	**D**
17	A	B	C	D
18	**A**	**B**	**C**	**D**
19	A	B	C	D
20	**A**	**B**	**C**	**D**

For credit, please return this completed page to:

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Montana Geriatric Education Center

Screening for Diabetes in Older Persons

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A 2-hour screening module from the
Montana Geriatric Education Center

A Consortium of
The University of Montana, Missoula
St. Vincent Healthcare
Montana Tech

http://www.health.umt.edu/mtgec/home

February 2013

MONTANA GERIATRIC EDUCATION CENTER
Required Disclosures to Participants

MTGEC Goal/Purpose
Improve health outcomes for older adults in rural Montana via increased knowledge of geriatric care and treatment of health problems by health professionals.

Successful Completion of this Continuing Education Activity:
- Completion of Participant Profile
- Completion of Pre-Test
- Reading of text and visiting associated website resources
- Completion of Post-Test with at least 70% accuracy
- Completion of module evaluation

Contact Hours: 2
MT Nurses Association Continuing Education Expiration Date: March 4, 2015

Conflicts of Interest
A conflict of interest occurs when an individual has an opportunity to affect educational content about health-care products or services of a commercial company with which she/he has a financial relationship.

The planners and presenters of this CE activity have disclosed no relevant financial relationships with any commercial companies pertaining to this activity.

Noncommercial Sponsor Support
This CE activity is supported 100% by a federally funded grant from the Health Resources and Services Administration (HRSA) Grant Number UB4HP19056 for $2,136,009 (07/01/2010 – 06/30/2015).

Non-Endorsement of Products
Approved provider status does not imply that there is real or implied endorsement by MTGEC, ANCC, or MNA of any product, service, or company referred to in this activity nor of any company subsidizing costs related to the activity.

Content

This 2-hour module will discuss the basic issues which surround screening for diabetes in the geriatric population. This module is also used by the ImProving Health Among Rural Montanans (IPHARM) program to train health professions students to perform diabetes screening at IPHARM events throughout the state.

Module Goal:
Learners will increase their knowledge of diabetes and issues surrounding screening for diabetes in older adults.

Learning objectives:

1. Summarize the impact of diabetes on the nation, particularly on older adults and Native Americans.
2. Describe the macrovascular and microvascular complications found in patients with diabetes.
3. Identify patients who are good candidates for diabetes screening.
4. Describe how to perform hemoglobin A1c test using Afinion™ HbA1c test.
5. Identify which screened patients should be referred for follow up.

Table of Contents

Screening for Diabetes

I. Introduction

Diabetes mellitus represents a major health concern in the United States. Diabetes mellitus is the 7th leading cause of death in the country and is the 3rd costliest disease with an estimated $174 billion dollars spent in 2007 on medical expenditures and lost productivity.(1) *(Diabetes mellitus will be referred to only as diabetes from this point on.)*

Diabetes, which is a group of metabolic disorders, is characterized as a disease in which chronic high blood sugars (hyperglycemia) result from inadequate insulin secretion by the pancreas, improper action of insulin on tissues, or a combination of both. Detrimental effects on tissues, due to chronic exposure to hyperglycemia, may result in vision loss from retinopathy, renal failure from nephropathy, and nerve damage from neuropathy.(2) Additionally, hyperglycemia plays havoc with the vascular system resulting in diabetic patients being 2 to 4 times more likely to have a heart attack or stroke compared to other patients of the same age and sex without diabetes.(3)

Therefore, identifying patients with diabetes allows for aggressive treatment of their hyperglycemia, as well as initiation of therapies to ultimately prevent the long-term complications associated with this disease.

The scope of this module is to:

A. Describe the impact diabetes has on health;
B. Provide an overview of diabetes, its classification, causes, risk factors, complications and prevention;
C. Describe how diabetes can be screened for in specific populations;
D. Describe how to use the Afinion™ HbA1c Analyzer
E. Briefly describe non-pharmacologic and pharmacologic therapies available for treatment of diabetes.

II. Impact of Diabetes on Health

A. Prevalence of Disease

In 2011, the total prevalence of diabetes in the United States was estimated to be 25.8 million people or roughly 8.3% of the population. Approximately 18.8 million individuals had a diagnosis of diabetes in 2011, which left almost 30% of the patients not yet diagnosed and at risk for hyperglycemic-related effects on the body. Among U. S. residents aged 65 years and older, 10.9 million or 26.9%, had diabetes. Since 1990, the age group with the greatest growth rate in diabetes is the 45 to 64 year old group.[3] Furthermore, it is projected by the year 2050 the number of patients with diabetes will reach 29 million with the largest increases in patients ≥ 75 years old and among black Americans.[4]

Type 2 diabetes, which accounts for 90 to 95% of all diabetes diagnoses, was previously referred to as adult-onset diabetes, as most of the people who are diagnosed are well into their adult years.[3] Trends towards increasing obesity and lack of exercise in the American population over the last 20 years have led to an increasing prevalence of type 2 diabetes diagnoses among all age groups (Figure 1).[5,6]

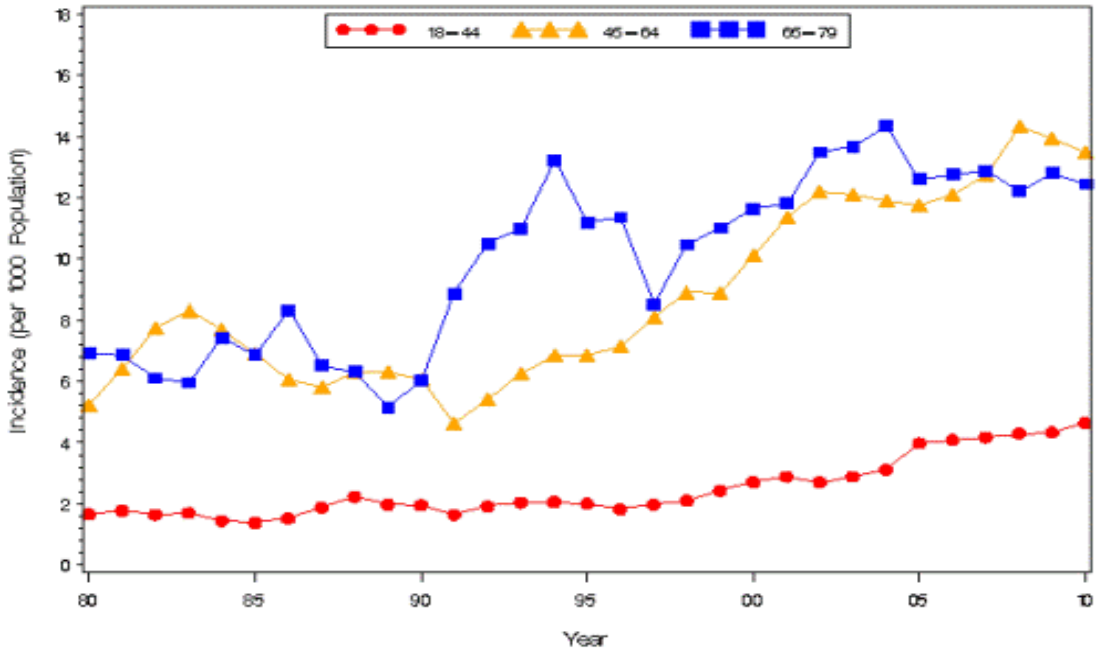


Figure 1. Incidence of Diagnosed Diabetes per 1,000 Population Aged 18–79 Years, by Age, United States, 1980–2010 [6]

While age is a risk factor for developing diabetes, sex is not a strong predictor with comparable incidence rates between men and women. Non-Hispanic blacks do have higher incidence rates of diabetes than whites (see Table 1).

Table 1. Diagnosed Diabetes in People 20 Years and Older, United States, 2010[3]

Group	Number (percentage) who have diabetes
Age ≥20 years	25.6 million (11.3%) of all people in this age group
Age ≥65 years	10.9 million (26.9%) of all people in this age group
Men	13.0 million (11.8%) of men
Women	12.6 million (10.8%) of women
Non-Hispanic whites	15.7 million (10.2%) of whites
Non-Hispanic blacks	4.9 million (18.7%) of blacks

"Prediabetes" is defined as having blood glucose levels higher than normal but less than needed to diagnose diabetes. In 2005–2008, based on fasting glucose or A1c levels, 35% of U.S. adults aged 20 years or older had prediabetes (50% of those aged 65 years or older). Applying this percentage to the entire U.S. population in 2010 yields an estimated 79 million Americans aged 20 years or older with prediabetes.[3]

B. Cost

The substantial cost of diabetes is not only a burden on society as a whole but also on the individual patients and their families.

Health care expenditures in the United States for the year 2007 were estimated to be $2.5 trillion of which $207 billion (8.3%) were incurred by patients with diabetes.[1,7] Additionally, 18% of all inpatient hospitalization costs were related to diabetes. The breakdown of diabetes expenditures is approximately 67% for direct costs and 33% for indirect costs such as lost productivity and disability. [7] People with diabetes have medical expenditures that are approximately 2.3 times higher on average than those without diabetes. Because the prevalence of diabetes increases with age, it is not surprising to find that our elderly incur a greater degree of the health expenditures for diabetes than younger working people with diabetes. [7] The leading cost expenditure for patients with diabetes is related to cardiovascular disease complications, which consumes

19% of all diabetes-related health care dollars.[7] In 2007, 231,404 deaths were attributed to diabetes which is likely an underestimate since diabetes is often listed as a secondary cause of death. The value of lost productivity due to premature death was $26.9 billion. [7]

C. Relation to Obesity

Considerable evidence exists which correlates increasing body weight with the increased risk of developing type 2 diabetes.[8] Results from the 2009–2010 National Health and Nutrition Examination Survey (NHANES) show that 75% of the U.S. population weighs more than recommended. The survey estimated 33.0% of U.S. adults aged 20 and over are overweight (BMI 25.0–29.9), 35.7% are obese (BMI $\geq$30), and 6.3% are extremely obese (BMI $\geq$ 40 kg/m^2).[9] Given these statistics, the correlation between body weight and type 2 diabetes will likely continue. Data suggest that for every kilogram increase in body weight, the risk for developing diabetes increases 4.5 to 9%.[10]

D. Special Populations

1. Older Adults

Older patients typically have multiple health problems which reinforces the need to properly identify patients at risk for diabetes to help prevent or slow diabetic complications. And as would be expected, older patients with diabetes have higher rates of premature death as well as greater functional disability. Older adults with diabetes have the highest rates of major lower extremity amputations, heart attacks, and end stage renal disease of any age group. They also have higher rates of complications from diabetes treatment including emergency room visits for hypoglycemia episodes. Common geriatric conditions that may be exacerbated by diabetes include polypharmacy, depression, cognitive impairments, urinary incontinence, injurious falls, and persistent pain. Older patients with diabetes will have special needs not found in younger patients; thus, treatment recommendations have been developed by the American Diabetes Association (ADA).[11,12]

2. Native Americans

Diabetes is one of the greatest health concerns facing Native Americans today. Native Americans and Alaska Native adults are over twice as likely as white adults to be diagnosed with diabetes. In 2009, they were 1.8 times more likely than non-Hispanic whites to die from diabetes.[13]

Native Americans make up 6% of Montana's population (versus 91% Caucasian),[14] and most Native Americans receive their healthcare from the Indian Health Service (IHS) provided on seven reservations found throughout the state.[15] Nationally, the IHS has estimated the prevalence of diabetes within their adult population to be approximately 16.1%. The percent population with diabetes varies by region from 5.5% among Alaska Native adults to 33.5% among Native American adults in southern Arizona.[3,13]

Awareness of the issues surrounding diabetes in Native Americans is important to provide supportive care and counseling to these individuals, because not only do Native Americans acquire diabetes at a higher rate, they are also at greater risk for complications.

