Recommendations

for Management of

DIABETES

in South Dakota

South Dakota Diabetes Prevention and Control Program
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http://diabetes.sd.gov
Recommendations for Management of Diabetes in South Dakota
March 2008

Dear Provider;

We are pleased to provide you with the enclosed Recommendations for Management of Diabetes in South Dakota. These recommendations were produced through the collaborative efforts of the South Dakota Department of Health, the South Dakota Foundation for Medical Care, and numerous providers.

More than 38,170 South Dakotans over the age of 17 have been diagnosed with diabetes and an additional 16,359 could have the disease and not even know it, according to Centers for Disease Control and Prevention estimates that 30% of people with diabetes are undiagnosed. These recommendations utilize current research and evidence-based practices and are meant to serve as a guide to providing appropriate care and treatment to people at-risk-for and with diabetes.

Providers are encouraged to adapt the recommendations to provide individualized, culturally sensitive care to all patients for optimal health outcomes and to provide consistency in the treatment and prevention of the long-term complications of diabetes.

The recommendations were developed as part of a statewide initiative to improve the health care of people with diabetes, and are consistent with the South Dakota Diabetes State Plan 2007-2009, available at http://diabetes.sd.gov.

If you have any questions, please feel free to contact the South Dakota Diabetes Prevention and Control Program at 1-800-738-2301 or the South Dakota Foundation for Medical Care at 1-800-658-2285.

Sincerely,

Doneen B. Hollingsworth
Secretary of Health

Dr. Steve Schroeder, Medical Director
South Dakota Foundation for Medical Care
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Welcome to the second edition of *Recommendations for Management of Diabetes in South Dakota*. This guide has been developed as part of a statewide initiative to improve the health care of people with diabetes, and is consistent with the *South Dakota Diabetes State Plan (2007-2009)*.

Much work has been done, but many challenges still lie ahead. According to information accessible at [http://doh.sd.gov/Statistics/default.aspx](http://doh.sd.gov/Statistics/default.aspx), the Behavioral Risk Factor Surveillance Survey (BRFSS) is the main behavioral surveillance tool used in South Dakota for data collection for *Healthy People 2010* objectives. The South Dakota Department of Health’s Survey “The Health Behaviors of South Dakotans” conducted in 2006 and reported in 2007, indicates the prevalence of diabetes has increased in South Dakota from a low of 2.9 percent in 1995 to a high of 7.1 percent in 2003. Currently, there is a 6.5 percent prevalence rate in the state.

The highest prevalence of diabetes was noted in the 55 to 75+ age range, in sparsely populated geographic locations across the state, including central South Dakota and the Native American counties. Lower socioeconomic income status and lower levels of education completed were also prevalent in this population group. Further, this survey indicates that disparities exist in South Dakota in both race and geographic location. Survey data lists the prevalence of diabetes in South Dakota at 6.1 percent for whites and 13.4 percent for Native Americans. Aberdeen Area Indian Health Service reports their 2007 prevalence rate for diabetes in all ages of their population at 12 percent, up from 11.8 percent in 2006.

This disparity translates into shorter life spans for the Native American population. The South Dakota Vital Statistics Report (2006) reveals that diabetes ranks as the 7th leading cause of death for whites and 5th for American Indians, resulting in the median age of death at 82 years for whites and 69 years for American Indians.

As health care providers, if we are to address the global epidemic of diabetes and obesity in the world today, focus must be centered on forming partnerships to create awareness, provide education, treatment, and preventive practices to mitigate the burden of diabetes
in South Dakota. In order to provide culturally relevant care that honors the values of the population, we must begin at the local level if we are to have an impact on the worldwide diabetes epidemic.

Armed with the positive outcomes from the Diabetes Prevention Program, health care providers and their interdisciplinary partners have the knowledge and tools to focus on prevention activities. There are no quick fixes for the social and health problems facing citizens today, but by joining together, South Dakotans can overcome the public health threat of diabetes and secure a healthier future for our children, adults, elders, and future generations yet to come.

These recommendations provide practitioners with the current research and evidence-based practice according to existing national standards, and are meant to serve as a guide to provide appropriate care and treatment to people at risk for and with diabetes. Providers are encouraged to adapt recommendations to provide individualized, culturally sensitive care to all patients to improve health outcomes and to avoid disparity in treatment, and to provide consistency in the treatment and prevention of the long-term complications of diabetes.

