

# Instructions on Completing the Modules

Screening for Diabetes in Older Persons

*\*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.  
Use questions in Appendix **E** and 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 **E** and record your answers on the examination form marked Post-Test. (*Found at the end of the module*)  
Keep the completed answer form to turn in with the pre-test at the completion of the module.
4. Complete the Module Evaluation. (*Found after the post-test*)
5. **To obtain credit for the module you must:**
  - a. Turn in the Pre-Test, Post-Test, and Module Evaluation
  - b. Obtain a score of 70% or better on the Post-Test

Rachael Curran  
**MTGEC/IPHARM**  
Skaggs Building Room 317  
University of Montana  
32 Campus Drive  
Missoula MT, 59812-1522

Email: [IPHARM@umontana.edu](mailto:IPHARM@umontana.edu)

Phone# (406) 243-2339 & Fax# (406) 243-4353

## Pre-test Continuing Education Questions

### *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 function
  - c) Eye
  - d) All of the above
- 2) According to 2002 medical expenditures, diabetes is the 3<sup>rd</sup> most costly disease in the United States.
  - a) True
  - b) False
- 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) Increased mobility
  - c) Persistent pain
  - d) Polypharmacy
- 6) American Indians are how many times more likely to be diagnosed with diabetes compared to Caucasians of similar age?
  - a) 1.5
  - b) 2.0
  - c) 2.6
  - d) 3.2
- 7) Which of the following characteristics is NOT commonly associated with type 2 diabetes?
  - a) Generally obese
  - b) Rare insulin resistance
  - c) Generally occurs after the age of 40
  - d) Varying degrees of endogenous insulin production
- 8) Patients with glucose values in the pre-diabetes range have the same risk of developing type 2 diabetes as patients with normal glucose.
  - a) True
  - b) False

- 9) Which of the following is **NOT** considered to be a risk factor for developing type 2 diabetes?
- Body mass index  $\geq 25$  kg/m<sup>2</sup>
  - Chronic inactivity
  - Female sex
  - Hypertension ( $\geq 140/90$  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?
- LDL-cholesterol goal  $< 100$  mg/dL
  - LDL-cholesterol goal  $< 130$  mg/dL
  - HDL-cholesterol goal  $> 40$  mg/dL (men) &  $> 50$  mg/dL (women)
  - Blood pressure  $< 130/<80$  mmHg
  - Blood pressure  $< 140/<90$  mmHg
- I, III, V
  - II, III, IV
  - II, III, V
  - I, III, IV
- 11) Type 2 diabetes accounts for what percentage of all end-stage renal dysfunction patients?
- 25%
  - 39%
  - 49%
  - 62%
- 12) Which of the following statements is **TRUE** regarding the relationship of albumin in diabetic nephropathy?
- The degree of nephropathy is directly associated with the degree of albuminuria.
  - As renal function diminishes, the renal excretion of albumin also decreases.
  - Macroalbuminuria is classified as albumin content in the urine between 30-299 mcg/mg of creatinine.
  - Macroalbuminuria takes approximately 12 months to develop in diabetic nephropathy.
- 13) Which of the following neuropathies would **NOT** be considered to be autonomic in origin?
- Neurogenic bladder
  - Erectile dysfunction
  - Inability to detect cold or heat
  - Gastroparesis
- 14) The American Diabetes Association recommends patients with diabetes be vaccinated annually with the influenza vaccine.
- True
  - False
- 15) 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?
- Peripheral neuropathy
  - Peripheral vascular disease
  - Severe nail pathology
  - Well controlled blood sugars

- 16) 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  $\geq 24$  kg/m<sup>2</sup> should be screened at least every 3 years starting at age 45.
  - c) Patients with a body mass index  $\geq 24$  kg/m<sup>2</sup> 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.
- 17) A 67 year old female, American Indian patient who is obese and taking antihypertensive medications is being screened for diabetes using the A1cNow<sup>®</sup>. Her A1cNow<sup>®</sup> result is 6.1%. 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.
- 18) A 72 year old male patient, who appears to be in good health, is screened for diabetes using the A1cNow<sup>®</sup> test. His A1cNow<sup>®</sup> 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<sup>®</sup> result suggests chronic hyperglycemia.
  - c) Counsel this patient on the importance of risk factor reduction.
  - d) Both b & c
- 19) While performing a A1cNow<sup>®</sup> test, the display panel on the device gives you the following message, "OR 5". What action should you take?
- a) The blood sample may have too little A1c, or there was under-sampling of whole blood. Call Metrika.
  - b) The blood sample may have too much A1c, or there was over-sampling of whole blood. Call Metrika.
  - c) The monitor temperature is above 28° C (82°F). Repeat the test at room temperature. Call Metrika.
  - d) The monitor temperature is below 18°C (64°F). Repeat the test at room temperature. Call Metrika.
- 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

## Module: *Screening for Diabetes in Older Persons*

### 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 continuing education credit, please return this completed page to:

Rachael Curran  
**MTGEC/IPHARM**  
 Skaggs Building Room 317  
 University of Montana  
 32 Campus Drive  
 Missoula MT, 59812-1522  
 Phone# (406) 243-2339 & Fax# (406) 243-4353

# ***Screening for Diabetes in Older Persons***

Developed by Kim Cybulski, Pharm.D.

Revised by Rose Macklin, Pharm. D., BCPS  
Partners in Home Care  
Missoula, MT

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

A Consortium of:  
The University of Montana, Missoula  
Northwest Research and Education Institute  
Montana Tech

<http://mtgec.montana.edu>

June 2008

Copyright 2008  
Montana Geriatric Education Center

## **Description of module:**

This 2-hour module will discuss the basic issues which surround screening for diabetes in the geriatric population.

## **Learning objectives:**

1. Summarize the impact of diabetes on health in relation to disease prevalence, health care expenditures, and its relation to obesity.
2. Describe the specialized needs of an older adult with diabetes.
3. Describe how diabetes impacts the health of American Indians.
4. Differentiate between type 1 and type 2 diabetes in regards to typical age of onset, etiology, endogenous insulin secretion and insulin resistance.
5. Define insulin resistance and describe its role in type 2 diabetes.
6. Identify patient risk factors for type 2 diabetes.
7. Differentiate between macrovascular and microvascular complications found in patients with diabetes.
8. Describe treatment recommendations and/or goals for diabetic patients who may have dyslipidemia or hypertension.
9. Describe how kidney disease plays a significant role in patients with diabetes.
10. Describe the progressive changes found in non-proliferative and proliferative diabetic retinopathies.
11. Briefly discuss the three main types of neuropathies seen in patients with diabetes.
12. Identify patients who are good candidates for diabetes screening.
13. Describe how to perform hemoglobin A1c test using the A1cNow+<sup>®</sup> device, and identify which screened patients should be referred.
14. Briefly describe non-pharmacologic and pharmacologic therapies available for treatment of diabetic patients.

## **Table of Contents**

## Contents

<b>I.</b>	<b>INTRODUCTION.....</b>	<b>8</b>
<b>II.</b>	<b>IMPACT OF DIABETES ON HEALTH.....</b>	<b>9</b>
A.	PREVALENCE OF DISEASE .....	9
B.	COST .....	10
C.	RELATION TO OBESITY .....	11
D.	SPECIAL POPULATIONS .....	11
1.	<i>Older Adults.....</i>	<i>11</i>
2.	<i>American Indians.....</i>	<i>11</i>
<b>III.</b>	<b>OVERVIEW OF DIABETES.....</b>	<b>12</b>
A.	DEFINITION OF DIABETES MELLITUS .....	12
B.	CLASSIFICATIONS OF DIABETES .....	12
C.	ROLE OF INSULIN IN DIABETES.....	13
D.	DIAGNOSTIC CRITERIA FOR DIABETES.....	14
1.	<i>Methods of Diagnosis.....</i>	<i>14</i>
E.	RISK FACTORS .....	15
F.	COMPLICATIONS.....	16
1.	<i>Macrovascular.....</i>	<i>18</i>
2.	<i>Microvascular.....</i>	<i>20</i>
3.	<i>Infections.....</i>	<i>26</i>
4.	<i>Lower Extremity Complications.....</i>	<i>27</i>
G.	PREVENTION .....	28
<b>IV.</b>	<b>SCREENING FOR DIABETES.....</b>	<b>29</b>
A.	WHO SHOULD BE SCREENED? .....	29
B.	USE OF HEMOGLOBIN A1C FOR SCREENING .....	30
C.	USE THE METRIKA A1C NOW+® .....	32
1.	<i>The Metrika A1cNow+® Device<sup>(53)</sup>.....</i>	<i>32</i>
2.	<i>Use of the Metrika A1cNow+®<sup>(53,54)</sup>.....</i>	<i>32</i>
3.	<i>Performing a finger stick for blood collection.....</i>	<i>33</i>
4.	<i>Interpretation of Results.....</i>	<i>34</i>
<b>V.</b>	<b>THERAPIES FOR DIABETES.....</b>	<b>35</b>
A.	DIET AND EXERCISE .....	36
<b>VI.</b>	<b>USEFUL DIABETES WEBSITES.....</b>	<b>39</b>
<b>VII.</b>	<b>REFERENCES .....</b>	<b>40</b>
<b>VIII.</b>	<b>APPENDIX A .....</b>	<b>43</b>
<b>APPENDIX B</b>	<b>PROTECTION OF STAFF &amp; PUBLIC FROM BLOOD-BORNE PATHOGENS .....</b>	<b>44</b>
<b>APPENDIX C</b>	<b>A1C NOW+® PROCEDURE<sup>(54)</sup> .....</b>	<b>45</b>
<b>APPENDIX D</b>	<b>BODY MASS INDEX CHART .....</b>	<b>48</b>
<b>APPENDIX E:</b>	<b>CONTINUING EDUCATION QUESTIONS.....</b>	<b>49</b>
<b>IX.</b>	<b>EVALUATION FOR MTGEC MODULE: <i>SCREENING OF DIABETES IN OLDER PERSONS</i>... </b>	<b>54</b>