- Native Americans are nearly twice as likely to develop end-stage renal disease.[16]
- Lower limb amputations are an unfortunate long-term complication of diabetes, and data for 2000 indicates that Native Americans have amputation rates 3 to 4 times higher than the general population.[17]

III. Overview of Diabetes

A. Definition of Diabetes Mellitus

As mentioned previously, diabetes is a chronic disorder caused by insufficient insulin secretion, improper action of insulin on tissues, or a combination of both which leads to impaired metabolism of carbohydrates, proteins, and lipids.

B. Classifications of Diabetes

The ADA has four general classifications for diabetes mellitus:[2]

(i) Type 1

(ii) Type 2

(iii) Other (caused by genetics, infections, endocrine disorders, etc.)

(iv) Gestational (occurs in 7% of all pregnant women; these women are at greater risk of developing type 2 diabetes)

Only type 2 diabetes will be discussed further in greater detail, as this type pertains to most of the diagnosed cases and is the most receptive to lifestyle and dietary changes. But as a brief review, Table 2 will describe some of the distinguishing characteristics between type 1 and type 2 diabetes.

Table 2: Comparison between Type 1 and Type 2 Diabetes[2,18]

	Type 1	**Type 2**
Typical age of onset	Generally in childhood or adolescence	Usually > 40 years old
Synonyms	Juvenile-onset Insulin-dependent diabetes mellitus (IDDM)	Adult-onset Non-insulin dependent diabetes mellitus (NIDDM)
Etiology	Immune-mediated and idiopathic (unknown)	Insulin resistance and secretory deficiencies
Body weight	Non-obese	Obese (80%)
Endogenous insulin secretion	Minimal secretion	Varying degrees of secretion
Insulin resistance	Not usually	Common

C. *Role of Insulin in Diabetes*

Insulin is a peptide hormone which is synthesized by β-cells within the pancreas. After the ingestion of food, the plasma glucose rises stimulating the release of insulin from the pancreas which then facilitates the process of glucose transport into the cells.[19] Figure 2 summarizes the normal actions of insulin on glucose metabolism.

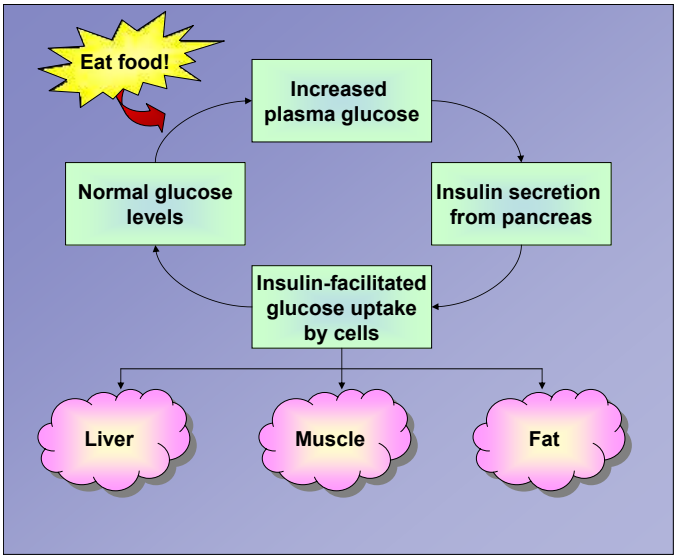


Figure 2: Normal Insulin-Glucose Cycle

It is not fully understood what causes type 2 diabetes, but insulin resistance is a major contributing factor. Insulin resistance occurs when tissues, which normally responded to the actions of insulin (i.e., muscle, liver and fat), become less susceptible to the actions of insulin. This results in the decreased clearance of glucose from the plasma which in turn stimulates the pancreas to secrete more insulin. The pancreas can only continue this compensatory response of over producing insulin for a limited time, because eventually the β-cells will no longer be able to produce enough insulin to overcome the insulin resistance. This leads to the subsequent development of high plasma glucose or hyperglycemia.[20,21] Rising insulin levels normally turn off liver production of glucose. Because of insulin resistance, the liver overproduces glucose overnight, resulting in fasting hyperglycemia by morning.[22]

Insulin resistance is not only associated with type 2 diabetes. It has also been linked to other disorders such as cardiovascular disease, hypertension, dyslipidemia, atherosclerosis, and polycystic ovary disease. The association between insulin resistance and type 2 diabetes is felt to involve both genetic and environmental factors, and there is great interest in how obesity plays into this relationship.[20]

D. Contributing Pathologies

Besides impaired insulin secretion and tissue insulin resistance, other factors contribute to the pathology of type 2 diabetes. Two gut hormones, glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are significantly reduced in diabetes. These gut hormones are normally secreted in response to a meal. They stimulate a bolus release of insulin to match the glucose load, suppress glucagon secretion (that normally increases blood glucose levels), slow gastric emptying, and cause satiety to reduce food intake. This is referred to as the incretin effect. With GLP-1 and GIP deficiencies, patients with diabetes experience post-prandial hyperglycemia and increased caloric intake. Patients with type 1 diabetes and patients with long-standing type 2 diabetes also develop a significant amylin deficiency. Amylin is a glucoregulatory hormone secreted with insulin that helps lower blood glucose by slowing gastric food emptying, suppressing glucagon output, and increasing satiety. [22]

Visceral adipose tissue (VAT) refers to fat cells in and around body organs and in the abdominal cavity. VAT is more insulin resistant and more atherogenic than peripheral subcutaneous fat. There are direct correlations among weight gain, VAT and insulin resistance. Furthermore, fat cells can produce adiponectin, which improves insulin resistance. Adiponectin is made in decreasing amounts as an individual becomes more overweight. [22]

E. Diagnostic Criteria for Diabetes

While the purpose of screening patients is not to diagnose the disease, it is important to understand the criteria required to diagnose a patient and the types of tests involved.

1. Methods of Diagnosis

Currently there are four diagnostic methods approved by the ADA which are summarized in Table 3. Only one of the four methods needs to be performed, but a confirmatory test **MUST** be performed on a subsequent day to make a diagnosis[2, 22]

Some patients have glucose levels that are higher than normal but less than the diagnostic criteria for diabetes. Patients who fall into this category are classified as having pre-diabetes or borderline diabetes. Patients with pre-diabetes are at risk of developing type 2 diabetes within the next ten years. With moderate weight loss (5-10% of total body weight), exercise (150 minutes/week), and the use of certain pharmacological agents, the development of type 2 diabetes may be delayed or prevented.[2,22]

Table 3: Diagnostic Criteria for Diabetes [2,22,49,]

Test Method		Diabetes	Pre-Diabetes	Normal
1	Hemoglobin A1c performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the DCCT assay.	≥6.5%	5.7-6.4%	<5.7%
2	Casual* plasma glucose with diabetes symptoms (i.e., polyuria, polydipsia, and unexplained weight loss.	≥ 200 mg/dL		
3	Fasting plasma glucose (no caloric intake ≥ 8 hours.)	≥ 126 mg/dL	≥ 100 mg/dL but < 126mg/dL (Referred to as impaired fasting glucose or IFG)	< 100 mg/dL
4	Two-hour postprandial plasma glucose during an oral glucose tolerance test (OGTT). Patient should be fasted for ≥ 8 hours and then given 75 gm anhydrous glucose orally dissolved in water.	≥ 200 mg/dL	≥ 140 mg/dL but < 200 mg/dL (Referred to as impaired glucose tolerance or IGT)	< 140 mg/dL

* Casual is defined as any time of day without regard to time since last meal.

F. Risk Factors

Certain factors have been identified with an increased risk of developing type 2 diabetes (Table 4). Properly identifying patients with these risk factors is an important step to initiate intervention therapies as well as to address lifestyle changes related to modifiable risk factors. The ultimate goal is to prevent or delay the onset of diabetes.

Table 4: Risk Factors for Type 2 Diabetes[2,22]

Risk Factors
▪ Age ≥ 45 years old ▪ Overweight (Body mass index ≥ 25 kg/m^2; See Appendix D) ▪ Acanthosis nigricans ▪ Family history of diabetes (parents or siblings with diabetes) ▪ Habitual physical inactivity ▪ Race/ethnicity (African-American, Native Americans, Hispanic-Americans, Asian-Americans, and Pacific Islanders) ▪ Previously identified impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) ▪ History of gestational diabetes or delivery of a baby weighing > 9 lbs ▪ Hypertension (≥ 140/90 mmHg in adults) ▪ HDL cholesterol ≤35 mg/dL and/or a triglyceride level ≥250 mg/dL ▪ Polycystic ovary syndrome ▪ History of cardiovascular disease

G. Complications

As a result of the insidious nature of type 2 diabetes, complications are often present by the time diabetes is diagnosed. Once the complications are present, they may be slowed but not reversed. In support of tight glycemic control, a 10-year study [the United Kingdom Prospective Diabetes Study (UKPDS 33)] in newly diagnosed type 2 diabetic patients found better managed blood glucose, by use of an intensive treatment regimen, resulted in significant reductions in microvascular complications compared to conventional therapy. The goal set for fasting blood glucose for the intensive regimen was <108 mg/dL and the conventional group goal was set to be <270 mg/dL, which resulted in median hemoglobin A1c values of 7% (intensive group) versus 7.9% (conventional group) – a relative reduction of 11%. A seemingly small difference in the A1c test, which is a measure of long-term glycemic control, resulted in significant reductions in all diabetes-related complications by 12%, microvascular endpoints by 25%, retinal photocoagulation (a treatment for retinopathy) by 29%, and a borderline reduction in myocardial infarction by 16%.[23]

In a similarly named study, the United Kingdom Prospective Diabetes Study 35 compared the relationship of glycemic control (A1c test) to the incidence of micro- and macrovascular complications in 3,600 newly diagnosed type 2 diabetic patients. No therapeutic interventions were implemented, but rather patients were observed for approximately 10 years (7.5-12.5 years). Results strongly suggest a direct relationship between the risk of diabetic complications and glycemic control (Figures 3 & 4).[24] Every 1% reduction in A1c resulted in a 37% (median) decreased risk of microvascular complications and a 21% decrease in either a macro- or microvascular event or diabetes-related death.[24]

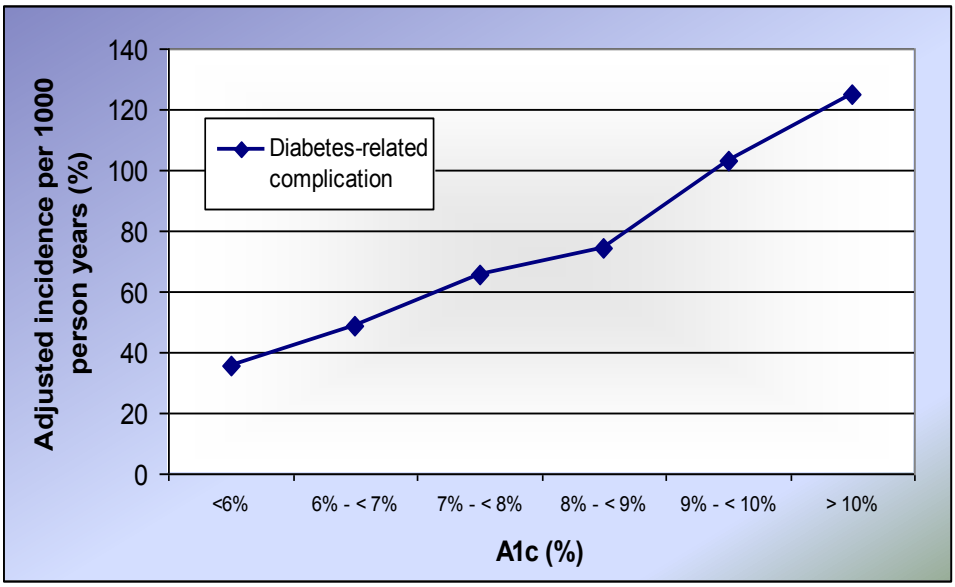


Figure 3: Relationship between Glycemic Control and Diabetes-Related Complications[24]