Funding for this project is through a cooperative agreement between the Centers for Disease Control and Prevention, Division of Diabetes Translation and the South Dakota Department of Health, Diabetes Prevention and Control Program.
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Screening/Diagnosis for Type 2 Diabetes Mellitus

- The purpose of screening is to identify asymptomatic individuals who are at high-risk or likely to have diabetes or pre-diabetes.
- Screening to detect pre-diabetes (Impaired Fasting Glucose-IFG or Impaired Glucose Tolerance-IGT) and diabetes should be considered in individuals ≥ 45 years of age, particularly in those with a BMI ≥ 25 kg/m2, and if normal, should be repeated at 3-year intervals.
- Testing should be considered at a younger age or be carried out more frequently in individuals who are/have: 1) Overweight (BMI ≥ 25 kg/m2) and have additional risk factors; 2) Habitually physically inactive; 3) A first-degree relative with diabetes; 4) Are members of a high-risk ethnic population (e.g. African American, Latino, Native American, Asian American, Pacific Islander); 5) Delivered a baby weighing > 9 lbs or have been diagnosed with Gestational Diabetes Mellitus (GDM); 6) Hypertensive (≥ 140/90 mmHg); 7) HDL cholesterol level < 35 mg/dl (0.90 mmol/l) and/or a triglyceride level > 250 mg/dl (2.82 mmol/l); 8) Polycystic Ovary Syndrome (PCOS); 9) Previous IGT, IFG, or clinical conditions associated with insulin resistance (e.g. PCOS or Acanthosis Nigricans); 10) History of vascular disease; 11) Medications that cause hyperglycemia—i.e. steroids, etc.; and 12) Psychiatric illness (American Association of Clinical Endocrinologists (AACE) risk factor).
- Providers caring for Native Americans or Alaskan Natives are encouraged to follow the Indian Health Service Standards of Care for Adults with Type 2 Diabetes (2006).
- A fasting plasma glucose test (FPG) is the preferred test to diagnose diabetes in children and non-pregnant adults due to its simplicity and cost effectiveness.
- Use of the A1C for the diagnosis of diabetes is not recommended at this time.
- A FPG result ≥ 126 mg/dl on two separate occasions is diagnostic of diabetes. Values of 100 to 125 mg/dl are termed impaired fasting glucose or pre-diabetes. FPG values < 100 mg/dl are considered normal according to both American Diabetes Association (ADA) and AACE Standards/Guidelines.
- Individuals with glucose levels of 144 to 199 mg/dl after a two-hour glucose tolerance test are considered to have Impaired Glucose Tolerance (IGT) or pre-diabetes, even though these individuals do not meet the criteria for diagnosed diabetes.
- Individuals with impaired glucose tolerance can significantly reduce the risk of developing type 2 diabetes through intervention with diet and exercise or Metformin.
- People with psychiatric illness such as schizophrenia are at a greater risk for obesity, type 2 diabetes, metabolic syndrome with dyslipidemia, and hypertension than the general population.
Who should be screened for type 2 diabetes mellitus?
Diabetes screening is recommended for high-risk children and adults who have not previously been diagnosed and who are asymptomatic. Type 2 diabetes is frequently not diagnosed until symptoms appear. Incidence of type 2 diabetes in adolescents has shown a dramatic increase in the last decade. Consistent with screening recommendations for adults, only children and youth at increased risk for type 2 diabetes should be tested. Early detection and treatment can decrease the burden of diabetes.

Who are high-risk individuals?
Adults:
Individuals with one or more major risk factors should be screened. No single risk factor is correlated with a 100 percent risk for type 2 diabetes. The greater the number of major risk factors present, the greater the risk of diabetes. The likelihood of diagnosing type 2 diabetes in a person with no risk factors is very low.

What are the major risk factors?
- First degree relatives with diabetes (parents or siblings)
- Overweight (> 20 percent over desired body weight or Body Mass Index (BMI*) > 25 kg/m2)
- Age greater than 45 years old
- Sedentary lifestyle (habitually physically inactive)
- Other clinical conditions associated with insulin resistance (e.g. polycystic ovary syndrome (PCOS) or Acanthosis Nigricans)
- History of vascular disease
- Dyslipidemia (HDL cholesterol level < 35 mg/dl [0.90 mmol/l]) and/or triglyceride level > 250 mg/dl (2.82 mmol/l)
- Previously identified impaired fasting glucose or impaired glucose tolerance (see below)
- History of gestational diabetes or delivery of a baby over 9 pounds
- Hypertension (> 140/90 mmHg)
- African Americans, Hispanic Americans, Native Americans, Asian Americans, Pacific Islanders
- Psychiatric illness (new addition from AACE)

*Body Mass Index (BMI) = weight in kilograms/(height in meters)2, or
BMI = weight in pounds x 703/height in inches x height in inches
What are the testing criteria for type 2 diabetes in children?