### I. Introduction

Diabetes mellitus represents a major health concern in the United States. Diabetes mellitus is the 6<sup>th</sup> leading cause of death in America and is the 3<sup>rd</sup> costliest disease with an estimated \$174 billion dollars spent in 2007 on medical expenditures and lost productivity.<sup>(1,1.5)</sup> (*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) results 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.<sup>(2)</sup> Additionally, hyperglycemia plays havoc with the vascular system resulting in diabetic patients being 2-4 times more likely to have a heart attack or stroke compared to other patients of equal age and sex without diabetes.<sup>(3)</sup>

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 article is to:*

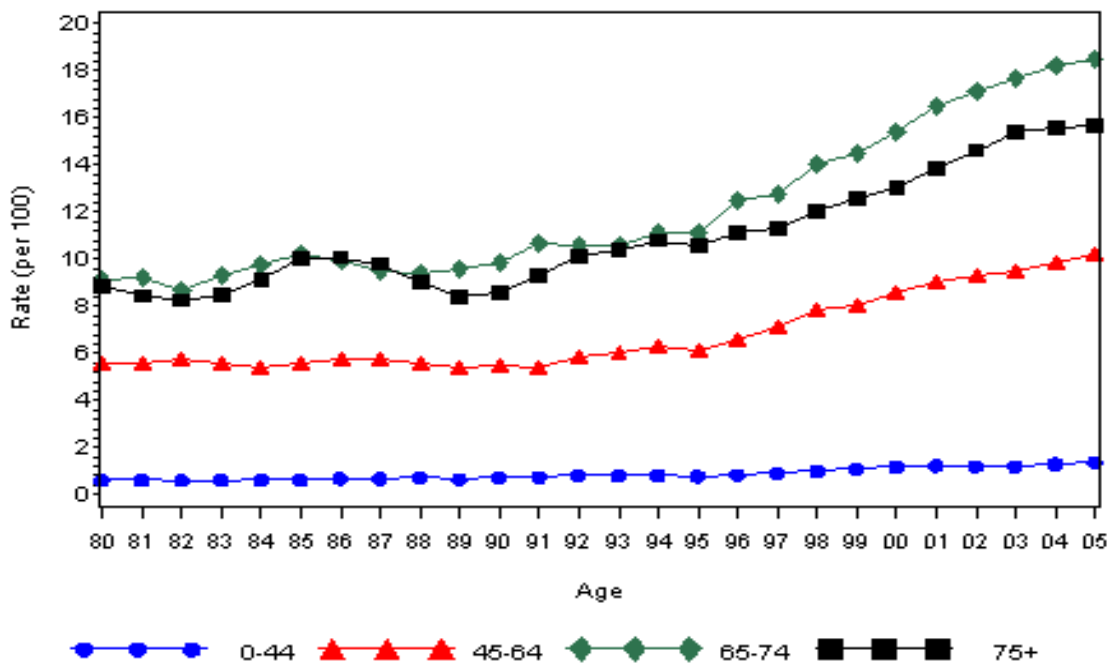
- A. Describe the impact diabetes has on health;
- B. Provide an overview of diabetes: classification, causes, risk factors, complications and prevention;
- C. Describe how diabetes can be screened for in specific populations;
- D. Describe how to use the A1c Now+<sup>®</sup> testing device; and
- E. Briefly describe non-pharmacologic and pharmacologic therapies available for treatment of diabetes.

## II. Impact of Diabetes on Health

### A. Prevalence of Disease

In 2005, the total prevalence of diabetes in the United States was estimated to be 20.8 million people or roughly 7% of the population. 14.6 million individuals had a diagnosis of diabetes in 2005, which left almost 30% of the patients not yet diagnosed and at risk for hyperglycemic-related effects on the body.<sup>(4)</sup> Furthermore, it is projected by the year 2050 the number of patients with diabetes will reach 29 million with the largest increases in patients  $\geq 75$  years old and among Black Americans.<sup>(5)</sup>

Type 2 diabetes, which accounts for 90-95% 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.<sup>(4)</sup> Trends towards increasing obesity and lack of exercise in the American population over the last 20 years have lead to an increasing prevalence of type 2 diabetes diagnoses among all age groups (Figure 1).<sup>(6,7)</sup>



**Figure 1: Prevalence of Diabetes by Age, 1980-2005<sup>(7)</sup>**

Interestingly, the older one gets, the greater the likelihood of being diagnosed with diabetes, as 78% of diabetic patients over the age of 60 years old were accurately diagnosed with diabetes whereas only 64% of diabetic patients between 40-59 years old carried a diagnosis of diabetes. This leaves approximately 22% and 36% of diabetic patients over the age of 60 and 40-59 years old, respectively, without a diagnosis of diabetes (Table 1).<sup>8</sup>

**Table 1: Percent of Patients Diagnosed with Diabetes by Age, 1999-2000<sup>(8)</sup>**

Ages	Physician diagnosed & undiagnosed patients <sup>*,§</sup>	Physician-diagnosed patients <sup>*</sup>		Undiagnosed patients <sup>§</sup>	
	% of population	% of population	% of total with diabetes	% of population	% of total with diabetes
40-59	9.1%	5.8%	64%	3.3%	36%
60+	19.2%	15%	78%	4.2%	22%

Data based on physical examination of a sample of civilian non-institutionalized patients

\* Diagnosed diabetes excludes gestational diabetes.

§ Undiagnosed diabetes is defined as a fasting blood glucose  $\geq 126$  mg/dL.

## **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 \$2.1 trillion of which \$174 billion (8.3%) were incurred by patients with diabetes.<sup>(1,5)</sup> Additionally, 18% of all inpatient hospitalization costs were related to diabetes.<sup>(1)</sup> The breakdown of diabetes expenditures is approximately 70% for direct costs and 30% for indirect costs such as lost productivity and disability.<sup>(1,5)</sup>

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.<sup>(1,5)</sup> The leading cost expenditure for patients with diabetes is related to cardiovascular disease complications, which consumes 19% of all diabetes-related health care dollars.<sup>(1)</sup> In 2007, 284,000 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 is \$26.9 billion. <sup>(1.5)</sup>

### **C. Relation to Obesity**

Considerable evidence exists which correlates increasing body weight with the increased risk of developing type 2 diabetes.<sup>(9,10,11)</sup> The National Health and Nutritional Examination Survey (NHANES 2003-2004) estimates 66% of American adults are overweight (body mass index [BMI] between 25-29.9) or obese (BMI  $\geq$  30) and 17% of American children (age 2-19 years) are overweight.<sup>(12)</sup> Given these statistics, the correlation between body weight and type 2 diabetes will likely continue. Data from two studies suggest that for every kilogram increase in body weight, the risk for developing diabetes increases 4.5-9%.<sup>(10,13)</sup>

### **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. 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, and as such, treatment recommendations have been developed by the American Geriatric Society with support from the American Diabetic Association (ADA).<sup>(14,15)</sup>

#### **2. American Indians**

Diabetes is one of the greatest health concerns facing American Indians today, as they are 2.6 times more likely to be diagnosed with diabetes compared to Caucasians of similar age.<sup>(16)</sup> Diabetes is currently the 4<sup>th</sup> leading cause of death in American Indians compared to 7<sup>th</sup> for Caucasians.<sup>(8)</sup>

American Indians make up 6.2% of Montana's population (versus 90.6% Caucasian),<sup>(17)</sup> and most American Indians receive their healthcare from the Indian Health Service (IHS) provided on seven reservations found throughout the state.<sup>(18)</sup> Nationally, the IHS has estimated the prevalence of diabetes within their population to be approximately 15%.<sup>(16)</sup>

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

- American Indians are six times more likely to develop end-stage renal disease.<sup>(19)</sup>
- Lower limb amputations are an unfortunate long-term complication of diabetes, and American Indians have amputation rates 3-4 times higher than the general population.<sup>(19)</sup>

### **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:<sup>(2)</sup>

- (i) Type 1
- (ii) Type 2
- (iii) Other (caused by genetics, infections, endocrine disorders, etc.)
- (iv) Gestational (occurs in 4% 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

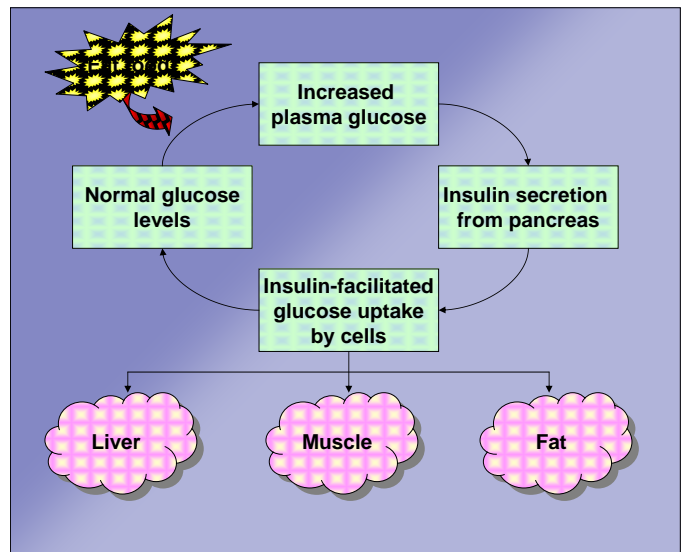
and dietary changes. But as a brief review, Table 2 will describe some of the distinguishing characteristics between type 1 and type 2 diabetes.

**Table 2: Comparison Between Type 1 and Type 2 Diabetes<sup>(2,20)</sup>**

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

**C. Role of Insulin in Diabetes**

Insulin is a peptide hormone which is synthesized by  $\beta$ -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.<sup>(21)</sup> 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 contributory 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

$\beta$ -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.<sup>(22,23)</sup>

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.<sup>(22)</sup>

#### ***D. 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 three diagnostic methods approved by the ADA which are summarized in Table 3. Only one of the three methods needs to be performed, but a confirmatory test (using one of the three methods) **MUST** be performed on a subsequent day.<sup>(2)</sup>

Some patients have glucose levels that are higher than normal but less than the diagnostic criteria for diabetes. Patient 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, but with moderate weight loss (5-10% of total body weight), exercise, and the use of certain pharmacological agents, the development of type 2 diabetes may be delayed or prevented.<sup>(2,24)</sup>

**Table 3: Diagnostic Criteria for Diabetes<sup>(2)</sup>**

Test Method	Diabetes	Pre-Diabetes	Normal
1 Casual* plasma glucose with diabetes symptoms (i.e., polyuria, polydipsia, and unexplained weight loss.	≥ 200 mg/dL		
2 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
3 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.