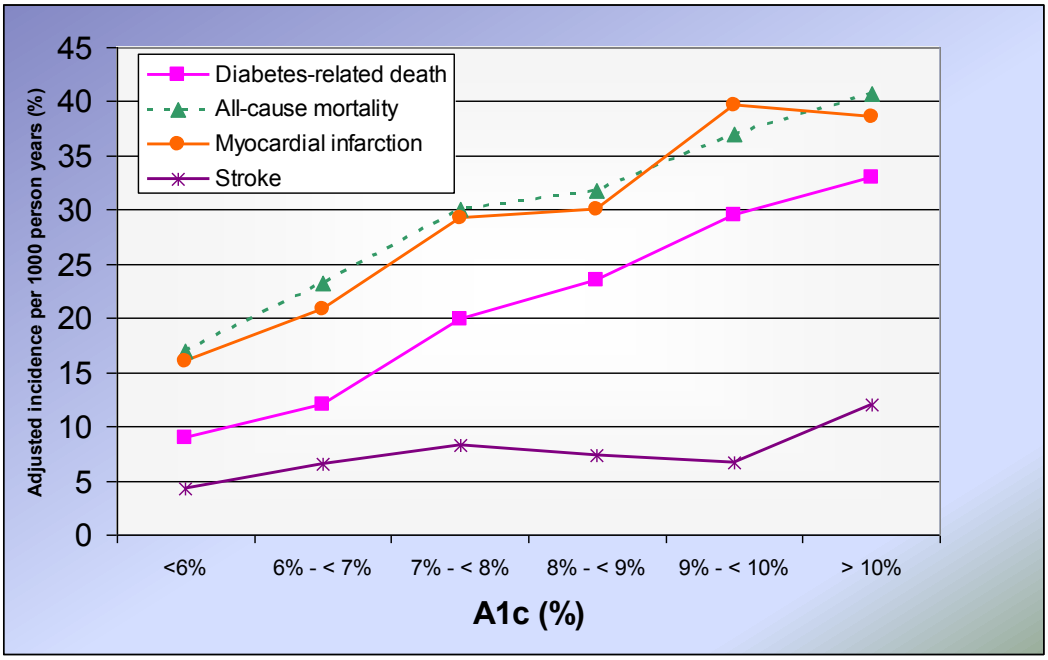


Figure 4: Relationship between Glycemic Control and Mortality, Myocardial Infarction and Stroke [24]

Therefore, a brief discussion will follow on the detrimental effects diabetes has on the body, which may be helpful when counseling patients regarding the importance of proper glycemic control. Diabetic complications are usually classified as either macrovascular or microvascular. Furthermore, people with diabetes are also more susceptible to infections and peripheral complications, primarily in the lower extremities.

1. Macrovascular

Macrovascular complications involve the large blood vessels such as the coronary, cerebral, and some peripheral vessels, and are primarily a result of atherosclerosis.[18] As mentioned previously, people with diabetes are 2 to 4 times more likely to have a heart attack or stroke compared to people of the same age and sex without diabetes. In addition, cardiovascular disease is the leading cause of death in diabetic patients. Heart disease was noted on 68% of diabetes-related death certificates among people aged 65 years or older.[4] Diabetic patients are at increased risk of atherosclerosis for three primary reasons:[18]

I. The incidence of other cardiac risk factors is increased in diabetes, such as hypertension, high cholesterol, and obesity.

II. Diabetes is itself a risk factor for cardiovascular disease (CVD), which is supported by the National Cholesterol Education Program which classifies diabetes as an equivalent to having coronary heart disease.[25]

III. Diabetes may act synergistically with other risk factors by increasing atherogenecity (i.e., altering lipid particles, modifying the blood vessel wall, or by promoting a prothrombotic environment).

Therefore, patients with diabetes need intensive treatments for coexisting risk factors. An overview of the recommended treatment guidelines for diabetic patients may be found in Section V: Therapies for Diabetes.

a) Dyslipidemia

Lipid abnormalities are common in patients with diabetes. The typical abnormalities include:[26]

- Decreased high-density lipoproteins (HDL) cholesterol;
- Elevated triglycerides; and
- Average low-density lipoproteins (LDL) cholesterol, but these particles tend to be smaller, denser, and potentially more atherogenic.

Monitoring: Fasting lipid profile annually for adults with diabetes

Lipid Goals for Diabetic Patients[27]
LDL-cholesterol < 100 mg/dL
- Optional goal of <70 mg/dL if history of CVD)[12]

HDL > 40 mg/dL (men) & > 50 mg/dL (women)
Triglycerides < 150 mg/dL

Treatment Recommendations: Lifestyle changes with statin therapy (e.g., atorvastatin, simvastatin) is treatment of choice due to proven cardiovascular benefit. [12]

b) Hypertension

Hypertension is a common co-morbidity in patients with diabetes and contributes to cardiovascular disease, strokes and nephropathy. One study found 39% of all newly diagnosed type 2 diabetic patients were hypertensive. The Centers for Disease Control and Prevention reports 67% of diabetic patients had high blood pressure or used prescription medications for hypertension.[4]

Monitoring: Blood pressure check at every office visit

Blood Pressure Goals for Diabetic Patients[12, 28]
Blood pressure <140/<80 mmHg or lower if tolerated
(The National Kidney Foundation recommends <125/<75 mmHg in patients with kidney disease present.)
Treatment Recommendations: Lifestyle changes with antihypertensives. ACE inhibitors (e.g., lisinopril) or angiotensin receptor blockers (e.g., losartan) are drugs of choice. Two or more antihypertensive drugs are typically needed.[12]

c) Smoking

It is not clear if a direct relationship exists between smoking and diabetes, but there is substantial evidence concerning the relationship of smoking with increased risk of coronary heart disease. Therefore, it is strongly advised to get patients who smoke to stop.[12,29]

d) Thrombosis or Blood Clots

Patients with diabetes have at least double the risk of stroke or heart attack compared to people without diabetes. Furthermore, heart disease is the number one cause of death in diabetics.[4] It is no wonder many patients with diabetes were placed on antiplatelet therapy by their physicians. However, we have learned over time that the bleeding risk associated with long-term aspirin therapy may outweigh the benefit of preventing strokes, heart attacks and other clots. The American Diabetes Association has revised their general

recommendation for antiplatelet therapy to now select use of aspirin or clopidogrel (Plavix®).[12]

Aspirin Therapy in Diabetic Patients [12]

- Consider aspirin (75-162 mg/day) as primary prevention in adults with diabetes (E.g., men >50 or women >60 years + one additional risk factor).
- Secondary prevention: All adults with diabetes who have already had a CV event.
- Aspirin should not be used by those with low CV risk due to bleeding risk outweighing potential benefit.
- For patients with CVD and documented aspirin allergy, clopidogrel (75mg/day) should be used.

2. Microvascular

The true mechanism for the development of microvascular complications is unclear, but three distinct metabolic pathways appear to be involved.

I. Excess glucose in the blood can interact and bind (glycate) to proteins causing irreversible changes in the protein structure and potentially the function of the protein. This newly formed glycated protein is referred to as an advanced glycation end (AGE) product. AGE products have been linked to detrimental effects in the extracellular matrix as well as within the cell (intracellular).[18,30]

II. High levels of intracellular glucose can cause the premature activation of enzymatic processes (i.e., protein kinase C) which can lead to increased neovascularization in the eye, increased pro-inflammatory responses, and potentially prothrombotic states.[30]

III. Some tissues such as nerves, retina, kidney and blood vessels do not require insulin to transport glucose intracellularly. In hyperglycemic conditions, increased intracellular glucose can be converted by the enzyme, aldose reductase, to sorbitol. This enzymatic reaction requires the cofactor NADPH, which results in the depletion of this cofactor. NADPH is also used to form

glutathione which is one of the body's more potent antioxidants. Therefore, elevated glucose levels indirectly lower our defense mechanisms against oxidative stress and damage.[18,30]

Irregularities found in the arterioles and capillaries result in microvascular complications. The three main microvascular complications are nephropathy, retinopathy and neuropathy.

a) Nephropathy

Kidney disease or nephropathy is a common complication of diabetes. In the United States, diabetic nephropathy is the leading cause for end-stage renal disease (ESRD) accounting for 45% of all cases (Figure 5).[31] And just as the prevalence of diabetes is increasing at national and state levels, so too, is the incidence of ESRD which continued to increase in 2012 with higher incidence in the elderly and those with diabetes.[31] In 2008, a total of 202,290 people in the U.S. with end-stage kidney disease due to diabetes were living on chronic dialysis or with a kidney transplant.[4]

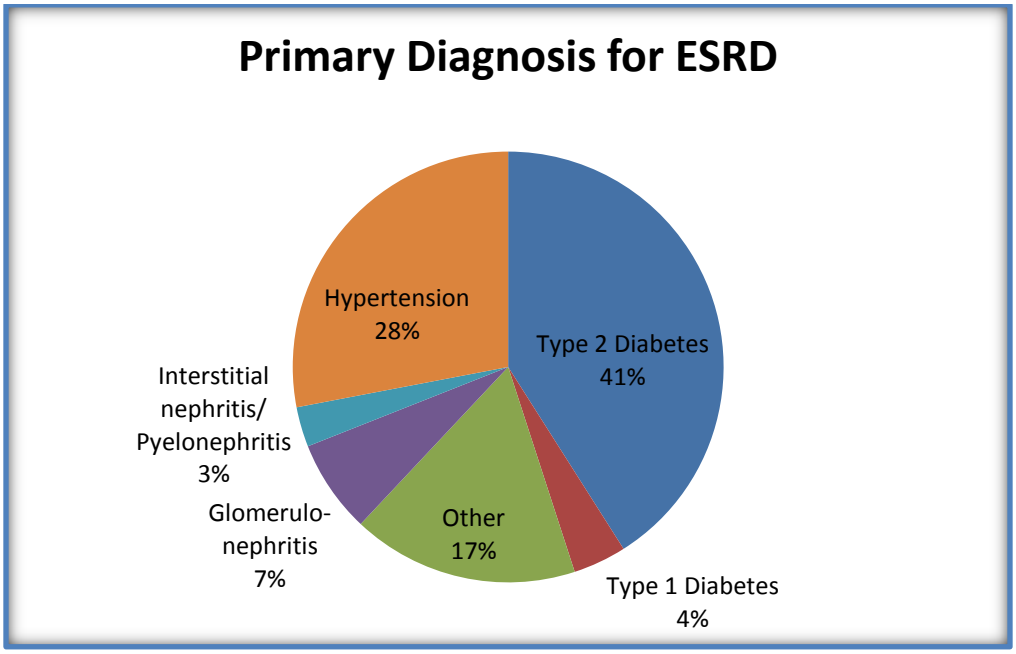


Figure 5: Primary Diagnosis for Kidney Failure [31]