- Overweight (BMI > 85th percentile for age and sex, weight for height > 85th percentile, or weight > 120 percent of ideal for height)

**Plus any two of the following risk factors:**

- Family history of type 2 diabetes in first or second-degree relative
- Race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander)
- Signs of insulin resistance or conditions associated with insulin resistance (Acanthosis Nigricans, hypertension, dyslipidemia, or polycystic ovary syndrome (PCOS))
- Maternal history of diabetes or gestational diabetes mellitus (GDM)

**Age of initiation:** Age 10 years or at onset of puberty, if puberty occurs at a younger age

**Frequency:** Every 2 years

**Test:** Fasting plasma glucose (FPG) preferred

Clinical judgment should be used to test for diabetes in high-risk patients who do not meet these criteria.

**When should re-screening be done?**

If the initial screening is negative, those over 45 years of age should be re-screened every three years. Multiple risk factors or a high degree of clinical suspicion are indications for shorter intervals between screenings in certain individuals, and/or considering a more sensitive screening test such as a two-hour glucose tolerance test (see below). Children whose initial screening is negative, but are at high risk for development of type 2 diabetes, should be screened every two years utilizing FPG testing.

**What screening tests should clinicians use?**

The FPG test is the preferred screening test for asymptomatic individuals because it is convenient and inexpensive. Fasting is defined as no consumption of food or caloric beverage for at least eight hours prior to testing.

The oral glucose tolerance test (OGTT) is also appropriate for screening, but is less convenient and more expensive than a FPG. The OGTT is a more sensitive test for type 2 diabetes and other states of impaired glucose metabolism, and should be considered when the FPG is negative, but the clinical suspicion for abnormal glucose metabolism is high. The DECODE study found that the two-hour value on OGTT correlated better with risk of both cardiovascular and all-cause mortality than did the FPG. Data from the Diabetes Prevention Program indicates that individuals with impaired glucose tolerance can significantly reduce the risk of developing type 2 diabetes through intervention with diet and exercise or Metformin.

Random plasma glucose can be used as a non-diagnostic screening test. A random test is any plasma glucose test obtained without regard to the time since the meal. A level of > 160 mg/dl should be interpreted as abnormal and > 200 is a provisional diagnosis of diabetes. A subsequent elevated FPG or OGTT result is needed to confirm the diagnosis of diabetes.

If an individual has symptoms of diabetes (increased thirst, increased urination, unexpected weight loss) and has a random plasma glucose > 200 mg/dl, the diagnosis needs to be confirmed on a subsequent day by measurement of FPG, 2-hour OGTT, or a second random plasma glucose.
A1C is not recommended by the American Diabetes Association as a screening test because of inter-laboratory variability and the absence of established cut-off values for the normal range of results. Patients with diabetes may have normal A1C values, and such a result does not rule out diabetes. Elevated A1C results, although not diagnostic, are strongly suggestive of diabetes.

*Whole blood glucose testing*, finger stick or venous blood, is not recommended for screening or diagnostic testing. Results are usually 10 to 15 percent lower than plasma glucose levels and much less accurate if obtained by a home blood glucose monitoring device.

**How should FPG and OGTT results be interpreted?**
Screening test results fall into three categories: diabetic, impaired, or normal.

For fasting plasma glucose:
- Diabetic range is defined as FPG > 126 mg/dl
- Impaired fasting glucose is defined as FPG > 100 mg/dl, but < 126 mg/dl
- Normal fasting glucose is < 100 mg/dl (ADA and AACE)

For the OGTT (75-g oral glucose tolerance test):
- Diabetic range is defined as a two-hour post-load glucose value > 200 mg/dl
- Impaired glucose tolerance or pre-diabetes is defined as two-hour values > 140 mg/dl, but < 200 mg/dl
- Normal range is two-hour post-load value < 140 mg/dl

**What action should be taken based on screening test results?**
An elevated result requires retesting on a different day to confirm the diagnosis. A second elevated result confirms the diagnosis of diabetes.

*Impaired fasting glucose* or *impaired glucose tolerance* are major risk factors for the development of diabetes. The interval between the next screening should be no greater than three years. Lifestyle treatment may be appropriate. Intervention with diet and exercise, or Metformin, can significantly reduce the risk of developing type 2 diabetes.