### **E. 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 intervening 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.

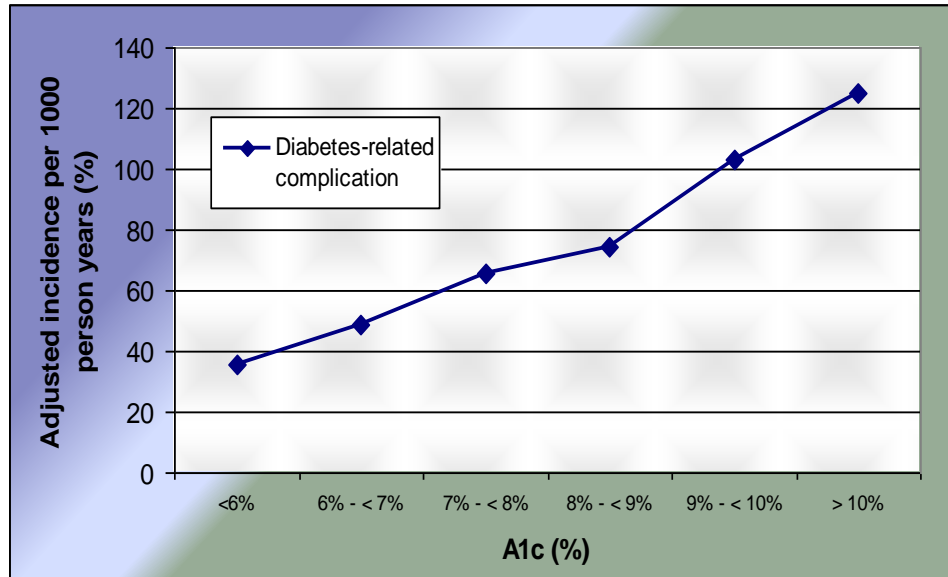
**Table 4: Risk Factors for Type 2 Diabetes<sup>(2)</sup>**

Risk Factors
<ul style="list-style-type: none"> <li>▪ Age ≥ 45 years old</li> <li>▪ Overweight (Body mass index ≥ 25 kg/m<sup>2</sup>; See Appendix D)</li> <li>▪ Acanthosis nigricans</li> <li>▪ Family history of diabetes(i.e., parents or siblings with diabetes)</li> <li>▪ Habitual physical inactivity</li> <li>▪ Race/ethnicity (e.g., African-American, American Indian, Hispanic-Americans, Asian-Americans, and Pacific Islanders)</li> <li>▪ Previously identified impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)</li> <li>▪ History of gestational diabetes or delivery of a baby weighing &gt; 9 lbs.</li> <li>▪ Hypertension (≥ 140/90 mmHg in adults)</li> <li>▪ HDL cholesterol ≤35 mg/dL and/or a triglyceride level ≥250 mg/dL</li> <li>▪ Polycystic ovary syndrome</li> <li>▪ History of cardiovascular disease</li> </ul>

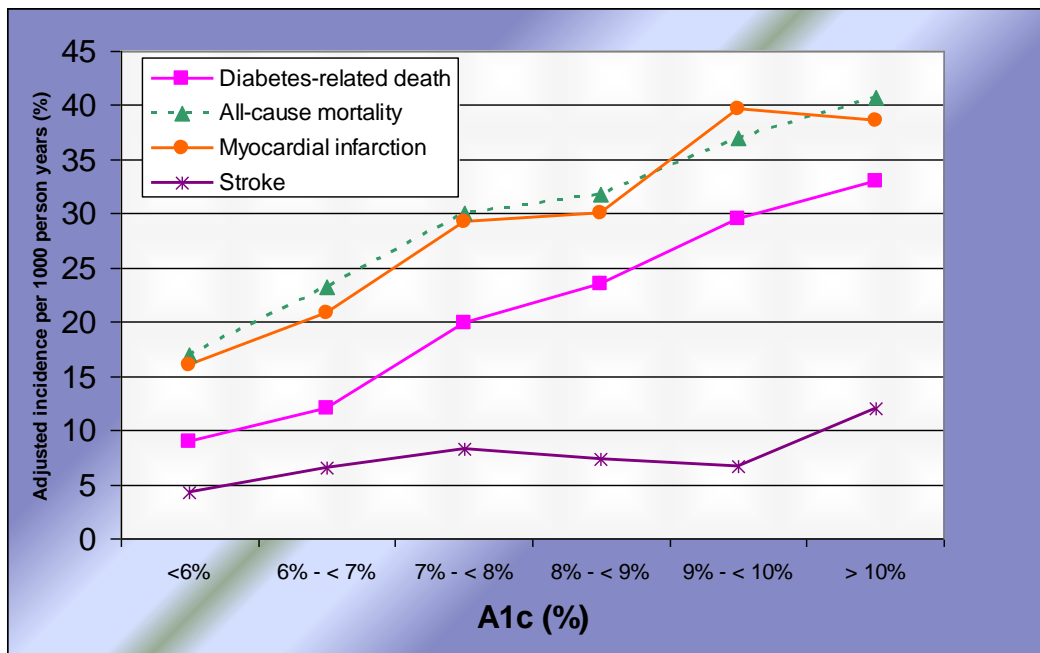
## **F. Complications**

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 cured. In support of tight glycemic control, a 10-year study [the United Kingdom Prospective Diabetes Study (UKPDS 33)] in newly diagnosed type 2 diabetes 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%.<sup>(25)</sup>

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).<sup>(26)</sup> 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.<sup>(26)</sup>



**Figure 3: Relationship between Glycemic Control and Diabetes-Related Complications<sup>(26)</sup>**



**Figure 4: Relationship between Glycemic Control and Mortality, Myocardial Infarction and Stroke<sup>(26)</sup>**

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, which involve the large blood vessels such as the coronary, cerebral, and some peripheral vessels, and are primarily a result of atherosclerosis.<sup>(20)</sup> As mentioned previously, people with diabetes are 2-4 times more likely to have a heart attack or stroke compared to other people of equal age and sex without diabetes. In addition, cardiovascular disease is leading cause of death in diabetic patients at 65% of all deaths.<sup>(4)</sup> Diabetic patients are at increased risk of atherosclerosis for three primary reasons:<sup>(20)</sup>

- I. The incidence of other cardiac risk factors is increased in diabetes, such as hypertension, dyslipidemias, and obesity.
- II. Diabetes is itself a risk factor for coronary heart disease, which is supported by the National Cholesterol Education Program which classifies diabetes as an equivalent to having coronary heart disease.<sup>(27)</sup>
- III. Diabetes may act synergistically with other risk factors by increasing atherogenicity (i.e., altering lipid particles, modifying the blood vessel wall, or by promoting a prothrombotic environment).

Therefore, patients with diabetes need intense treatments for coexisting risk factors. An overview of the recommended treatment guidelines for diabetic patients may be found in Appendix D.

### a) Dyslipidemia

Lipid abnormalities are common in patients with diabetes. The typical abnormalities include:<sup>(28)</sup>

- 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.

**Lipid Goals for Diabetic Patients<sup>(29)</sup>**

LDL-cholesterol &lt; 100 mg/dL

- (National Cholesterol Education Program supports optional goal of <70 mg/dL)<sup>(27)</sup>

HDL &gt; 40 mg/dL (men) &amp; &gt; 50 mg/dL (women)

Triglycerides &lt; 150 mg/dL

**b) Hypertension**

Hypertension is a common co-morbidity in patients with diabetes. One study found 39% of all newly diagnosed type 2 diabetic patients were hypertensive, and the Centers for Disease Control and Prevention reports 73% of all diabetic patients have a blood pressure  $\geq 130/80$  mmHg or use an antihypertensive medication.<sup>(4)</sup>

**Blood Pressure Goals for Diabetic Patients<sup>(30,31,32)</sup>**

Blood pressure &lt;130/&lt;80 mmHg

(The National Kidney Foundation recommends &lt;125/&lt;75 mmHg in patients with kidney disease present.)

**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.<sup>(33)</sup>

**d) Thrombosis**

Given the increased risk of heart disease in patients with diabetes, the use of anti-platelet medications may be recommended, especially in patients with a known cardiac history. As an anti-platelet medication, aspirin should be used cautiously. There is no evidence of benefit to using aspirin therapy in individuals younger than 30 years old, and for patients at risk for bleeding, aspirin therapy should be closely monitored.<sup>(34)</sup>

### **Aspirin Therapy in Diabetic Patients<sup>(34)</sup>**

1. Use aspirin therapy (75-162 mg/day) for patients with a history of myocardial infarction, vascular bypass, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina.
2. Use aspirin therapy (75-162 mg/day) in patients with increased cardiovascular risk, including those over 40 years old or who have additional risk factors (family cardiac history, hypertension, smoking, and dyslipidemia).

## **2. Microvascular**

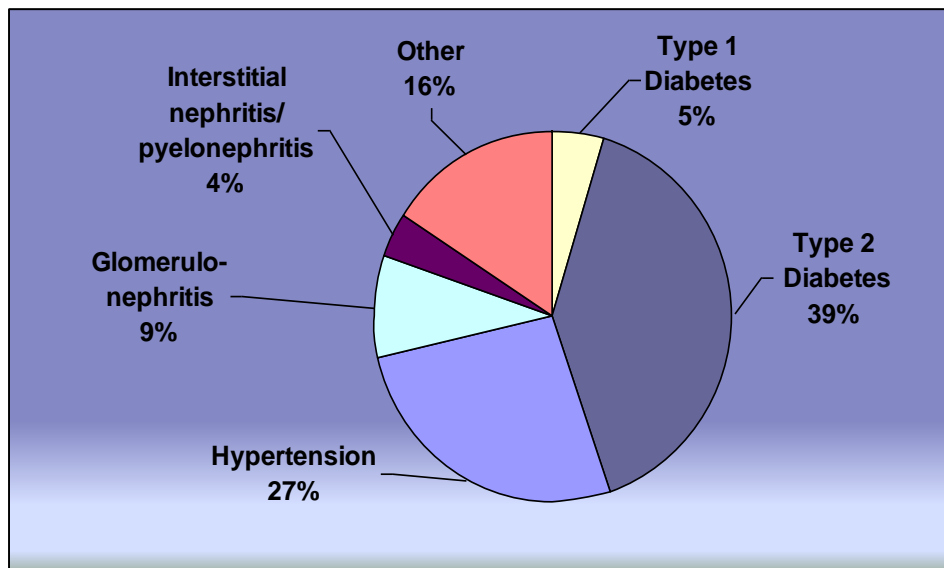
The true mechanism for the development of microvascular complications is unclear, but three distinct metabolic pathways appear to be involved.