The progression of nephropathy usually starts with a dysfunction in the glomerulus. In normal physiology, the glomerulus is comprised of a vascular capillary bed which filters the blood, generating a filtrate which progresses further down the nephron, the filtering unit of the kidney.[18] Early in diabetes, changes in the glomerulus, i.e., thickening of the capillary vessels, cause a decrease in the volume of filtrate produced, which specialized cells within the kidney sense as low blood flow or pressure. This triggers the renin-angiotension system, and often subsequent hypertension, to increase blood pressure to maintain adequate blood flow through the kidney. This hypertensive state also leads to progressive damage within the glomerulus. As the glomerular function deteriorates, so does its ability to discriminate which types of molecules are being filtered. Albumin, a serum protein, is generally not filtered through the kidney, but with decreased glomerular function, small amounts of albumin are found in the urine. The detection of microalbuminuria is often the first sign of diabetic nephropathy, and as the nephropathy progresses, larger amounts of albumin are found in the urine. The degree of nephropathy is classified by the amount of albuminuria, which approximates renal function.[22,32] (Figure 6)

Classification	Amount of Albumin (mcg/mg creatinine)
Normal	< 30
Microalbuminuria	30-299
Macroalbuminuria	≥ 300

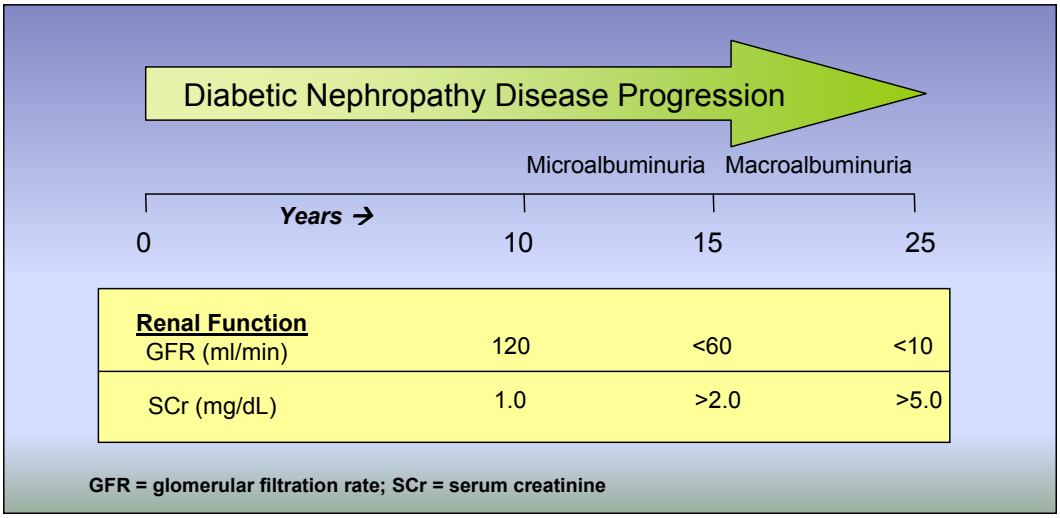


Figure 6: Disease Progression of Diabetic Nephropathy with Corresponding Decreases in Renal Function[32]

Monitoring: All type 2 diabetic patients should be tested for microalbuminuria and serum creatinine at the time of diagnosis (type 1 diabetics after 5 years of disease) and annually thereafter.

Goals:
Optimized blood glucose control and blood pressure control to reduce the risk of or slow the development of nephropathy.

Treatment of Nephropathy:
Nonpregnant patients with either microalbuminuria or albuminuria should receive either an ACE inhibitor or an angiotension blocker.

Reduction of dietary protein intake to 0.8–1.0 g/kg/day in early nephropathy and to 0.8 g/kg/day in the later stages of nephropathy[12,33]

b) Retinopathy

In the United States, diabetes is the leading cause of blindness among adults between the ages of 20-74 years old.[4] Diabetic retinopathy is the major cause of visual impairment and blindness among diabetic patients with an estimated prevalence of 10%. Approximately 20% of type 2 diabetic patients have some degree of diabetic retinopathy at the time of their diagnosis.[34] Furthermore, patients with diabetes have a higher prevalence of other visual impairments including cataracts and glaucoma (Figure 7).[35]

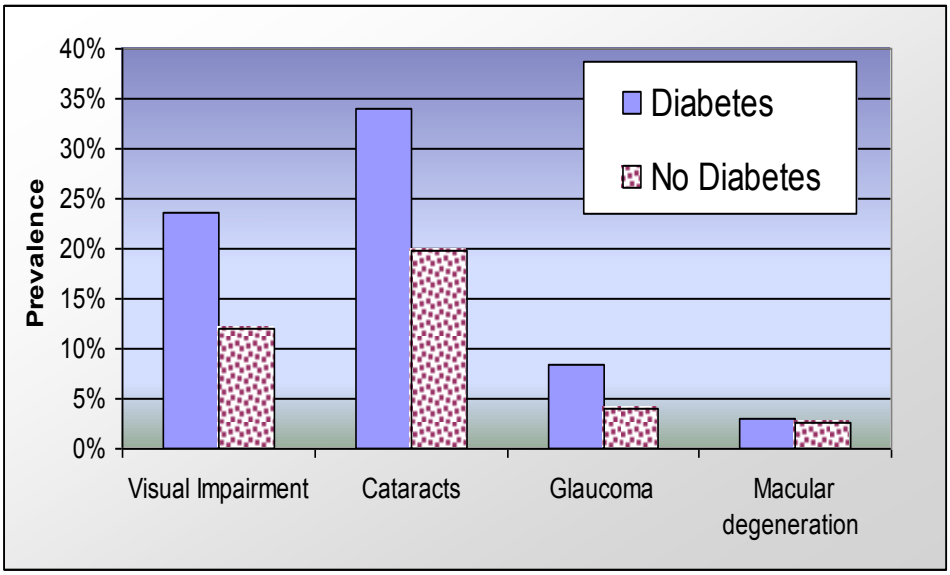


Figure 7: Prevalence of Eye Disorders Among Persons >50 Years Old With and Without a Diagnosis of Diabetes[35]

Diabetic retinopathy is a progressive disease characterized by two stages: non-proliferative and proliferative diabetic retinopathy.

(1) Non-proliferative diabetic retinopathy[18,32]

Non-proliferative diabetic retinopathy usually occurs early in the disease. Initially, microaneurysms occur in retinal capillaries which increase the permeability of the vessel walls to fats, leading to hard, yellow exudates in the retinal vessel wall. Exudates in the area of the macula (point of central vision) can lead to macular edema. The progression of this stage eventually leads to decreased vascular flow in the retina or retinal ischemia. Figure 8 compares a normal retina to one with advanced retinopathy.

(2) Proliferative diabetic retinopathy[18,32]

Secondary to the ischemic changes in the retina, new blood vessels are formed (neovascularization) to restore blood flow, but unfortunately, these blood vessels, which often appear near the optic nerve or macular region, are weaker and more susceptible to rupture. If this stage is detected early, treatment with laser photocoagulation may prevent further deterioration.

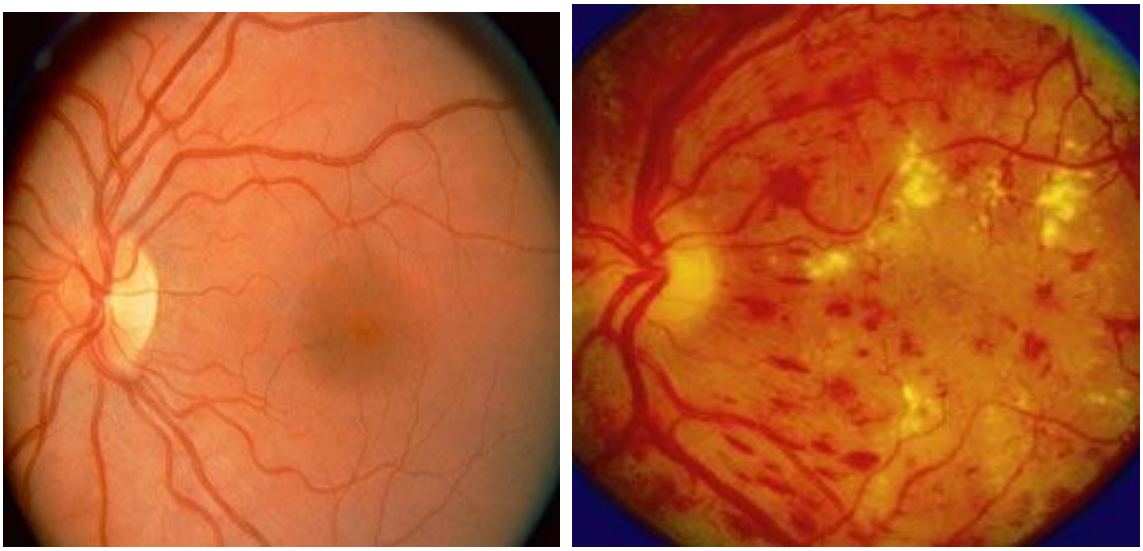


Figure 8: Pictures of a Normal Retina (left) and an Abnormal Retina (right) Showing Scattered Hemorrhages and Yellow Exudates

ADA Monitoring Recommendation: Retinopathy[12,34]
All type 2 patients should receive an ophthalmologic dilated eye examination at the time of diagnosis and yearly thereafter.

Preventing retinopathy is the goal. Optimizing blood glucose, cholesterol, and blood pressure control helps reduce the risk of retinopathy. Of note, low dose daily aspirin therapy does not appear to increase the risk of retinal bleeding and is allowable if indicated for cardiovascular event protection. Once a patient does develop diabetic retinopathy, they should be referred to an ophthalmologist who is knowledgeable and experienced in the management and treatment of the condition. [12]

c) Neuropathy

Neuropathies, which are functional disturbances of the peripheral nervous system, affect approximately 60 to 70% of all diabetic patients in some form.[32,36] Three broad categories of neuropathies affect diabetic patients: sensory, autonomic and motor.

(1) Sensory[32,36]

Loss of sensory nerve input (i.e., hot and cold), due to demyelination of peripheral nerves, results in symmetric distal

polyneuropathies. Early symptoms include numbness or tingling sensations in the extremities (usually the feet and sometimes the hands) typically followed by painful neuropathies, and eventually the permanent loss of sensation in the affected areas.

(2) Autonomic Neuropathies (18,32,36)

Autonomic nerves support the involuntary activities of the body, such as actions of the stomach, bladder and intestines. Dysfunction of the autonomic nerves may lead to debilitating complications summarized in Table 5.

Table 5: Common Autonomic Dysfunctions Found in People with Diabetes

Neuropathy	Description
Gastroparesis	A paralysis of the stomach causing delayed gastric emptying and impaired absorption of food. Symptoms include a bloated feeling after eating, nausea and sometimes emesis.
Diabetic diarrhea	Erratic functioning of the intestine resulting in episodic, voluminous, and watery stools which may be passed without warning. Periods of constipation may also occur, which may increase the risk of an impacted bowel.
Neurogenic bladder	The bladder fails to respond to normal nerve stimulation resulting in incomplete emptying of the bladder leading to urinary retention. The holding of residual urine in the bladder puts patients at increased risk of urinary tract and kidney infections.
Erectile dysfunction (ED)	The ability to attain and maintain an erection may be impaired in diabetic men, and ED may often be a presenting problem leading to a type 2 diabetes diagnosis.

(3) Motor Neuropathies(18,32)

Motor neuropathies, the rarest of the diabetic neuropathies, affect the nerves which cause movement, primarily in the extremities, and may result in decreased motor function and gait disturbances.

Because the types and presentations of diabetic neuropathies are so diverse, a general recommendation is an annual screening for the above neuropathies by a health care provider. People with diabetes should be educated about the types

and typical presentation of the various neuropathies. If signs or symptoms appear, patients should notify their provider for prompt further evaluation.