*If test results are normal*, the interval between the next screening should be no greater than three years if other major risk factors persist.

**What medications can produce hyperglycemia and result in false positive screening results?**
Glucocorticoids, furosemide, thiazides, estrogen containing products, β-blockers, and nicotinic acid may produce hyperglycemia.

**Is screening recommended for type 1 DM?**
Screening for type 1 diabetes is not recommended because the incidence is too low to justify the expense, the interval between insulin failure and acute symptoms is short, there is no consensus on appropriate interventions for the “prediabetic” phase, and normal levels for autoantibodies related to type 1 diabetes have not been established. Screening for gestational diabetes is covered in a separate section of this manual.
Why are patients with psychiatric illness at risk for type 2 diabetes?
People with psychiatric illness, such as schizophrenia, are at a greater risk of obesity, type 2 diabetes, metabolic syndrome with dyslipidemia, and hypertension than the general population. Data from recent clinical trials documents an increased incidence of cardiovascular disease (CVD) as well as a high prevalence of undiagnosed and untreated metabolic disease (obesity, glucose homeostasis disorders, and dyslipidemia) in patients with severe mental illness who are prescribed antipsychotic drugs. Clinical evidence data links the use of certain second-generation anti-psychotics and increased risk of developing metabolic syndrome and CVD.

The problem represents a major public health issue with multiple causative factors such as lifestyle factors, inequalities in the provision of healthcare, and medication-related adverse effects. In addition, smoking, poor diet, reduced physical activity, and alcohol or drug abuse are prevalent in people with schizophrenia, and contribute to the overall CVD risk. Increasing evidence suggests that having a diagnosis of schizophrenia per se may be a risk factor for development of diseases with metabolic disorders. Management and minimization of metabolic risk factors are pertinent when providing optimal care to patients with schizophrenia. Health care practitioners are encouraged to develop a plan of care that includes ongoing assessment, monitoring, and management of clients with schizophrenia and psychiatric illness.

Why does the Indian Health Service have their own Standards of Care for patients with type 2 diabetes?
The Indian Health Service has developed guidelines specific to the Native American and Alaskan Native population to address the unique aspects of diabetes care delivered in a culturally sensitive manner. Although many of the criteria are consistent with those of the American Diabetes Association, some differences exist including the following: 1) Three plasma blood tests when establishing the diagnosis of diabetes; 2) Use of A1Cs are not recommended for the diagnosis of diabetes; 3) Provision of wholistic (care of the whole person) care; and 4) Screening for depression, cancer, tobacco use, tuberculosis, nonalcoholic fatty liver, anemia, and alcohol and drug abuse. The overall goal for treatment is to ensure consistent quality care to everyone. The 2006 Guidelines are available at http://www.ihs.gov/MedicalPrograms/diabetes/IHSDiabetesStandardsofCare2006.pdf.
References:
## Pre-Diabetes

- Pre-diabetes refers to the intermediate metabolic state between normal and diabetic glucose homeostasis, i.e. impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), and is a component of metabolic syndrome.
- IGT is categorized by the World Health Organization (WHO) and the ADA as a stage in the natural progression of disordered carbohydrate metabolism. Diagnosis is determined by OGTT with normal fasting plasma glucose, but elevated two-hour plasma glucose readings of 140 to 199 mg/dL. Although higher than normal, this reading is not high enough to be classified as type 2 diabetes.
- IFG is used to classify individuals who have fasting plasma glucose values above the normal range, but below 126 mg/dL.

### What is pre-diabetes?

Pre-diabetes is a major risk factor for development of type 2 diabetes. IGT has been associated with an increased risk of cardiovascular disease and mortality. Data from the Diabetes Intervention Study and the Honolulu Heart Study indicated an increased risk of CVD with impaired glucose tolerance (Lui et al, 2007). Considerable evidence indicates that pre-diabetes, specifically impaired glucose tolerance (IGT), can be modified with lifestyle or drug therapy intervention to either delay or prevent the onset of type 2 diabetes.

Pre-diabetes describes two distinctive abnormalities of glucose metabolism. Impaired fasting glucose (IFG) is thought to be secondary to increased hepatic gluconeogenesis and decreasing or impaired pancreatic beta cell function. Impaired glucose tolerance arises from peripheral insulin resistance.

People with pre-diabetes have blood glucose levels higher than normal but not high enough to be classified as diabetes. Pre-diabetes is considered to be a precursor to type 2 diabetes and raises the risk of developing heart disease and stroke. Approximately 30 percent to 40 percent of patients with pre-diabetes develop type 2 diabetes within a 5-year time frame.