- 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 glycosylated 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).<sup>(20,35)</sup>
- 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.<sup>(35)</sup>
- 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.<sup>(20,35)</sup>

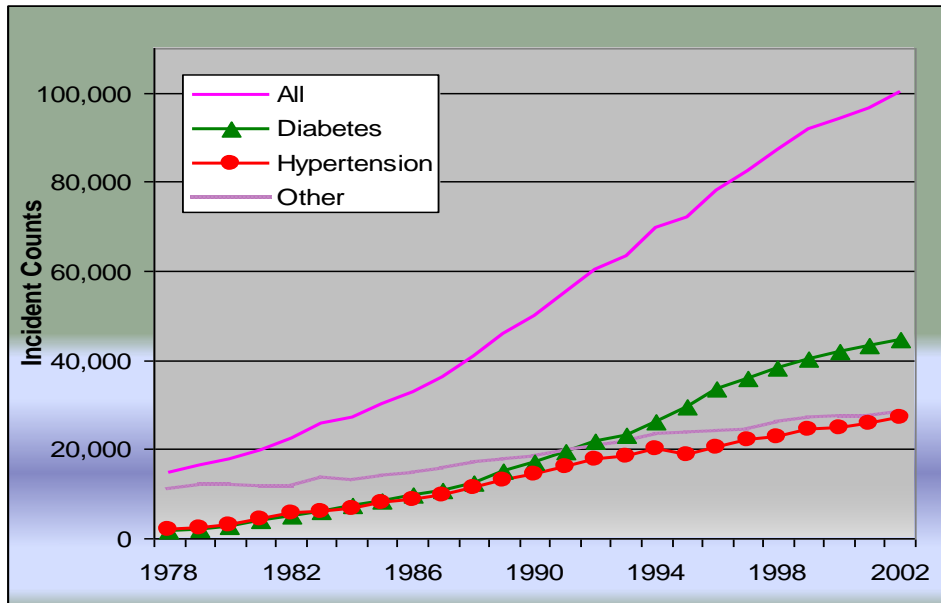
Irregularities found in the arterioles and capillaries result in microvascular complications. The three main microvascular complications are nephropathy, retinopathy and neuropathy.

a) Nephropathy

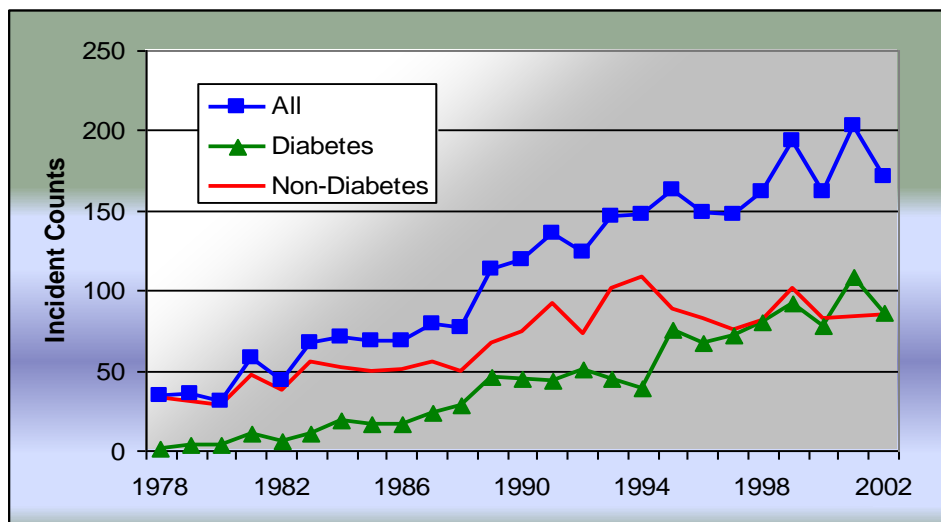
Kidney disease or nephropathy is a common complication of diabetes. In the United States, diabetic nephropathy is the leading cause for end-stage renal disease (ESRD) accounting for 44% of all cases.<sup>(36)</sup> (Figure 5) And just as the prevalence of diabetes is increasing at national and state levels, so too, is the incidence of ESRD which continued to increase in 2007 with higher incidence in the elderly and those with diabetes.<sup>(36)</sup> (Figures 6 & 7)



**Figure 5: Primary Diagnosis for Kidney Failure (1998-2002)<sup>(36)</sup>**



**Figure 6: Increasing Incidence of Kidney Disease; United States (1978-2002)<sup>(36)</sup>**



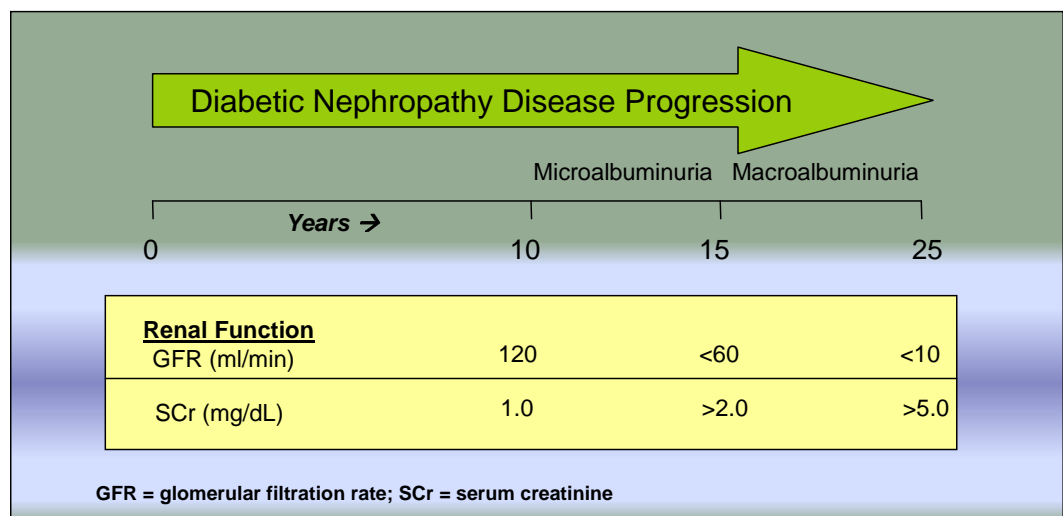
**Figure 7: Increasing Incidence of Kidney Disease: Montana (1978-2002)<sup>(36)</sup>**

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.<sup>(20)</sup>

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 albuminuria 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.<sup>(20,37)</sup> (Figure 8)

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

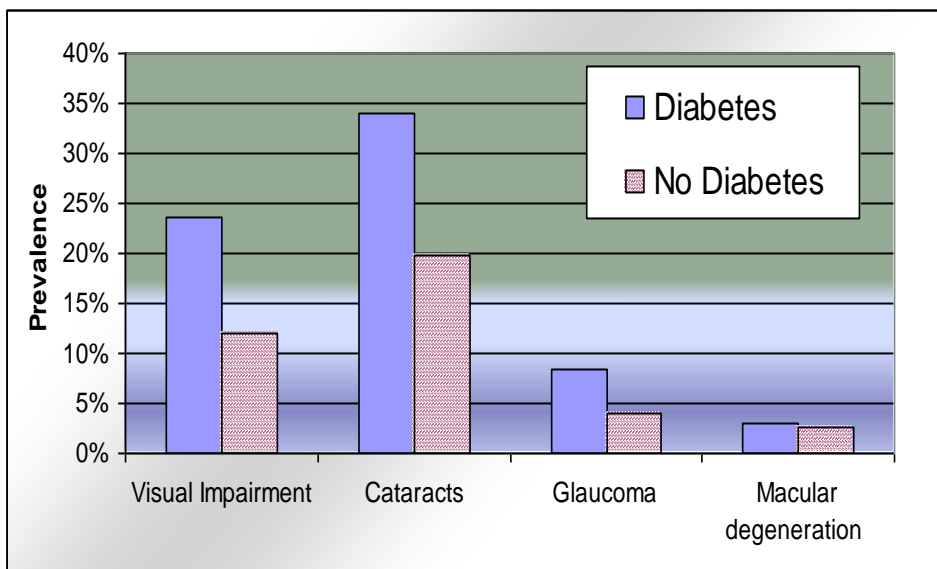


**Figure 8: Disease Progression of Diabetic Nephropathy with Corresponding Decreases in Renal Function**

**American Diabetes Association Recommendation: Nephropathy<sup>(38)</sup>**  
 All type 2 diabetes patients should be tested for microalbuminuria and serum creatinine at the time of diagnosis and annually thereafter.

b) Retinopathy

In the United States, diabetes is the leading cause of blindness among adults between the ages of 20-74 years old, causing 12,000 to 24,000 new cases of blindness per year.<sup>(4)</sup> Diabetic retinopathy is the major cause of visual impairment and blindness among diabetes patients with an estimated prevalence of 10% among diabetes patients. Approximately 20% of type 2 diabetic patients have some degree of diabetic retinopathy at the time of their diagnosis.<sup>(39)</sup> Furthermore, patients with diabetes have a higher prevalence of other visual impairments including cataracts and glaucoma (Figure 9).<sup>(40)</sup>



**Figure 9: Prevalence of Eye Disorders Among Persons >50 Years Old With and Without a Diagnosis of Diabetes<sup>(40)</sup>**

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

**(1) Non-proliferative diabetic retinopathy<sup>(20,37)</sup>**

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 10 compares a normal retina to one with advanced retinopathy.

## **(2) Proliferative diabetic retinopathy<sup>(20,37)</sup>**

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

### **American Diabetes Association Recommendation: Retinopathy<sup>(39)</sup>**

All type 2 patients should receive an ophthalmologic dilated eye examination at the time of diagnosis and yearly thereafter.