3. Infections

Diabetic patients are more susceptible to pneumonia, urinary tract infections, and skin and soft tissue infections. They often have a worse prognosis compared to patients without diabetes. The increased risk of infection may be related to an impaired cell-mediated immunity and phagocytic function, a decrease in peripheral circulation, or the increased growth of organisms under hyperglycemic conditions. Furthermore, hyperglycemia prevents adequate wound healing; therefore, glycemic control is paramount to speed wound healing.[32] Because diabetic patients are at greater risk of pneumonia, the ADA recommends vaccinations be kept up-to-date for this patient population.

American Diabetes Association Recommendation: Vaccinations[12, 37]

- All diabetic patients should receive an annual influenza vaccine.
- All diabetic patients should receive at least one lifetime pneumococcal vaccine. (A one-time revaccination is recommended for patients >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago).
- Unvaccinated diabetic patients older than 60 years of age may consider receiving the Hepatitis B vaccine.

4. Lower Extremity Complications

Diabetes is the leading cause of non-traumatic lower-limb amputations in the United States causing approximately 71,000 amputations annually.[22] Patients with diabetes are predisposed to lower extremity complications due to neuropathies, poor peripheral circulation, and impaired wound healing. People with diabetes often cannot feel painful warnings of blister formation or an ingrown toenail. Therefore, it is essential to educate patients to inspect their feet daily for signs of skin damage and infection.[32] Risk factors which have been identified with increasing likelihood of an amputation are:[38]

- Peripheral neuropathy with loss of protective sensation
- Altered biomechanics (in the presence of neuropathy)
- Evidence of increased pressure (erythema, hemorrhage under a callus)
- Bony deformity
- Peripheral vascular disease (decreased or absent pedal pulses)
- A history of ulcers or amputations
- Severe nail pathology
- Poorly controlled blood glucose

The best defense is once again good screening and detection of early signs of foot and lower extremity problems. Patients with diabetes should have at least an annual comprehensive foot examination which includes inspection, palpation of dorsal and tibial pulses, reflex checks, and sensation, vibration, and monofilament testing.[12] People with diabetes should inspect their feet daily for signs of inflammation or wounds. Wearing cotton socks, good-fitting shoes, trimming nails straight across to avoid ingrown toenails, and keeping the skin in good condition are advised. Diabetics should avoid going barefoot, using abrasive treatments (corn removers), and should stop smoking to help prevent lower extremity complications.

H. Prevention of Diabetes

Preventing type 2 diabetes is a "hot topic" in diabetes research. Several randomized, controlled trials have demonstrated the ability to prevent this devastating disease. Table 6[39-43] summarizes the most significant type 2 diabetes prevention trials. Intensive lifestyle changes (5-10% weight loss and moderate physical activity of 30 minutes/day) can reduce the onset of diabetes by 58% in those patients at high risk for developing type 2 diabetes. Metformin, acarbose, orlistat and pioglitazone can also decrease the incidence of diabetes. In the DREAM trial, rosiglitazone was shown to reduce the development of type 2 diabetes by 60%, but rosiglitazone use is now restricted due to increased cardiovascular event concerns. The ADA Consensus Development Panel recommends that all persons with pre-diabetes (IFG or IGT) should institute lifestyle changes to lower their risk of developing type 2 diabetes. For very high-risk patients (pre-diabetes with at least one other risk factor), drug therapy with metformin may be considered. [12]

Table 6[39-43]: *Summary of Clinical Trials for Diabetes Prevention*

Study Descriptor	Patient Population	Treatment Groups	Primary Result
Finnish Diabetes Prevention Study Group[39]	# of pts = 522 Sexes = male & female Ave. age = 55 y.o. Ave. BMI = 31 kg/m^2 Pre-diabetic pts (+ IGT) Years of follow-up = 3.2	1. Brief diet & exercise counseling 2. Intense, individualized diet & exercise counseling	Intensely counseled group had a 58% relative reduction in incidence of type 2 diabetes compared to brief counseling.
Diabetes Prevention Program[40]	# of pts = 3,234 Sexes = male & female Ave. age = 51y.o. Ave. BMI = 34 kg/m^2 Pre-diabetic pts (+ IGT) Years of follow-up = 2.8	1. Lifestyle group: counseled on better nutrition & exercise 2. Metformin 3. Placebo	Both the lifestyle and metformin groups had a 58% and 31% relative reduction, respectively, in the incidence of type 2 diabetes compared to placebo.
STOP-NIDDM[41]	# of pts = 1,429 Sexes = male & female Ave. age = 55 y.o. Ave. BMI = 31 kg/m^2 Pre-diabetic pts (+ IGT) Years of follow-up = 3.3	1. Acarbose (drug to slow carbohydrate absorption) 2. Placebo	The acarbose-treated group had a 36% relative reduction in the incidence of developing type 2 diabetes compared to placebo.
XENDOS[42]	# of pts = 3,277 Sexes = male & female Ave. age = 43 y.o. BMI $\geq$ 30 kg/m^2 Normal BG or IGT Duration = 4 years	1. Lifestyle changes + orlistat 120 mg TID 2. Lifestyle changes + placebo	The orlistat-treated group had a 37% risk reduction in incidence of type 2 diabetes compared to control. Orlistat group lost more weight.
ACT NOW[43]	Pts = 602 Sexes = male & female Ave. age = 52 y.o. IGT Duration = 2.4 years	1. Pioglitazone 45 mg per day 2. Placebo	The pioglitazone-treated group had a 72% reduction in incidence of type 2 diabetes.

Key: BMI: body mass index, IGT: impaired glucose tolerance

IV. Screening for Diabetes

A. Who should be screened?

While there is considerable evidence that certain individuals are predisposed to diabetes, there have been no clinical trials which have addressed the effectiveness of diabetes screening on decreasing mortality or morbidity, or on the cost-effectiveness of early detection. For these reasons, the ADA currently recommends diabetes screening only be performed in patients at higher risk of developing diabetes.[12]

ADA Criteria for Testing for Diabetes [12]

- The A1c, fasting plasma glucose (8 hr fast), or 75-g 2-hr Oral Glucose Tolerance Test may be used.
- Testing should be considered in all adults who are overweight (BMI $\geq$25 kg/m^2) and have one or more risk factor (see Table 4 for risk factors)
- In the absence of the above criteria, testing for diabetes should begin at age 45 years.
- Repeat adult testing at least every 3 years, except those with prediabetes should be tested yearly.
- In children,
    - Test if high risk: weight > 120% of weight ideal for height + 2 risk factors
    - Test every 3 years starting at 10 years old or puberty

B. Use of Hemoglobin A1c for Screening

Hemoglobin, which is found in red blood cells, is a protein which delivers oxygen to cells. Like most proteins, it has the ability to be glycated or linked with sugars found in the blood, such as glucose. Therefore, the amount or percentage of glycated hemoglobin in the blood is a measurement of how much glucose the hemoglobin has been exposed to in the preceding weeks. Since hemoglobin is only found within red blood cells, which typically have a lifespan of 120 days, the percent of glycated hemoglobin is a measure of glycemic control over the past 8 to12 weeks. A person without diabetes usually has about 5% of the hemoglobin glycated, but for patients with chronic

hyperglycemia, the percentage of glycated hemoglobin is considerably higher.[44,45]

The A1c test, which is a measurement of glycated hemoglobin, is routinely recommended for use at least twice a year as a monitoring tool for patients diagnosed with diabetes to assess how well the patients are managing their diabetes.[12,45] The A1c test is currently used as a screening device, as studies have evaluated the A1c test in this capacity and have found good reliability when National Glycohemoglobin Standardization Program (NGSP)-certified methods are used.[12,49]

Therefore, the ImProving Health Among Rural Montanans (IPHARM) program chose to utilize the A1c test as a screening device for three main reasons.

1. Analyses suggest that the A1c test has the best combination of sensitivity and specificity at a cut point of 5.7%, which can be used to identify cases of impaired fasting glucose. Among the nondiabetic population, an A1c of 5.6% corresponds to an FPG of 110mg/dL and an A1c of 5.4% corresponds to an FPG of 100mg/dL. Table 7 demonstrates further correlations of A1c and average plasma glucose. Clinical judgment is necessary to evaluate patients whose values fall between 5.7 - 6.4%, with considerable emphasis placed on co-existing risk factors. The A1c test can help identify individuals with high risk for future diabetes.[12]

Table 7: Correlation of Hemoglobin A1c with average plasma glucose[12]

A1c %	mg/dL	mmol/L
6	126	7.0
7	154	8.6
8	183	10.2
9	212	11.8
10	240	13.4
11	269	14.9
12	298	16.5

2. The test is easy to administer and only takes about five minutes to perform, requiring minimal blood sample collection.

3. The test does NOT have to be performed in a fasted state. This is important as it is not practical for patients to attend screening events in the afternoon without eating a meal since the previous night.

Finally, it should be emphasized that the use of the A1c test for screening purposes is not a diagnostic procedure. Follow-up care by a health care professional will be necessary to confirm a diagnosis of diabetes.

C. Use the Afinion™ HbA1c test

1. The Afinion™ HbA1c test [46]

The Afinion™ HbA1c test is a CLIA waived, single-use, point-of-care test read by the fully automated Afinion™ Analyzer. The device uses a boronate affinity method unlike the more commonly used DCA immunoassay method. The HbA1c test cartridge contains all reagents necessary for the measurement of glycated hemoglobin. It utilizes 1.5 µL of blood to provide A1c results (measuring range of HbA1c of 4-15%) in about three minutes.

Afinion™ HbA1c test has demonstrated 98% accuracy when compared to a central laboratory high-performance liquid chromatography (HPLC) method.[47] In CLIA waived labs, it is recommended analyzing controls with each new lot of HbA1c kits, at least every 30 days, when training new users and anytime an unexpected test result is obtained.

A quick guide for use of the Afinion™ HbA1c test is found in Appendix C and provides a reference on the Afinion™ Analyzer, how to set up the testing device, and how to run a sample and controls. To view a 2-minute video on the use of the device go to www.youtube.com/watch?v=-6Rf_H142l4 or visit the manufacturer's website at http://www.afinion.net/demo

2. Performing a finger stick for blood collection

Obtaining an adequate quantity of blood from a finger stick is sometimes the most challenging component of diabetic screening.

Among the following steps are some suggestions to assist with minimizing collection difficulties.

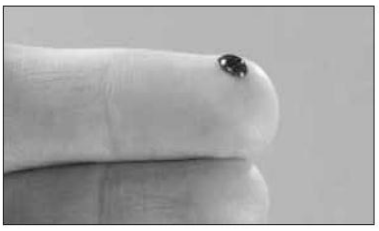
a. Patients with thick calluses or poor peripheral circulation may be the most difficult. Warming the hands under warm water or holding onto hand warmers can substantially help with getting adequate blood supply down to the finger tips. For patients with thick calluses, try to look for a finger with the least amount of callus.

b. It is generally a better idea to obtain the blood sample from the non-dominant hand, as a band-aid will be placed on the finger utilized for the blood sample, and the non-dominant hand may be less callused.

c. Inspect the patient's fingers and gently press on the tips of the fingers to assess which fingertip has good blood return. (The tip should become a rosy-red color compared to the other finger areas.) The middle (3^{rd}) finger or the ring (4^{th}) finger is generally a good choice to perform the finger stick.

d. Cleaning of the finger area with an alcohol swab prepares the site for penetration with the lancet. The fingertip needs to be completely dry prior to performing the finger stick.

e. The recommended placement of the lancet on the finger is on the outside edge of the fingertip. (About the 2 o'clock position when looking at the fingertip.) Place the lancet firmly on the tip and push downward AND hold in place for two seconds. Holding the lancet in place prevents the reflexive impulse to pull the lancet away from the skin before it has fully penetrated.



f. When trying to get the area which was pricked to bleed, keep in mind the lancet provides a slit-like cut which responds better to gently opening the cut as opposed to squeezing the cut (which pushes the cut edges together.) A drop of blood should appear with gentle massaging. Try to avoid "milking" the finger (which is squeezing along the finger towards the tip), as this may lead to an inaccurate result.