ADA recommendations for pre-diabetes screening include patients 45 years or older, especially if BMI is 25 kg/m2 or higher with a FPG or OGTT, respectively. Patients with either IGT or IFG should be screened every one to two years to check for the development of type 2 diabetes, and those with normal values should be re-screened in three years. High-risk patients should be counseled regarding the potential benefits of increased activity and weight loss based on data garnered from clinical trials. Because of the high prevalence of CVD associated with pre-diabetes, in addition to measurement of weight and BMI, patients should be assessed for tobacco use, dyslipidemia, and hypertension.
What are the guidelines for diagnosis?
Current ADA guidelines are as follows:

- **IFG**: Fasting glucose level between 100 and 125 mg/dL (5.6 and 6.9 mmol/L).
- **IGT**: 2-hour post-75-g glucose load/glucose concentration of between 140 to 199 mg/dL (7.8 to 11.0 mmol/L).

Currently there are no standards for use of A1C tests to screen for pre-diabetes, but individuals with an A1C above the population mean (often considered 5.5 percent) are at increased risk for developing diabetes.

What are the treatment goals for patients with pre-diabetes?
Pre-diabetes is a major risk factor associated with metabolic syndrome. For patients with pre-diabetes, the goal is to decrease the risk of diabetes and cardiovascular disease by promoting physical activity and healthy food choices that result in moderate weight loss that is sustainable, or at a minimum, prevents further weight gain. Refer to pages 103 and 104 for the goals of medical nutrition therapy (MNT). It should be noted that MNT is the same for both pre-diabetes and type 2 diabetes.

Is drug therapy useful in patients with pre-diabetes?
Drug therapy is not recommended by the ADA due to the limited efficacy of treatment versus lifestyle modification, potential for adverse drug reactions, lack of data supporting reduction of microvascular or macrovascular complications of diabetes in this patient population, and insufficient assessment of the cost-effectiveness of drug treatment. However, not all patients are able to implement lifestyle modifications due to physical or other limitations, and based on limited data available, drug therapy may be a reasonable option to delay onset of type 2 diabetes and provide a cardiovascular benefit (TRIPOD and STOP-NIDDM data).

References:
**Metabolic Syndrome (Insulin Resistance Syndrome)**

- People with metabolic syndrome are at increased risk of coronary heart disease and other diseases related to plaque deposits/buildups in artery walls (stroke and peripheral vascular disease) and type 2 diabetes mellitus.
- Underlying risk factors for this syndrome are abdominal obesity and insulin resistance.
- Criteria for diagnosis of metabolic syndrome are based on common clinical measures including waist circumference, triglycerides, HDL-C, blood pressure, and fasting glucose levels. The presence of defined abnormalities in any three of these five measures constitutes a diagnosis of metabolic syndrome.

**What is metabolic syndrome?**

Metabolic syndrome is characterized by a group of metabolic risk factors in an individual, which include abdominal obesity, atherogenic dyslipidemia, elevated blood pressure, insulin resistance or glucose intolerance, prothrombotic state (as evidenced by high fibrinogen or plasminogen activator inhibitor-1 in the blood), and proinflammatory state with elevated C-reactive protein in the blood.

**What is the main reason for an increased number of patients with metabolic syndrome?**

The National Cholesterol Education Program’s Adult Treatment Panel III report (ATP III) considers the rising obesity epidemic in the United States to be responsible for the increasing prevalence of metabolic syndrome. Risk factors associated with obesity increase proportionately as abdominal girth expands, causing elevation of serum cholesterol, low HDL cholesterol, hyperglycemia, and hypertension. Other factors, such as aging, physical inactivity, proinflammatory state, hormonal changes/imbalances, and genetic predisposition have been implicated as contributors as well.

**What are the major components of metabolic syndrome?**

The National Cholesterol Education Program identifies metabolic syndrome as a multiplex risk factor for cardiovascular disease. Although criteria established by ATP III differ slightly from other organizations, all recognize CVD as a primary outcome of metabolic syndrome. World Health Organization (WHO) agrees that CVD is a risk factor associated with metabolic syndrome, but posits that insulin resistance is a required component for diagnosis. The American Association of Clinical Endocrinologists (AACE) proposes a third set of clinical criteria for insulin resistance syndrome and parallel those of WHO and ATP III, but do not define a specific number of risk factors. ATP III considers the six following components to be characteristic of metabolic syndrome:

1. *Abdominal obesity* is the form of obesity most often associated with metabolic syndrome. It presents clinically as increased waist circumference greater than 40 inches in men and 35 inches in females.