## **c) Neuropathy**

Neuropathies, which are functional disturbances of the peripheral nervous system, affect approximately 60-70% of all diabetes patients in some form.<sup>(37,41)</sup> Three broad categories of neuropathies affect diabetes patients: sensory, autonomic and motor.

### **1) Sensory<sup>(37,41)</sup>**

Loss of sensory nerve input (i.e., hot & 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** <sup>(20,37,41)</sup>

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**

<b>Neuropathy</b>	<b>Description</b>
<i>Gastroparesis</i>	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.
<i>Diabetic diarrhea</i>	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.
<i>Neurogenic bladder</i>	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.
<i>Erectile dysfunction (ED)</i>	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** <sup>(20,37)</sup>

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.

### **3. Infections**

Diabetes patients are more susceptible to pneumonia, urinary tract infections, and skin and soft tissue infections, and 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.<sup>(37)</sup> Because diabetes 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<sup>(42)</sup>**

1. All diabetes patients should receive an annual influenza vaccine.
2. All diabetes 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).

#### **4. Lower Extremity Complications**

Diabetes is the leading cause of non-traumatic lower-limb amputations in the United States causing approximately 82,000 amputations in 2002.<sup>(4)</sup> Patients with diabetes are predisposed to lower extremity complications due to neuropathies, poor peripheral circulation, and impaired wound healing. People with diabetes often can not 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.<sup>(37)</sup> Risk factors which have been identified with increasing likelihood of an amputation are:<sup>(43)</sup>

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

## **G. Prevention**

Preventing type 2 diabetes is a “hot topic” in diabetes research, and a several randomized, controlled trials have demonstrated the ability to prevent this devastating disease. Table 6<sup>(44-48)</sup> 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 rosiglitazone can also decrease the incidence of diabetes. In 2007, the ADA Consensus Development Panel recommended 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. <sup>(14)</sup>

**Table 6<sup>(44-48)</sup>: Summary of Clinical Trials for Diabetes Prevention**

<b>Study Descriptor</b>	<b>Patient Population</b>	<b>Treatment Groups</b>	<b>Primary Result</b>
Finnish Diabetes Prevention Study Group <sup>(44)</sup>	# of pts = 522 Sexes = male & female Ave. age = 55 y.o. Ave. BMI = 31 kg/m <sup>2</sup> Pre-diabetic pts (+ IGT) Years of follow-up = 3.2	1. Brief diet & exercise counsel 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 <sup>(45)</sup>	Pts = 3,234 Sexes = male & female Ave. age = 51 Ave. BMI = 34 kg/m <sup>2</sup> 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 <sup>(46)</sup>	Pts = 1,429 Sexes = male & female Ave. age = 55 Ave. BMI = 31 kg/m <sup>2</sup> 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 <sup>(47)</sup>	Pts = 3,277 Sexes = male & female Ave. age = 43 BMI $\geq$ 30 kg/m <sup>2</sup> 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.
DREAM <sup>(48)</sup>	Pts = 5,269 Sexes = male & female Ave. age = 55 IGT or IFG Duration = 3 years	1. Rosiglitazone 8 mg per day 2. Placebo	The rosiglitazone-treated group had a 60% reduction in incidence of type 2 diabetes.

## **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.<sup>(14)</sup>

**American Diabetes Association: Screening Recommendations<sup>(14)</sup>**

Evaluation for type 2 diabetes should be performed within a health care setting. Patients, particularly those with a BMI  $\geq 25$  kg/m<sup>2</sup>, should be screened at 3-year intervals beginning at age 45; testing should be considered at an earlier age or be carried out more frequently in those who are overweight if additional diabetes risk factors are present (See *Table 4: Risk Factors for Type 2 Diabetes*).

## **B. Use of Hemoglobin A1c for Screening**

The test which IPHARM uses as a diabetes screening device is the hemoglobin A1c test (also referred to as the A1c test), rather than the diagnostic tests mentioned in Section 3D.

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 glycosylated or linked with sugars found in the blood, such as glucose. Therefore, the amount or percentage of glycosylated 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 glycosylated hemoglobin is a measure of glycemic control over the past 8-12 weeks. A person without diabetes usually has about 5% of the hemoglobin glycosylated, but for patients with chronic hyperglycemia, the percentage of glycosylated hemoglobin is considerably higher.<sup>(49,50)</sup>

The A1c test, which is a measurement of glycosylated hemoglobin, is routinely used about twice a year as a monitoring tool for patients diagnosed with diabetes to assess how well the patients are managing their diabetes.<sup>(50)</sup> The use of the A1c test is currently not approved as a screening device, but a few studies have evaluated the A1c test in this capacity and have found good reliability when the test results are interpreted within the parameters of the test.<sup>(51,52)</sup>

Therefore, IPHARM chose to utilize the A1c test as a screening device for three main reasons.

1. A1c tests have high specificity for values >6.1% obtained from a patient, which implies the high probability that the patient has chronic hyperglycemia and should be referred for medical follow-up. Additionally, A1c values <5.2% are highly sensitive, which implies that patients with values below 5.2% probably do not have chronic hyperglycemia.<sup>(50,51)</sup> Table 7 demonstrates these principles. Clinical judgment is necessary to evaluate patients whose values fall between 5.2 - 6.1%, with considerable emphasis placed on co-existing risk factors.

**Table 7: A1c Test Devices Used for Diabetes Screening: Specificity & Sensitivity<sup>(51,52)</sup>**

A1c value	Specificity	Sensitivity
5.2% (normal)	50%	100%
5.6% (1 SD above mean)	84.4%	83.4%
6.1% (2 SD above mean)	97.4%	63.2%
6.5% (3 SD above mean)	99.6%	42.8%
7.0% (4 SD above mean)	99.9%	28.3%

SD = standard deviations

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 is solely for screening purposes and NOT as a diagnostic tool. Follow-up care by a health care professional will be necessary to confirm a diagnosis of diabetes.

## C. Use the Metrika A1cNow+®

### 1. The Metrika A1cNow+® Device<sup>(53)</sup>

The A1cNow+® is a CLIA waived, single-use, point-of-care testing device which utilizes one drop of blood to provide A1c results in about five minutes.

A1cNow+® has demonstrated 99% accuracy when compared to a laboratory method certified by the National Glycohemoglobin Standardization Program, and the device automatically performs over 25 internal control checks to ensure accurate results.

The A1cNow+® device utilizes immunoassay and clinical chemistry technology to directly measure the amount of glycated hemoglobin (HbA<sub>1c</sub>) and total hemoglobin (Hb). The test results are then expressed as a percentage of glycated hemoglobin.



$$\%HbA_{1c} = (HbA_{1c}/total\ Hb) \times 100$$

### 2. Use of the Metrika A1cNow+®<sup>(53,54)</sup>

The information found in Appendix C provides a reference on the materials included in the testing, how to set up the testing device, and how the run a sample.

**NOTE:** *The A1cNow+® test kits must be stored under refrigerated conditions (2-8°C). Prior to use, the test kits must be brought to room temperature for one hour, and the A1cNow+® test cartridge MUST be used within 2 minutes of removing it from the pouch. Test pouches brought to room temperature but not*

*removed from the pouch must be used within 3 months. Do not mix pouches and monitors from different lots.*<sup>(53)</sup>

### **3. 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 below 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 nondominant hand may be less callused.
- c. Inspect the patient's fingers and gently press on the tips of the fingers to assess which finger tip has good blood return. (The tip should become a rosy-red color compared to the other finger areas.) The middle (3<sup>rd</sup>) finger or the ring (4<sup>th</sup>) 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 can not provide a sufficient sample, inform the patient that no further attempts will be made, and rescheduling for another day will be necessary.*

- g. The first drop of blood needs to be removed with a gauze pad or tissue. Gently repeat the above step to get the finger to produce a second blood droplet.
- h. 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. **DO NOT SQUEEZE THE BULB.** 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.

#### **4. Interpretation of Results**

As mentioned previously, IPHARM utilizes the A1cNow+® testing device 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 > 6.1% 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 A1cNow+® Test Results**

A1c value	Action Required
< 6.1%	No follow-up recommended, but general counseling on risk factor reduction is advised.
> 6.1%	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 diabetes patient may include expert involvement of physicians, physician assistants, nurse practitioners, nurses, pharmacists, diabetes educators, dietitians, 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).<sup>(14,55)</sup>

**Table 9: Goals for Glycemic Parameters:  
American Diabetes Association & American Association of  
Clinical Endocrinologists<sup>(14,55)</sup>**

Glycemic Parameter	Expert Group	Goal
A1c	ADA	< 7%
	AACE	< 6.5%
Pre-prandial plasma glucose	ADA	90-130 mg/dL
	AACE	≤ 110 mg/dL
Post-prandial plasma glucose (generally 1-2 hours after the beginning of a meal)	ADA	< 180 mg/dL
	AACE	≤ 140 mg/dL

## **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.<sup>(14)</sup>

The following nutritional goals apply to patients with diabetes, but their application may be appropriate for patients at risk for diabetes.<sup>(14)</sup>

- 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. But before any patient initiates a physical activity program, it is recommended the patient be assessed by their healthcare provider.

**Table 10: Lifestyle Modifications for Diabetes Patients<sup>(14)</sup>**

<b>Activity</b>	<b>Comment</b>
Lose weight if BMI >25 kg/m <sup>2</sup>	Low-fat or low-carb diets may be effective for short-term weight loss.
Stop smoking	
Exercise appropriately	30 minutes of moderate exercise most days of the 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 <i>trans</i> fatty acids should be minimized Cholesterol 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 glycemia 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 oral agents used in the treatment of type 2 diabetes. Since it is uncommon for type 2 patients to start therapy with insulin, these products are not included.