NOTE: If a patient will not bleed after two different attempts, ask the patient to drink about 2 cups of water and return in an hour as the patient may be dehydrated. If the patient still cannot provide a sufficient sample, inform the patient that no further attempts will be made, and rescheduling for another day will be necessary.

g. Placing the collection capillary tube at a slight downward angle to the blood droplet and gently touching the side of the droplet with the capillary tube should result in the gentle sucking action of the blood up the tube. Blood will wick to the line and then stop. Once the blood reaches the designated line on the capillary tube, provide the patient with a tissue or gauze pad to press against the bleeding finger.

3. Interpretation of Results

As mentioned previously, IPHARM utilizes the Afinion™ Analyzer to screen patients who may be at higher risk of diabetes. Table 8 may be used as a general guideline for the interpretation of the results. Patients with an A1c ≥ 5.7% should be referred to a health care provider for follow-up, but it should be emphasized to the patient that this abnormal value does NOT diagnose them with diabetes.

Table 8: IPHARM Recommended Actions for Afinion™ Analyzer HbA1c Test Results

A1c value	Action Required

< 5.7%	No follow-up recommended, but general counseling on risk factor reduction is advised.
≥ 5.7%	Follow-up with a health care provider recommended; provide general counseling on risk factor reduction.

V. Therapies for Diabetes

A multidisciplinary approach to address the diverse needs of a diabetic patient may include expert involvement of physicians, physician assistants, nurse practitioners, nurses, pharmacists, diabetes educators, dieticians, physical therapists, mental health professionals and social workers. An individualized treatment plan with patient-specific goals, in conjunction with patient education, is essential to achieving successful therapeutic outcomes.

Table 9 describes the glycemic goals which have been established by two main professional diabetes organizations: American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE).[12,48]

Table 9: Goals for Glycemic Parameters: American Diabetes Association & American Association of Clinical Endocrinologists[12,48]

Glycemic Parameter	Expert Group	Goal
A1c	ADA AACE	< 7% ≤ 6.5%
Pre-prandial plasma glucose	ADA AACE	70-130 mg/dL ≤ 110 mg/dL
Post-prandial plasma glucose (generally 1-2 hours after the beginning of a meal)	ADA AACE	< 180 mg/dL ≤ 140 mg/dL

Lowering A1c to below or around 7% has been shown to reduce microvascular complications of 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 less than 7%. More stringent A1c goals (such as <6.5%) are reasonable for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects. Appropriate patients might include those with short duration of diabetes, long life expectancy, and no significant cardiovascular disease. Less stringent A1c goals (such as less than 8%) should be considered for people with a history of severe hypoglycemia, limited life expectancy, advanced complications, extensive comorbid conditions, and those with long-standing diabetes. Many elderly patients with diabetes fall into this latter category. For these patients, the risks of therapy (death or events associated with hypoglycemia) may not outweigh the benefits of tight blood glucose control that take years to fully appreciate. Goals should be individualized and patients should know their glycemic goals.[12,48]

A. Diet and Exercise

Diet and exercise are essential therapies for all patients with diabetes. Additionally, it has been shown that patients at risk for diabetes can prevent or delay diabetes onset with modifications in diet and weight control.[12]

The following nutritional goals apply to patients with diabetes, but their application may be appropriate for patients at risk for diabetes.[12]

- Attain and maintain recommended metabolic outcomes, including glucose and A1c levels; LDL cholesterol, HDL cholesterol, and triglyceride levels; blood pressure; and body weight.
- Prevent and treat the chronic complications and comorbidities of diabetes. Modify nutrient intake and lifestyle as appropriate for the prevention and treatment of obesity, dyslipidemia, cardiovascular disease, hypertension and nephropathy.
- Improve health through healthy food choices and physical activity.

- Address individual nutritional needs, taking into consideration personal and cultural preferences and lifestyle while respecting the individual's wishes and willingness to change.

Any of the lifestyle interventions listed in Table 10 may be appropriate for patients at risk for diabetes. Increasing dietary fiber (14 g fiber/1,000 kcal), including eating whole grains, and limiting sugary drinks are also recommended. Before any patient initiates a physical activity program, it is advised that the patient be assessed by their healthcare provider.[12]

Table 10: Lifestyle Modifications for Diabetic Patients[12]

Activity	Comment
Lose weight if BMI >25 kg/m^2	Low-fat or low-carb diets may be effective for short-term weight loss.
Stop smoking	
Exercise appropriately	30 minutes of moderate exercise 5 days a week (150 min/week). Exercise should include adequate warm-up and cool-down periods (about 5-10 minutes each). Use proper footwear and inspect feet daily after exercise.
Reduce dietary saturated fat and cholesterol	Total daily fat should be 20-35% of total calories Saturated fat should be < 7% of total calories Intake of *trans* fatty acids should be minimized Cholesterol intake should be < 300 mg/day
Reduce sodium intake if hypertensive	If hypertensive, daily sodium should be < 2.4 g/day which is about 1 teaspoon of salt per day.
Monitor carbohydrate intake	Carbohydrates should provide 45-60% of daily energy intake. Sucrose does not increase blood glucose to a greater extent than equal amounts of starch or fiber; therefore, sucrose and sucrose-containing foods should be eaten in context with a healthy diet.
Eliminate or limit alcohol	Abstain if possible. If using alcohol, daily intake should be limited to 1 drink/day in women or 2 drinks/day in men

B. Pharmacologic

Most patients will require pharmacologic assistance to achieve glycemic goals. Implementing drug therapy is beyond the scope of diabetes screening and will not be discussed further in this module, but Table 11 briefly describes the commonly prescribed agents used in the treatment of type 2 diabetes. Since the majority of patients with type 2 diabetes are not using insulin, insulin products are not included.[4]

Table 11: Commonly Prescribed Medications for Patients with Type 2 Diabetes[22]

Drug Class ▪ Generic (Brand)	**Mechanism Of Action**	**Major Side Effects**
Sulfonylureas First generation ▪ Tolbutamide (Orinase®) ▪ Tolazamide (Tolinase®) ▪ Chlorpropamide (Diabinese®) Second generation ▪ Glyburide (DiaBeta®, Micronase, Glynase®) ▪ Glipizide (Glucotrol®) ▪ Glimepiride (Amaryl®)	Primarily stimulates insulin release from the pancreas. Also decreases glucose output by the liver.	Hypoglycemia, weight gain, nausea, & headache (Note: These side effects pertain to the second generation drugs, because the first generation medications are rarely used due to increased toxicity.)
Biguanides ▪ Metformin (Glucophage®, Fortamet®, Riomet®) First line therapy for type 2 diabetes unless contraindications present.	Decreases liver glucose production. Improves insulin sensitivity in peripheral tissues. Decreases intestinal absorption of glucose.	Metallic taste, diarrhea, nausea, weight loss. **Renal function** must be monitored. Stop drug if serum creatinine > 1.5 mg/dl (men) & > 1.4 mg/dL (women) **Contraindicated** in patients with CHF, alcohol abuse, metabolic acidosis, liver or kidney disease, and ≥ 80 years old.
Alpha-Glucosidase Inhibitors ▪ Acarbose (Precose®) ▪ Miglitol (Glyset®)	Delays intestinal absorption of carbohydrates resulting in decreased post-prandial glycemia.	Flatulence, diarrhea, and abdominal pain.
Thiazolidinediones (a.k.a. glitazones) ▪ Rosiglitazone (Avandia®) RESTRICTED ACCESS ▪ Pioglitazone (Actos®)	Increases insulin sensitivity.	Increases total cholesterol, LDL & HDL; weight gain; edema; headache; fatigue; and nausea. Monitor liver function. **Contraindicated** in patients with CHF, liver disease, alcohol abuse, or pregnancy
Meglitinides ▪ Repaglinide (Prandin®) ▪ Nateglinide (Starlix®)	Increases insulin secretion from the pancreas.	Headache & hypoglycemia
DDP-IV Enzyme Inhibitors ▪ Saxaglyptin (Onglyza®) ▪ Sitagliptin (Januvia®) Linagliptin (Tradjenta®)	Prolongs active incretin levels in gut, reducing fasting and postprandial glucose levels	Headache, nausea, nasopharyngitis, UTI

Incretin Mimetics ▪ Exenatide (Byetta,Bydureon® ▪ Liraglutide (Victoza®)	Enhances glucose-dependent insulin secretion. Suppresses inappropriate glucagon secretion. Slows gastric empyting.	Nausea, vomiting, diarrhea, headache, dizziness, nervousness
Amylin Analog ▪ Pramlintide (SymlinPen ®)	Modulates gastric emptying. Prevents post-prandial rise in plasma glucagon. Produces satiety leading to decreased caloric intake.	Dizziness, fatigue, headache, abdominal pain, anorexia, nausea, vomiting, weight loss
Dopamine Agonist Bromocriptine (Cycloset®)	Resets dopaminergic mediation of circadian rhythms that play a role in insulin resistance/obesity	Hypotension, drowsiness, hypoglycemia, stomach upset, nasal congestion, lazy eye
Bile Acid Sequestrant Colesevelam (WelChol®)	Bile acid sequestrant	Constipation, dyspepsia, and increased triglycerides

VI. Useful Diabetes Websites

- Highly recommended websites for further understanding of key concepts related to geriatric screening.

(1) Governmental

(a) National Diabetes Education Program (NDEP). http://ndep.nih.gov

(b) National Institute of Diabetes & Digestive & Kidney Diseases. http://www2.niddk.nih.gov/

(c) Indian Health Service, Division of Diabetic Treatment & Prevention http://www.ihs.gov/MedicalPrograms/Diabetes/index.asp

(d) The Montana Diabetes Resource Center. http://www.dphhs.mt.gov/publichealth/diabetes/resourcecenter.shtml

(2) Diabetes Organizations

(a) American Diabetes Association. http://www.diabetes.org

(b) American Association of Diabetes Educators. http://www.diabeteseducator.org/

(c) National Diabetes Education Initiative. http://www.ndei.org/

(d) Defeat Diabetes Foundation, Inc. http://www.defeatdiabetes.org/

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APPENDIX A: IMPROVING HEALTH AMONG RURAL MONTANAS (IPHARM) AUTHORIZATION TO TEST FORM

IMPROVING HEALTH AMONG RURAL MONTANAS (IPHARM)
AUTHORIZATION TO TEST FORM

IPHARM will provide SCREENING test(s) to you today at your request and for the specific purpose of providing you with information that may relate to your health. An explanation of the results and how they may relate to your health will be provided by IPHARM personnel.

What will happen today?

IPHARM personnel will conduct the test(s) you have requested, obtain the results, and explain the results to you. You will receive the original and **only** copy of your complete test results. IPHARM personnel will record your results for statistical purposes on a data sheet that does NOT include your name. The results will be used in IPHARM reports compiled with all other test results and your results will never be individually identified or connected to you without your written permission. IPHARM will keep your agreement to be tested and the results sheets confidential, separated, and secure. IPHARM further agrees to use personnel trained to provide these tests and to follow general methods approved for these tests. IPHARM agrees to exercise due caution in those areas associated with the tests provided.

What do I agree to when I sign below?

By signing below, you indicate you have read and understand this form. You agree that IPHARM has no responsibility to contact your health care provider. You agree to receive testing from IPHARM for the test(s) you have requested. Finally, you agree to hold harmless IPHARM personnel for acts beyond their control or outside their responsibility in providing you these tests. ***A copy of this form is available upon request**.