**Table 11: Commonly Prescribed Oral Medications  
for Patients with Type 2 Diabetes<sup>(55,56)</sup>**

<b>Drug Class</b> ▪ Generic (Brand)	<b>Mechanism Of Action</b>	<b>Major Side Effects</b>
<b>Sulfonylureas</b> <u>First generation</u> <ul style="list-style-type: none"> <li>▪ Tolbutamide (Orinase<sup>®</sup>)</li> <li>▪ Acetohexamide (Dymelor<sup>®</sup>)</li> <li>▪ Tolazamide (Tolinase<sup>®</sup>)</li> <li>▪ Chlorpropamide (Diabinese<sup>®</sup>)</li> </ul> <u>Second generation</u> <ul style="list-style-type: none"> <li>▪ Glyburide (DiaBeta<sup>®</sup>, Micronase, Glynase<sup>®</sup>)</li> <li>▪ Glipizide (Glucotrol<sup>®</sup>)</li> <li>▪ Glimepiride (Amaryl<sup>®</sup>)</li> </ul>	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 their increased toxicity.)
<b>Biguanides</b> <ul style="list-style-type: none"> <li>▪ Metformin (Glucophage<sup>®</sup>, Fortamet<sup>®</sup>, Riomet<sup>®</sup>)</li> </ul> <p>First line therapy for type 2 diabetes unless contraindications present.</p>	Decreases liver glucose production. Improves insulin sensitivity in peripheral tissues. Decreases intestinal absorption of glucose.	Metallic taste, diarrhea, nausea, weight loss. <b>Renal function</b> must be monitored. Stop drug if serum creatinine > 1.5 mg/dl (men) & > 1.4 mg/dL (women) <b>Contraindicated</b> in patients with CHF, alcohol abuse, metabolic acidosis, liver or kidney disease, and ≥ 80 years old.
<b>Alpha-Glucosidase Inhibitors</b> <ul style="list-style-type: none"> <li>▪ Acarbose (Precose<sup>®</sup>)</li> <li>▪ Miglitol (Glyset<sup>®</sup>)</li> </ul>	Delays intestinal absorption of carbohydrates resulting in decreased post-prandial glycemia.	Flatulence, diarrhea, and abdominal pain.
<b>Thiazolidinediones (a.k.a., glitazones)</b> <ul style="list-style-type: none"> <li>▪ Rosiglitazone (Avandia<sup>®</sup>)</li> <li>▪ Pioglitazone (Actos<sup>®</sup>)</li> </ul>	Increases insulin sensitivity.	Increases total cholesterol, LDL & HDL; weight gain; edema; headache; fatigue; and nausea. Monitor liver function. <b>Contraindicated</b> in patients with CHF, liver disease, alcohol abuse, or pregnancy
<b>Meglitinides</b> <ul style="list-style-type: none"> <li>▪ Repaglinide (Prandin<sup>®</sup>)</li> <li>▪ Nateglinide (Starlix<sup>®</sup>)</li> </ul>	Increases insulin secretion from the pancreas.	Headache & hypoglycemia
<b>Sitagliptin (Januvia<sup>®</sup>)</b>	DDP-IV enzyme inhibitor: Prolongs active incretin levels in gut	Headache, nausea, nasopharyngitis

## 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/PHSD/Diabetes/Default.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/>

## VII. References

1. American Diabetes Association. Economic costs of diabetes in the U.S. in 2002. American Diabetes Association. *Diabetes Care* 2003; 26:917-32.
- 1a. American Diabetes Association. Direct and indirect costs of diabetes in the United States. Accessed February 18, 2008 from <http://www.diabetes.org/diabetes-statistics.jsp>
2. American Diabetes Association. Diagnosis and classification of diabetes mellitus (Position Statement). *Diabetes Care* 2008; 31(Supp):S55-S60.
3. General diabetes information: Diabetes – facts and statistics. American Association of Diabetes Education. Accessed on January 4, 2005 from <http://www.aadenet.org/GeneralDiabetesInfo/GovStats.html>
4. American Diabetes Association. Total prevalence of diabetes and complications of diabetes. Accessed February 18, 2008 from <http://www.diabetes.org/diabetes-statistics>
5. Projection of diabetes burden through 2050: Impact of changing demography and disease prevalence in the U.S. *Diabetes Care* 2001;24:1936-40.
6. Chartbook on trends in the health of Americans;Health, United States, 2003. Centers for disease control and prevention, National Center for Health Statistics, Hyattsville MD, 2003. Accessed August 24, 2004 from <http://www.cdc.gov/nchs/data/hus/hus03cht.pdf>
7. Center for Disease Control and Prevention. Data & trends; diabetes surveillance system. Accessed February 18, 2008 from <http://www.cdc.gov/diabetes/statistics/prev/national/figbyage.htm>
8. National Center for Health Statistics. Health, United States, 2004. Chartbook on trends in the health of Americans. Hyattsville, Maryland: 2004. Accessed February 18, 2008 from <http://www.cdc.gov/nchs/data/hus/hus07.pdf#contents>
9. Hanson RL, Narayan KM, McCance DR, Pettitt DJ, Jacobsson LT, Bennett PH, et al. Rate of weight gain, weight fluctuation, and incidence of NIDDM. *Diabetes* 1995;44:261-6.
10. Ford ES, Williamson DF, Liu S. Weight change and diabetes incidence: findings from a national cohort of US adults. *Am J Epidemiol* 1997;146:214-22.
11. Resnick HE, Valsania P, Halter JB, Lin X. Relation of weight gain and weight loss on subsequent diabetes risk in overweight adults. *J Epidemiol Community Health* 2000;54:596-602.
12. Centers for Disease Control and Prevention. National Center for Health Statistics, Hyattsville MD, 2004. Overweight and obesity: frequently asked questions. Accessed February 18, 2008 from <http://www.cdc.gov/nccdphp/dnpa/obesity/faq.htm#adults>
13. Mokdad AH, Ford ES, Bowman BA, Nelson DE, Engelgau MM, Vinicor F, Marks JS. Diabetes trends in the U.S.: 1990-1998. *Diabetes Care* 2000;23:1278-83.
14. American Diabetes Association. Standards of Medical Care in Diabetes - 2008 (Position Statement). *Diabetes Care* 2008; 31: S12-S54.
15. Brown AF, Mangione CM, Saliba D, Sarkisian CA; California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. Guidelines for improving the care of the older person with diabetes mellitus. *J Am Geriatr Soc* 2003;51(Supp):S265-80.
16. Diabetes in American Indians and Alaska Natives. National Institutes of Diabetes and Digestive and Kidney Diseases. NIH Publication No. 02-4567. Accessed January 4, 2005 from <http://diabetes.niddk.nih.gov/dm/pubs/americanindians/index.htm>
17. Montana Native American Population On and Off Reservations: 1980, 1990, and 2000 Census. Accessed January 4, 2005 from <http://ceic.commerce.state.mt.us/c2000/PL2000/809000reservationpop.pdf>
18. Montana Indian Health Service: Overview. Accessed January 4, 2005 from <http://www.ihs.gov/facilitieservices/AreaOffices/billings/billings-overview.asp>
19. Diabetes Statistics for Native Americans. American Diabetes Organization. Accessed January 5, 2005 from <http://www.diabetes.org/diabetes-statistics/native-americans.jsp>
20. Funk JL. Disorders of the endocrine pancreas. In: Nogueira I, Ransom J, Edmonson KG, editors. *Pathophysiology of Disease. An introduction to clinical medicine*. 4<sup>th</sup> ed. New York (NY): Lange Medical Books/McGraw-Hill; 2003.p.502-30.

21. Ganong WF. Endocrine function of the pancreas & regulation of carbohydrate metabolism. In: Foltin J, Nogueira I, Ransom J, Sheinis LA, editors. Review of Medical Physiology. 20<sup>th</sup> ed. Lange Medical Books/McGraw-Hill; 2001.p.322-43.
22. Campbell RK, McDonough RP. Understanding and managing insulin resistance in type 2 diabetes. Pharmacy Today 2004;(Supp September):1-12.
23. Le Roith D, Zick Y. Recent advances in our understanding of insulin action and insulin resistance. Diabetes Care 2001;24:588-97.
24. Diagnosis of Diabetes. National Institutes of Diabetes and Digestive and Kidney Diseases. NIH Publication No. 04-4642. Accessed January 4, 2005 from <http://diabetes.niddk.nih.gov/dm/pubs/diagnosis/index.htm>
25. UK Prospective Diabetes Study. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-53.
26. Stratton IM, Adler AI, Neil AW, Matthews DR, Manly SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 2000;321:405-12.
27. Grundy SM, Cleeman JI, Bairey-Merz CN, Brewer HB, Clark LT, Hunninhake DB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult; Adult Treatment Panel III Guidelines. Circulation 2004;110:227-39.
28. Vijan S, Hayward RA. Pharmacologic lipid-lowering therapy in type 2 diabetes mellitus: background paper for the American College of Physicians. Ann Intern Med 2004;140:650-8.
29. American Diabetes Association. Dyslipidemia management in adults with diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S68-71.
30. American Diabetes Association. Hypertension management in adults with diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S65-7.
31. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, et al. The seventh report of the Joint National Committee on prevention, detection and treatment of high blood pressure: The JNC 7 Report. JAMA 2003;289:2560-71.
32. National Kidney Foundation. Kidney disease outcomes quality initiative, Part 7: stratification of risk for progression of kidney disease and development of cardiovascular disease. Am J Kidney Dis 2002;39(Supp):S170-212.
33. American Diabetes Association. Smoking and diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S74-5.
34. American Diabetes Association. Aspirin therapy in diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S72-3.
35. Maitra A, Abbas A. The endocrine system. In:Kumar V, Abbas AK, Fausto N. editors. Kumar: Robbins and Cotran: Pathologic Basis of Disease. 7<sup>th</sup> ed. St. Louis (MO): W.B. Saunders;2005.p. 1155-1226.
36. U.S. Renal Data System. USRDS 2007 annual data report: atlas of end-stage renal disease in the United States, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD 2007. Accessed on February 21, 2008 from <http://www.usrds.org/adr.htm>
37. Powers AC. Chronic complications of DM. In:Kasper DL, Braunwald E, Fauci AS, Hauser SL, Longo DI, Jameson JL, Isselbacher KJ, editors. Harrison's Online. Accessed January 17, 2005 from <http://www3.accessmedicine.com>
38. American Diabetes Association. Nephropathy in diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S79-83.
39. American Diabetes Association. Retinopathy in diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S84-7.
40. CDC. Prevalence of visual impairment and selected eye diseases among persons aged 50 years with and without diabetes – United States, 2002. MMWR CDC Surveill Summ 2004;53:1069-71.
41. Ferri FF, editor. Ferri: Practical Guide to the Care of the Medical Patient. 6<sup>th</sup> ed. St. Louis (MO):Mosby;2004.p.267-348.
42. American Diabetes Association. Influenza and pneumococcal immunization in diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S111-13.
43. American Diabetes Association. Preventive foot care in diabetes (Position Statement). Diabetes Care 2004; 27(Supp):S63-4.

44. Tuomilehto J, Lindstrom J, Eriksson JG, Balle TT, Hamalainen H, Ilanne-Parikka P, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001;344:1343-50.
45. Knowler WE, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker AE, et al. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393-403.
46. Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasid A, Laakso M; STOP-NIDDM Trial Research Group. Acarbose for prevention of type 2 diabetes: the STOP-NIDDM randomized trial. *Lancet* 2002;359:2072-7.
47. Torgerson JS, Hauptman J, Boldrin MN, and Sjostrom L. Xenical in the prevention of diabetes in obese subjects (XENDOS) study. *Diabetes Care* 2004;27:155-161.
48. Gerstein HC, Yusuf S, Bosch J, et al. Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomized controlled trial. *Lancet* 2006;368:1096-1105.
49. A1c. Lab tests online. Accessed January 12, 2005 from <http://www.labtestsonline.org/understanding/analytes/a1c/related.html>
50. A1C test. American Diabetes Organization. Accessed on January 12, 2005 from <http://diabetes.org/type-1-diabetes/a1c-test.jsp>
51. Rohlfing CL, Little RR, Wiedmeyer HM, England JD, Madsen R, Harris MI, et al. Use of GHb (HbA<sub>1c</sub>) in screening for undiagnosed diabetes in the U.S. population. *Diabetes Care* 2000;23:187-91.
52. Greci LS, Kailasam M, Malkani S, Katz DL, Huninsky I, Ahmadi R, et al. Utility of HbA<sub>1c</sub> levels for diabetes case finding in hospitalized patients with hyperglycemia. *Diabetes Care* 2003;26:1064-8.
53. A1cNow<sup>®</sup> InView. Professional-Use Product Insert Metrika. Sunnyvale, CA. Accessed February 25, 2008 from [http://www.inview-alc.com/inview\\_a1cnow.pdf](http://www.inview-alc.com/inview_a1cnow.pdf)
54. Metrika. A1cNow+ Procedure. Accessed February 25, 2008 from <http://www.metrika.com/medical-professionals/a1c-now-overview/a1cnow-procedure-three-simple-steps>
55. The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management-2002 Update. *Endocr Prac* 2002;8(Suppl 1):40-82.
56. Freeman C. Oral Medications and Insulin Therapies: A practical guide for reaching diabetes target goals. Eau Claire (WI):PESI Healthcare, Inc.;2003.
57. Triplitt CL, et al. Diabetes Mellitus In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BD, Posey LM, editors. *Pharmacotherapy. A pathophysiologic approach*. 6<sup>th</sup> ed. New York (NY): McGraw Hill; 2005. p. 1333-67.

## VIII. APPENDIX A

### IPHARM SUBJECT INFORMATION AND CONSENT 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**

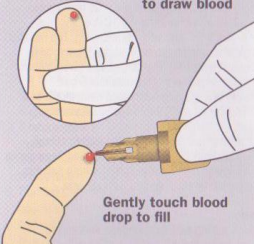
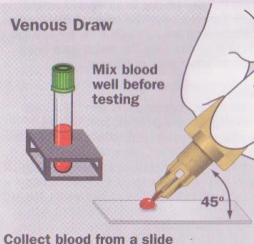
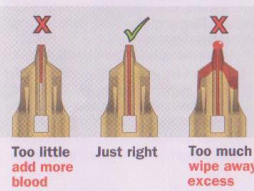
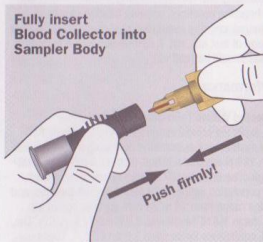
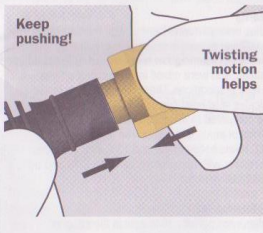
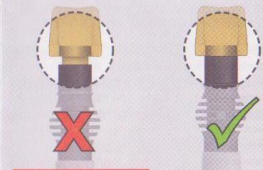

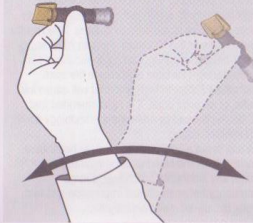
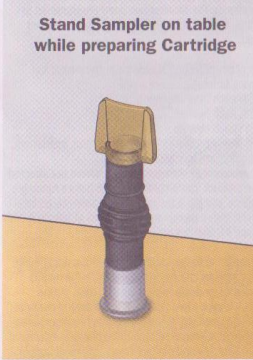
After a person has a finger-stick test, they should be told to compress the site for at least 3-5 minutes with gentle but firm pressure. The IPHARM staff member working the station should inspect the site after this in order to determine if the person's lancet wound has stopped bleeding. If not, a Band-aid 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 A1c Now+<sup>®</sup> Procedure<sup>(54)</sup>

A1CNow+ is a fast, easy and accurate way to perform in-office A1C testing. The simple process requires less than one minute of hands-on time and results are ready in just five minutes. The portable, hand held A1CNow+ monitor also empowers physicians' offices to perform parallel tests, greatly increasing workflow efficiency.

1 BEFORE YOU BEGIN	2 COLLECT BLOOD	3 INSERT BLOOD COLLECTOR	4 SHAKE
<p>Run the test with all parts of the test kit at the same temperature within the specified range.</p> <p>If the kit has recently been at high temperatures (above 82°F) or in the refrigerator, keep the kit at room temperature for at least one hour before use.</p> <p>Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold.</p> <p>Quality control materials should be used to confirm the test kit is working properly. Refer to the product insert for information on when to run controls.</p> <p><b>Monitor (back)</b></p> <p>Complete test within 15 minutes.</p> <p>Base (do not remove!)</p> <p>Pouched Test Cartridge</p> <p>Blood Collector</p> <p>Sampler Body</p> <p>Sample Dilution Kit</p> <p>WAIT TO OPEN</p> <p>LOT 0628216</p> <p>LOT 0628216 EXP 21 SEP 07</p> <p>LOT 0628216 2007-09-21 CODE A1</p> <p>Lot Number and Dating Label</p> <p><b>Ensure Lot #'s match</b></p> <p><b>0628216</b></p>	<p><b>Fingerstick</b></p> <p>Use your own lancet device to draw blood</p>  <p>Gently touch blood drop to fill</p> <p><b>Or</b></p> <p><b>Venous Draw</b></p> <p>Mix blood well before testing</p>  <p>Collect blood from a slide</p> <p>45°</p>  <p>Too little add more blood</p> <p>Just right</p> <p>Too much wipe away excess</p>	<p><b>Fully insert Blood Collector into Sampler Body</b></p>  <p>Push firmly!</p>  <p>Keep pushing!</p> <p>Twisting motion helps</p>  <p>Not fully inserted Keep pushing!</p>  <p>Fully inserted</p>	<p><b>Shake well 6-8 times</b></p> <p>This will mix the blood with the solution</p>  <p><b>Stand Sampler on table while preparing Cartridge</b></p> 

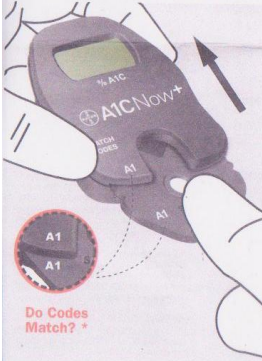
**5 INSERT CARTRIDGE**



**OPEN NOW**

**Use within 2 minutes.**

**"Click" Test Cartridge into place**

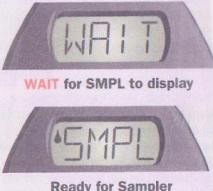


**Do Codes Match? \***

**Monitor and Test Cartridge codes must match**

**\* If not, Call Technical Support at 1-877-212-4968 x1**

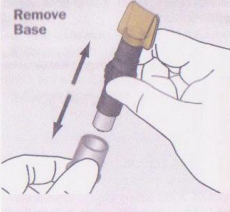
**6 PREPARE SAMPLER**



**WAIT for SMPL to display**

**Ready for Sampler**

**Remove Base**




**Ensure Monitor is on level surface**

**7 DISPENSE SAMPLE INTO CARTRIDGE**

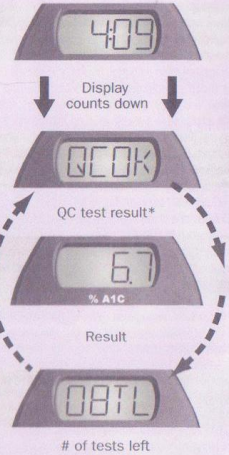
**Push down completely to dispense diluted sample**

**Remove quickly**



**Do not handle Monitor again until test is complete!**

**8 5 MINUTES TO RESULTS**



**Display counts down**

**QC test result\***

**Result**


**# of tests left**

**This result cycle remains displayed for 60 minutes or until the next Test Cartridge is inserted.**

**\* If "QCOK" is not displayed, please see list of error codes on reverse side.**

**If you cannot resolve an error, please call Technical Support at 1-877-212-4968 x1.**

**9 REUSE MONITOR**



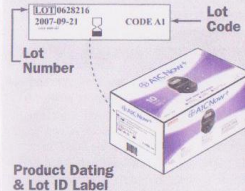
**Save Monitor**

**Discard Test Cartridge**

**THE MONITOR IS REUSABLE**

To run another test, use a new Sampler and Test Cartridge from the same kit and return to Step 1, "PREPARATION."

**Product Dating & Lot ID Label**



**Lot Number**

**Lot Code**

**ALWAYS MATCH LOT NUMBERS**

Use Monitor **only** with the materials included in the original kit. The Monitor will expire after the programmed number of tests have been run. If another Test Cartridge is inserted, the Monitor will display "00 TL."