Do I need to give these results to my health care provider?

IPHARM strongly encourages you to take your results to your provider when you next schedule an appointment. In some cases, IPHARM may suggest you schedule an appointment with your provider. IPHARM reminds you that **a single screening test result whether abnormal or normal does not provide you or your provider enough information on which to make therapeutic decisions about your health**. However, the tests may indicate that you should have further tests done or undertake changes in your life that could improve your health.

_____ _____
Client Signature Date

_____ _____
Printed name of client Daytime phone number

_____ Initial here if you will allow IPHARM to take a picture of you during testing to be used for publicity of the IPHARM program.

_____ Client record number (record on results sheet also)

Appendix B: Protection of Staff & Public from Blood-Borne Pathogens

IPHARM will follow the procedures outlined below in order to protect individuals administering finger-stick tests and individuals exposed to finger-stick test waste that might cause injury. In all cases, IPHARM's intent is to protect staff and the public from potential injury.

Procedure 1
All IPHARM workers will be instructed before any tests are completed by an IPHARM Clinical Pharmacist Specialist (CPS), Principal Investigator (PI), or Project Coordinator (PC).

Procedure 2
All IPHARM workers administering finger-sticks must wear non-latex gloves on both hands prior to administering any finger-stick.

Procedure 3
All IPHARM workers will administer finger-stick tests only after training on the proper method for doing this procedure and only after observation of an instructor (PI, CPS, or PC) administering this test.

Procedure 4
The following items must be placed in a "Sharps" container after use:

Lancets (closed, open, or retractable), pipettes or other collection tubes, any other devices or potentially sharp objects that are used and come into contact with blood or body fluids.

Items that may be discarded in a plastic garbage bag include the following: alcohol swabs, tissues including tissue with blood, used Band-Aids, and gloves that are properly removed and folded inside out into one another (gloves with blood may be handled in this manner also).

Procedure 5
After a person has a finger-stick test, they should be told to compress the site for at least 3-5 minutes with gentle but firm pressure. The IPHARM staff member working the station should inspect the site after this in order to determine if the person's lancet wound has stopped bleeding. If not, a Band-aid shall be applied.

Procedure 6
In the event any worker believes they have come into contact with blood or body fluid and such contact has consisted of contact with an open sore or mucous membrane, the worker should immediately contact the IPHARM Clinical Pharmacist Specialist at the event.

Appendix C:

Afinion™ HbA1c • Quick Guide

afinion™

CLIA statement

This is a CLIA-waived test. A CLIA Certificate of Waiver is needed to perform testing in waived labs. If the laboratory modifies the test instructions, including quality control, the test will no longer meet the requirements for waived categorization. A modified test is regarded as highly complex and is subject to all applicable CLIA requirements.

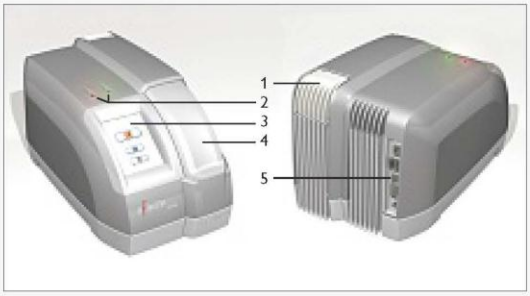
Important!

- Read the entire Afinion™ HbA1c Quick Guide before testing patient samples or controls.
- See the Afinion™ AS100 Analyzer User Manual for more information about the operation of the Analyzer and Test Cartridge.
- See the Afinion™ HbA1c Package Insert for more information about the HbA1c assay.
- Use quality control materials to confirm that the Analyzer and test kit are working properly.

1 GETTING STARTED

Take time to familiarize yourself with the Analyzer and the test kit.

Afinion™ AS100 Analyzer



1 ON/OFF button
2 Light emitting diodes
3 Touch screen
4 The lid
5 Connectors

Cleaning the Analyzer
Clean the Analyzer every 30 days. Follow the procedure in the User Manual. See section "Cleaning and Maintenance".

Important touch buttons

- Patient sample mode
- Control mode
- Patient ID
- Control ID
- Enter
- Accept

Important information codes

Code	Cause
103	Hemoglobin below 6.0 g/dL
104	Hemoglobin above 20.0 g/dL
105	HbA1c below 4.0%
106	HbA1c above 15.0%
202	Excess sample on the sampling device exterior
204	- Hemolyzed or coagulated sample - Analyzer failure

Afinion™ HbA1c Test Cartridge

Axis-Shield PoC AS, Oslo, Norway www.axis-shield-poc.com US 1115463 2008-02

Afinion™ HbA1c • Quick Guide

2 PREPARE FOR TESTING

- Switch the Analyzer on.
- Allow 15 minutes for the Test Cartridge to reach operating temperature (64-86°F) before use.
- Open the pouch just before use. Hold the Test Cartridge by the handle.
- Label the Test Cartridge with sample ID. Use the ID area.
- Analyze Afinion™ HbA1c Control before analyzing patient samples.

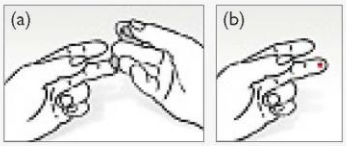
3 PROCEDURE FOR COLLECTING THE SAMPLE

Sampling from a control vial

Follow the procedure described below.
See page 4 for control testing recommendations.

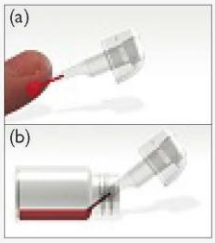
Sampling from finger

- Always use gloves.
- Cleanse the finger using alcohol. Allow the area to air dry.
- Use a lancet and firmly prick the finger (a). Properly dispose the lancet.
- Allow a good drop of blood to form before sampling (b).
- Apply direct pressure to the wound site with a clean gauze pad.



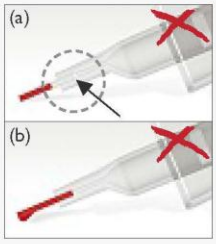
Specimen collection using the Afinion™ HbA1c Test Cartridge

1 Pull up the sampling device.



2 Touch the surface of the blood drop (a) or control (b).

3 Fill the capillary to the end. It is not possible to overfill.



4 Avoid air bubbles and incomplete filling (a). Avoid sample on the outside of the capillary (b). Do not wipe off.

5 Insert the sampling device immediately.

6 Within 1 minute place the Test Cartridge in the Analyzer.

Axis-Shield PoC AS, Oslo, Norway www.axis-shield-poc.com US 1115463 2008-02

afinion™

4 RUNNING SAMPLES ON THE ANALYZER

1

Patient sample:
Touch for patient samples.

Control:
Touch for controls.

2

The lid opens automatically.
Insert the Test Cartridge.
The barcode should face left.

3

Close the lid manually.

4

Patient sample:
Touch for patient samples.

Control:
Touch for controls.

Enter ID during processing.

Touch to confirm.

5

Record the result when it appears on the screen.

Touch to accept.

6

The lid opens automatically.
Remove and discard the cartridge.

Close the lid manually.

Information codes
Important information codes are listed on page 1. Consult the Analyzer User Manual for information codes not listed on page 1. Follow the actions listed in the User Manual to correct the error.

Verification of test results
Consult the HbA1c Package Insert. See section "Test result reporting".

Verification of Control results
Compare the results with the values listed on the front of the Afinion™ HbA1c Control Package Insert.

Technical Support?

Call 1-877-4-Afinion or 1-877-423-4646. This is a toll free number. Available for use only in the United States of America.
US Technical Support can also be reached by E-mail. Send your request to: techsupport@us.axis-shield.com

Axis-Shield PoC AS, Oslo, Norway www.axis-shield-poc.com US 1115463 2008-02

CONTROL TESTING

Read the entire Afinion™ HbA1c Control Package Insert before use.

How often do I have to run controls?

In CLIA waived labs, it is recommended analyzing controls:

- With each new shipment of HbA1c kits.
- With each new lot of HbA1c kits.
- At least every 30 days.
- When training new users.
- Anytime an unexpected test result is obtained.

How should I use the Afinion™ HbA1c controls?

- Allow the control to reach room temperature before use. This takes about 30 minutes.
- Mix the control well by thoroughly shaking the vial for 30 seconds.
- Inspect the vial to ensure that the control solution is homogenous.
- Analyze the control using the procedures described on page 2 (Specimen collection) and page 3 (Running samples on the Analyzer).
- Compare the test results with the values listed on the front page of the Afinion™ HbA1c Control Package Insert.

What do I do if Afinion™ HbA1c Control results are not within the acceptable range?

- Do not analyze any patient samples.
- Check the control vial label to make sure it is not expired.
- Ensure that the control has not been used for more than 60 days.
- Verify that the controls and test cartridges have been stored correctly.
- Verify that there is no visual sign of bacterial or fungal growth in the control vial.

Correct any procedural error. Re-test the control.

If the control values are still not within acceptable range, repeat the test using a new vial of control. If the control results are still not acceptable, call Afinion™ Technical Support.

www.signatur.no Kl62 • 280274

Technical Support?

Call 1-877-4-Afinion or 1-877-423-4646. This is a toll free number. Available for use only in the United States of America.
US Technical Support can also be reached by E-mail. Send your request to: techsupport@us.axis-shield.com

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APPENDIX D: Body Mass Index Chart

Body Mass Index Table

	Normal						Overweight					Obese										Extreme Obesity														
BMI	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**	**52**	**53**	**54**
Height (inches)	Body Weight (pounds)																																			
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Source: Adapted from *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.*

Appendix E: IPHARM Patient Brochure: Understanding Your Blood Sugars

Talk to Your Doctor

⇒ If you have a family history of diabetes or feel you may be at risk for pre-diabetes, ask your health care provider about being tested.

⇒ If you experience any of the following symptoms, you may have pre-diabetes or diabetes, and should call your doctor for further information.

- Frequent urination
- Excessive thirst
- Extreme hunger
- Unusual weight loss
- Increased fatigue (tiredness)
- Irritability
- Blurred vision

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IPHARM

ImProving Health Among Rural Montanans

Understanding your blood sugars

What you should know about the prevention and control of diabetes

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I don't have diabetes; why should I worry about my blood sugar?

When we eat, our food is broken down into glucose (a sugar), which then goes into the bloodstream. Insulin, a hormone released by the pancreas, helps the glucose get from the bloodstream into our cells to provide energy for our bodies. Lack of physical activity and excess weight can cause our bodies to stop using insulin properly, which can lead to blood sugar complications.

One complication is **pre-diabetes**. Pre-diabetes is when blood glucose levels are higher than normal, but not high enough to have diabetes.

How do I know if I have pre-diabetes?

There are three tests which can be used to determine if a person has pre-diabetes.

Fasting Plasma Glucose (FPG) – This test is a blood test taken after fasting for at least 8 hours.

Oral Glucose Tolerance Test (OGTT) – This test is also done after fasting for at least 8 hours and 2 hours after drinking a sugary liquid.

Hemoglobin A1c (HbA1c) - This test gives the average of your blood sugar control over the past 3 months.

Facts & Figures

- Approximately 25.8 million Americans have diabetes.
- Another 79 million Americans have pre-diabetes.
- The approximate cost of diabetes is $174 billion per year.
- Approximately 65% of people with pre-diabetes will develop diabetes within 6 years if they do not make changes.
- Complications of diabetes, such as eye problems (retinopathy), have been seen in up to 16% of people with pre-diabetes.