## APPENDIX C: A1CNow+®™ Test Troubleshooting<sup>(53)</sup>

See the table below for a description of A1CNow+® operating and error codes  
(OR = Out of Range; QC = Quality Control, E= Monitor Error)

MESSAGE	DESCRIPTION AND RESOLUTION
OR 1	The Blood sample may have too little hemoglobin (less than 20% hematocrit), or there was under-sampling of whole blood.* You may wish to check hemocrit by another method.
OR 2	The blood sample may have too much hemoglobin (greater than 60% hematocrit), or there was over-sampling of whole blood.* You may wish to check hemocrit by another method
OR 3	The blood sample may have too little A1C, or there was under-sampling of whole blood.*
OR 4	The blood sample may have too much A1C, or there was over-sampling of whole blood.*
OR 5	The monitor temperature is below 18oC (64oF). Repeat the test at room temperature (18-28oC).
OR 6	The monitor temperature is above 28oC (82oF). Repeat the test at room temperature (18-28oC).
<4.0	The %A1C is less than 4%.
>13.0	The %A1C is greater than 13%.
QC 1 to QC99	The quality control checks did not pass. Call Metrika Technical Support toll free at 877-212-4968. The test will have to be repeated with another Test Cartridge and SampleDilution Kit.
E1 to E99	The Monitor has a Fatal Error. Call Metrika Technical Support tollfree at 877-212-4968

\*Carefully repeat the test using a new Test Cartridge and a new Sample Dilution Kit.

### Limitations

- This test is NOT for the screening or diagnosis of diabetes.
- If the patient has high levels of Hemoglobin F, Hemoglobin S, Hemoglobin C, or other hemoglobin variants, the A1cNow system may report incorrect results.
- Any cause of shortened red cell survival (e.g., hemolytic anemia or other hemolytic diseases, pregnancy, recent significant blood loss, etc.) will reduce exposure of red cells to glucose. This results in a decrease in %A1C values. Percent A1C results are not reliable in patients with chronic blood loss and consequent variable erythrocyte life span.
- This test is designed to be run at 18-28°C (64-82°F) and 15-80% humidity. Using the monitor outside this temperature range will give an error code.
- This test is not a substitute for regular doctor visits and blood glucose monitoring.
- As with any laboratory procedure, a large discrepancy between clinical impression and test results usually warrants investigation.

Accessed February 27, 2008 from <http://www.inview-a1c.com/troubleshooting.html>

# Appendix D Body Mass Index Chart

		Body Mass Index Table																																			
		Normal					Overweight					Obese					Extreme Obesity																				
BMI	Height (inches)	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
	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*.

# Post-test Continuing Education Questions

## *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 function
  - c. Eye
  - d. All of the above
2. According to 2002 medical expenditures, diabetes is the 3<sup>rd</sup> most costly disease in the United States.
  - a. True
  - b. False
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. Increased mobility
  - c. Persistent pain
  - d. Polypharmacy
6. American Indians are how many times more likely to be diagnosed with diabetes compared to Caucasians of similar age?
  - a. 1.5
  - b. 2.0
  - c. 2.6
  - d. 3.2
7. Which of the following characteristics is NOT commonly associated with type 2 diabetes?
  - a. Generally obese
  - b. Rare insulin resistance
  - c. Generally occurs after the age of 40
  - d. Varying degrees of endogenous insulin production
8. Patients with glucose values in the pre-diabetes range have the same risk of developing type 2 diabetes as patients with normal glucose.
  - a. True
  - b. False

9. Which of the following is **NOT** considered to be a risk factor for developing type 2 diabetes?
- Body mass index  $\geq 25$  kg/m<sup>2</sup>
  - Chronic inactivity
  - Female sex
  - Hypertension ( $\geq 140/90$  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?
- LDL-cholesterol goal  $< 100$  mg/dL
  - LDL-cholesterol goal  $< 130$  mg/dL
  - HDL-cholesterol goal  $> 40$  mg/dL (men) &  $> 50$  mg/dL (women)
  - Blood pressure  $< 130/ < 80$  mmHg
  - Blood pressure  $< 140/ < 90$  mmHg
- I, III, V
  - II, III, IV
  - II, III, V
  - I, III, IV
11. Type 2 diabetes accounts for what percentage of all end-stage renal dysfunction patients?
- 25%
  - 39%
  - 49%
  - 62%
12. Which of the following statements is **TRUE** regarding the relationship of albumin in diabetic nephropathy?
- The degree of nephropathy is directly associated with the degree of albuminuria.
  - As renal function diminishes, the renal excretion of albumin also decreases.
  - Macroalbuminuria is classified as albumin content in the urine between 30-299 mcg/mg of creatinine.
  - Macroalbuminuria takes approximately 12 months to develop in diabetic nephropathy.
13. Which of the following neuropathies would **NOT** be considered to be autonomic in origin?
- Neurogenic bladder
  - Erectile dysfunction
  - Inability to detect cold or heat
  - Gastroparesis
14. The American Diabetes Association recommends patients with diabetes be vaccinated annually with the influenza vaccine.
- True
  - False
15. 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?
- Peripheral neuropathy
  - Peripheral vascular disease
  - Severe nail pathology
  - Well controlled blood sugars

16. Which of the following statements is **TRUE** regarding screening recommendations for diabetes in the general population?
- Everyone should be tested annually after the age of 35.
  - Patients with a body mass index  $\geq 24$  kg/m<sup>2</sup> should be screened at least every 3 years starting at age 45.
  - Patients with a body mass index  $\geq 24$  kg/m<sup>2</sup> should be screened annually starting at age 45.
  - Multiple clinical trials have demonstrated the cost-effectiveness of early detection for diabetes in the general population.
17. A 67 year old female, American Indian patient who is obese and taking antihypertensive medications is being screened for diabetes using the A1cNow<sup>®</sup>. Her A1cNow<sup>®</sup> result is 6.1%. What action would you recommend?
- This patient clearly has diabetes and should be referred for follow-up care.
  - This patient does not have diabetes and should not be referred for follow-up care.
  - 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.
  - Counsel the patient to watch how much sugar she is eating.
18. A 72 year old male patient, who appears to be in good health, is screened for diabetes using the A1cNow<sup>®</sup> test. His A1cNow<sup>®</sup> result is 7.5%. What action would you recommend?
- This patient has very few risk factors and should not be referred for follow-up care.
  - This patient should be referred to his primary care provider for follow-up care, as the A1cNow<sup>®</sup> result suggests chronic hyperglycemia.
  - Counsel this patient on the importance of risk factor reduction.
  - Both b & c
19. While performing a A1cNow<sup>®</sup> test, the display panel on the device gives you the following message, "OR 5". What action should you take?
- The blood sample may have too little A1c, or there was under-sampling of whole blood. Call Metrika.
  - The blood sample may have too much A1c, or there was over-sampling of whole blood. Call Metrika.
  - The monitor temperature is above 28° C (82°F). Repeat the test at room temperature. Call Metrika.
  - The monitor temperature is below 18°C (64°F). Repeat the test at room temperature. Call Metrika.
20. Which of the following non-pharmacologic therapies is **NOT** recommended by the American Diabetes Association?
- Lose weight
  - Sucrose should be completely removed from the diet
  - Aerobic exercise for 20-30 minutes at least 3 days per week
  - Stop smoking

Continuing Education Examination Form  
 Module: *Screening for Diabetes in Older Persons*

**POST-TEST**

**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 continuing education credit,  
 please return this completed  
 page to ⇨ ⇨ ⇨

Rachael Curran  
**MTGEC/IPHARM**  
 Skaggs Building Room 317  
 University of Montana  
 32 Campus Drive  
 Missoula MT, 59812-1522  
 Phone# (406) 243-2339 & Fax# (406) 243-4353



## IX. Evaluation for MTGEC Module: *Screening of Diabetes in Older Persons*

Please circle your profession: Certified Nursing Assistant • Nursing Home Administrator •  
APRN • RN • LPN • Pharmacist • Physical Therapist • Social Work • Other \_\_\_\_\_

Please circle (or underline) the appropriate number:

	Yes				No	Don't Know
The overall visual presentation of the material enhanced my learning.	5	4	3	2	1	X
The module content was understandable.	5	4	3	2	1	X
The content was presented without bias.	5	4	3	2	1	X
The content will be useful for health-care professionals working with the elderly.	5	4	3	2	1	X
The objectives were clear.	5	4	3	2	1	X
This approach met my learning objectives.	5	4	3	2	1	X
To what extent have you achieved each objective?						
Obj 1 Summarize the impact of diabetes on health in relation to disease prevalence, health care expenditures and its relation to obesity.	5	4	3	2	1	X
Obj 2 Describe the specialized needs of an older adult with diabetes.	5	4	3	2	1	X
Obj 3 Describe how diabetes impacts the health of American Indians.	5	4	3	2	1	X
Obj 4 Differentiate between type 1 and type 2 diabetes in regard to typical age of onset, etiology, endogenous insulin secretion and insulin resistance.	5	4	3	2	1	X
Obj 5 Define insulin resistance and describe its role in type 2 diabetes.	5	4	3	2	1	X

Obj 6 Identify patient risk factors for type 2 diabetes.	5	4	3	2	1	X
Obj 7 Differentiate between macrovascular and microvascular complications found in patients with diabetes.	5	4	3	2	1	X
Obj 8 Describe treatment recommendations and/or goals for diabetic patients who may have dyslipidemia or hypertension.	5	4	3	2	1	X
Obj 9 Describe how kidney disease plays a significant role in patients with diabetes.	5	4	3	2	1	X
Obj 10 Describe the progressive changes found in non-proliferative and proliferative diabetic retinopathies.	5	4	3	2	1	X
Obj 11 Briefly discuss the three main types of neuropathies seen in patients with diabetes.	5	4	3	2	1	X
Obj 12 Identify patients who are good candidates for diabetes screening.	5	4	3	2	1	X
Obj 13 Describe how to perform hemoglobin A1c test using the A1cNow® device, and identify which screened patients should be referred.	5	4	3	2	1	X
Obj 14 Briefly describe non-pharmacologic and pharmacologic therapies available for treatment of diabetic patients.	5	4	3	2	1	X
The module objectives related well to the over all purpose/goal of the web based curriculum.	5	4	3	2	1	X
The test questions were unambiguous.	5	4	3	2	1	X
The test questions were appropriate to the module content.	5	4	3	2	1	X
This teaching method was appropriate and used effectively.	5	4	3	2	1	X
I would recommend this course to other health care professionals.	5	4	3	2	1	X

How did you learn about the modules?

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)

Any other suggestions?