Risk Factors for Pre-Diabetes

- Excess weight or obesity
- Age 45 or older
- A parent or sibling with diabetes
- Non-white ancestry
- Delivery of a baby weighing more than 9 pounds, or gestational diabetes
- High blood pressure
- Abnormal cholesterol levels
- Lack of physical activity
- Polycystic ovarian syndrome
- Cardiovascular disease
- Previous high blood glucose levels

Symptoms

- Pre-diabetes usually does not have symptoms, but high blood glucose levels can still cause damage to the body if they are ignored.

Prevention and Treatment

⇒ Good news! Lifestyle changes are very effective at reversing pre-diabetes and preventing its progression to diabetes.

- Reduce weight by 5-10%.
- Exercise 30-60 minutes per day at least 5 days per week.
- Eat a healthy diet (See list on last page).
- Stop smoking and avoid excess alcohol.

⇒ Control blood pressure and cholesterol levels. The American Diabetes Association recommends the same guidelines for pre-diabetes that apply to diabetes.[1]

- Blood Pressure: 130/80 mmHg or less
- LDL (bad cholesterol): 100 mg/dL or less
- HDL (good cholesterol):
  - 40 mg/dL or more for women
  - 50 mg/dL or more for men
- Triglycerides: 150 mg/dL or less

⇒ If lifestyle changes alone are unsuccessful, patients can talk to their doctor about medications that can help control pre-diabetes.

What if I have pre-diabetes?

⇒ Several tests should be performed at least once per year.

- Fasting blood glucose should be checked with the FPG or OGTT test.
- A hemoglobin A1c (HbA1c) test (measure of blood glucose control over 3 months).
- Cholesterol levels.
- Urinalysis to test for presence of protein in urine.
- Blood pressure should be monitored regularly.

How to choose fruit…

One serving of fruit should contain 15 grams of carbohydrates.

The following fruit servings contain about 15 grams of carbohydrates:

- ½ medium banana
- 1 small apple
- 1 ¼ cup cubed watermelon
- 1 ¼ cup whole strawberries
- 1 small orange
- ½ large grapefruit

What are carbohydrates?

- Carbohydrates are a source of energy for your body.
- Foods with carbohydrates raise your blood sugar (glucose).
- Keeping track of carbohydrates can help keep your blood sugar in range.
- The three main types of carbohydrates include the following:

Starches - e.g., oats, rice, peas & potatoes

Sugars - naturally occurring (e.g., milk and fruit) and added sugar (e.g. soda)

Fiber - the indigestible parts of plants including fruits, vegetables, whole grains, nuts, and legumes.

- All carbohydrates have a glycemic index (GI), which is a number that helps classify carbohydrates based on **how quickly** and **how high they boost blood sugar** compared to pure glucose (sugar).
- In general, you want to choose foods with a low GI (score of <55).
- Also, the more a food is processed the higher its GI.
- Foods with a low GI are foods such as whole grains, beans, fruits, and vegetables

Diabetes Superfoods!

These foods have a low GI and provide important nutrients.

Food	Examples
Beans	Kidney, pinto, navy or black beans
Dark green leafy vegetables	Spinach, kale, collards
Citrus fruit	Oranges, grapefruits
Sweet potatoes	Full of fiber!
Berries	Strawberries, blueberries, raspberries
Tomatoes	Low-carb and full of fiber, vitamin A and C
Fish high in omega-3 fatty acids	Salmon
Whole grains	Pearled barley, oatmeal
Nuts	Almonds, walnuts, flax seeds
Dairy	Fat-free milk and yogurt

Appendix F: Post-test: *Screening for Diabetes in Older Adults*

Record responses on examination form.

1) **Chronic exposure to elevated glucose levels may have detrimental effects on which of the following organ systems?**
   a) Heart & blood vessels
   b) Kidney
   c) Eye
   d) All of the above

2) **According to 2007 medical expenditures, diabetes is : the 3rd most costly disease in the United States.**
   a) the most costly disease in the United States.
   b) the 2nd most costly disease in the United States.
   c) the 3rd most costly disease in the United States.
   d) the 5th most costly disease in the United States.

3) **Which of the following diseases is the leading cause of death among patients with diabetes?**
   a) Kidney failure
   b) Cancer
   c) Heart disease
   d) Pneumonia

4) **Older patients with diabetes have higher rates of premature death and greater functional disability compared to younger patients with diabetes.**
   a) True
   b) False

5) **Which of the following geriatric conditions would NOT be exacerbated by diabetes?**
   a) Depression
   b) Cancer
   c) Persistent pain
   d) Polypharmacy

6) **Native Americans are how many times more likely to be diagnosed with diabetes compared to Caucasians of similar age?**
   a) Similar diagnosis rate to Caucasians
   b) Over twice as likely
   c) Three times as likely

d) Four times as likely

7) Which of the following characteristics is NOT commonly associated with type 2 diabetes?

a) Obesity
b) Insulin resistance
c) Onset before age 40
d) Varying degrees of endogenous in insulin production

8) Patients with glucose values higher than normal but less than the diagnostic cut-off for diabetes are said to have:

a) Gestational diabetes
b) Pre-diabetes
c) Adult onset diabetes
d) Insulin resistance

9) Which of the following is NOT considered to be a risk factor for developing type 2 diabetes?

a) Body mass index ≥ 25 kg/m2
b) Chronic inactivity
c) Female sex
d) Hypertension (≥140/90 mmHg)

10) Diabetic patients are at increased risk of heart attack and stroke compared to non-diabetic patients. As such, which of the following statements best represents treatment recommendations for patients with both dyslipidemia and hypertension?

I. LDL-cholesterol goal < 100 mg/dL
II. LDL-cholesterol goal < 130 mg/dL
III. HDL-cholesterol goal > 40 mg/dL (men) & > 50 mg/dL (women)
IV. Blood pressure <140/<80 mmHg
V. Blood pressure <130/<90 mmHg

a) I, III, V
b) II, III, IV
c) II, III, V
d) I, III, IV

11) The American Diabetes Association recommends daily low dose aspirin therapy to prevent thrombosis in which subset of patients:

a. Adults with type 2 diabetes who have at least a 10% risk of a cardiovascular event in the next 10 years.
b. All adults over 30 years of age with type 2 diabetes
c. ONLY adults with type 2 diabetes who have already had a heart attack or stroke
d. ONLY adults with type 2 diabetes who have an allergy to clopidogrel.

12) Type 2 diabetes accounts for what percentage of all end-stage renal dysfunction patients?

a. 22%
b. 41%
c. 55%
d. 66%

13) Which of the following statements is TRUE regarding the relationship of albumin in diabetic nephropathy?

a) The degree of nephropathy is associated with the degree of albuminuria.
b) As renal function diminishes, the renal excretion of albumin also decreases.
c) Macroalbuminuria is classified as albumin content in the urine between 30-299 mcg/mg of creatinine.
d) Macroalbuminuria takes approximately 12 months to develop in diabetic nephropathy.

14) Which of the following neuropathies would NOT be considered to be autonomic in origin?

a) Neurogenic bladder
b) Erectile dysfunction
c) Inability to detect cold or heat
d) Gastroparesis

15) The American Diabetes Association recommends patients with diabetes be vaccinated annually with the influenza vaccine.

a) True
b) False

16) Diabetes is the leading cause of non-traumatic lower-limb amputations in the United States. Which of the following risk factors would NOT increase the likelihood of incurring an amputation?

a) Peripheral neuropathy
b) Peripheral vascular disease
c) Severe nail pathology
d) Well controlled blood sugars

17) Which of the following statements is TRUE regarding screening recommendations for diabetes in the general population?

a. Everyone should be tested annually after the age of 35.
b. Patients with a body mass index ≥ 25 kg/m^2 should be screened at least every 3 years starting at age 45.
c. Patients with a body mass index ≥ 25 kg/m^2 should be screened annually starting at age 45.

d. Multiple clinical trials have demonstrated the cost-effectiveness of early detection for diabetes in the general population.

18) A 67 year old female, American Indian patient who is obese and taking antihypertensive medications is being screened for diabetes using the Afinion™ HbA1c test. Her HbA1c result is 5.7%. What action would you recommend?

a) This patient clearly has diabetes and should be referred for follow-up care.
b) This patient does not have diabetes and should not be referred for follow-up care.
c) This patient has multiple risk factors for diabetes, and given the A1c result, should be referred to her primary care provider at the patient's earliest convenience to discuss the results.
d) Counsel the patient to watch how much sugar she is eating.

19) A 72 year old male patient, who appears to be in good health, is screened for diabetes using the Afinion™ test. His HbA1c result is 7.5%. What action would you recommend?

a) This patient has very few risk factors and should not be referred for follow-up care.
b) This patient should be referred to his primary care provider for follow-up care, as the A1cNow® result suggests chronic hyperglycemia.
c) Counsel this patient on the importance of risk factor reduction.
d) Both b & c

20) Which of the following non-pharmacologic therapies is NOT recommended by the American Diabetes Association?

a) Lose weight
b) Sucrose should be completely removed from the diet
c) Aerobic exercise for 20-30 minutes at least 3 days per week
d) Stop smoking

POST-TEST: Examination Form

Screening for Diabetes in Older Adults

Participant Information

1. Name: _____

2. Mailing address: _____

_____

_____

_____

3. Date exam completed _____

Questions: (Please circle one response per question)				
1	A	B	C	D
2	**A**	**B**	**C**	**D**
3	A	B	C	D
4	**A**	**B**	**C**	**D**
5	A	B	C	D
6	**A**	**B**	**C**	**D**
7	A	B	C	D
8	**A**	**B**	**C**	**D**
9	A	B	C	D
10	**A**	**B**	**C**	**D**
11	A	B	C	D
12	**A**	**B**	**C**	**D**
13	A	B	C	D
14	**A**	**B**	**C**	**D**
15	A	B	C	D
16	**A**	**B**	**C**	**D**
17	A	B	C	D
18	**A**	**B**	**C**	**D**
19	A	B	C	D
20	**A**	**B**	**C**	**D**

For credit, please return this completed page to:

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Appendix G: Evaluation for MTGEC Module:

Screening for Diabetes in Older Persons

Please Circle your profession: Dietitian ▪ Nursing Home Administrator ▪ APRN ▪ RN ▪ LPN ▪ Pharmacist ▪ Physical Therapist ▪ Physician ▪ Social Worker ▪ Other_____

	Please circle or underline the appropriate number.	Yes					Don't Know
1	The overall visual presentation of the material enhanced my learning.	5	4	3	2	1	X
2	The module content was understandable.	5	4	3	2	1	X
3	The content was presented without bias.	5	4	3	2	1	X
4	The content will be useful for health-care professionals working with the elderly.	5	4	3	2	1	X
5.	The objectives were clear.	5	4	3	2	1	X
6	This approach met my learning objectives.	5	4	3	2	1	X
7	To what extent have you achieved each objective?	5	4	3	2	1	X
8	The module objectives related well to the overall purpose/goal of the web-based curriculum.	5	4	3	2	1	X
9	The test questions were unambiguous.	5	4	3	2	1	X
10	The test questions were appropriate to the module content.	5	4	3	2	1	X
11	This teaching method was appropriate and used effectively.	5	4	3	2	1	X
12	I would recommend this course to other health care professionals.	5	4	3	2	1	X
13	How did you learn about the modules? ☐ Instructor/Course ☐ Website ☐ Email ☐ Other: (Describe)						

14	Describe how you plan to use the information you obtained from these modules: ☐ Establish a new program ☐ Provide patient information ☐ Change your practice with elderly patients ☐ Other: (Describe)
15	How many hours did you take to complete this module including the pretest, posttest, and evaluation? Please use decimals, for example, 2.25 hours. _____Hours
16	Any other suggestions?

For Credit, please return this complete form to

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