2. *Atherogenic dyslipidemia* is evidenced by raised triglycerides and low concentrations of HDL cholesterol on lipid profile studies. Other lipid abnormalities may also be noted with elevated LDL and small HDL particles.
3. *Elevated blood pressure* is associated with obesity and insulin-resistance as increasing arterial stiffness contributes significantly to systolic hypertension in the elderly.

4. *Insulin resistance* is present in the majority of people with metabolic syndrome and is strongly linked to CVD. Patients with longstanding insulin resistance often show symptoms of *glucose intolerance*, and if left untreated will evolve into full-blown type 2 diabetes.

5. *A proinflammatory state* manifests itself through elevations of highly sensitive C-reactive protein (hs-CRP). As a result of obesity, excess adipose tissue releases inflammatory cytokines that may be reflected in elevated hs-CRP levels. Prospective studies (Aguilar et al, 2006) in middle-aged individuals have observed that increased serum CRP levels may predict the development of metabolic syndrome.

6. *A prothrombotic state* is characterized by increased plasma plasminogen activator inhibitor (PAI)-1 and fibrinogen in metabolic syndrome. Fibrinogen is an acute-phase reactant (like CRP) and rises in response to a high-cytokine state. Prothrombotic and proinflammatory states may be metabolically interconnected.

**What are the criteria for diagnosis of metabolic syndrome?**

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) proposed a simple set of diagnostic criteria based on common clinical measures including waist circumference, triglycerides, HDL-C, blood pressure, and fasting glucose level.

The presence of defined abnormalities in any three of these five measures constitutes a diagnosis of metabolic syndrome. Patients having fewer than three abnormalities are at high-risk for developing metabolic syndrome and type 2 diabetes mellitus, and require close monitoring and ongoing assessment.

Please refer to Table 1 on the following page for diagnostic criteria for Metabolic Syndrome.
### Table 1: Diagnostic Criteria for Metabolic Syndrome (Adapted from AHA, 2004)

<table>
<thead>
<tr>
<th>Measure (Any 3 of 5 Criteria Constitute Diagnosis of Metabolic Syndrome)</th>
<th>Categorical Cut Points</th>
</tr>
</thead>
</table>
| Elevated waist circumference* +  
*To measure waist circumference, locate top of right iliac crest. Place a measuring tape in a horizontal plane around the abdomen at level of iliac crest. Before reading tape measure, ensure the tape is snug but does not compress the skin and is parallel to floor. Measurement is made at the end of normal expiration.  
+Some US adults of non-Asian origin (e.g. white, black, Hispanic) with marginally increased waist circumference (e.g. 94-101 cm or 37-39 inches in men; and 80-87 cm or 31-34 inches in women) may have strong genetic contribution to insulin resistance and should benefit from changes in lifestyle habits, similar to men with categorical increases in waist circumference. Lower waist circumference cut point (e.g. > 90 cm/35 inches in men; and > 80 cm/31 inches in women) appears to be appropriate for Asian Americans. |  
≥ 102 cm (≥ 40 inches) in men  
≥ 88 cm (≥ 35 inches) in women  
| Elevated Triglyceride  
#Fibrates and nicotinic acid are the most commonly used drugs for elevated Triglyceride and reduced HDL-C. Patients taking one of these drugs are presumed to have high triglyceride and low HDL. | ≥ 150 mg/L (1.7 mmol/L) or  
Drug treatment for elevated triglyceride |
| Reduced HDL-C | < 40 mg/dL (1.03 mmol/L) in men  
< 50 mg/dL (1.3 mmol/L) in women or  
Drug treatment for reduced HDL-C |
| Elevated BP | ≥ 130 mm Hg systolic BP, or  
≥ 85 mm Hg diastolic BP, or  
Drug treatment for hypertension |
| Elevated fasting glucose | ≥ 100 mg/dL or drug treatment for elevated glucose |

### What is the primary goal of clinical management of metabolic syndrome?

The primary goal of clinical management of metabolic syndrome is to reduce the risk for clinical atherosclerotic disease. A second closely related goal is to reduce the risk for type 2 diabetes mellitus in patients who are at high-risk. First line therapy is to reduce major modifiable risk factors such as cessation of tobacco use, target lowering LDL-C and triglycerides, raise HDL, and lower blood pressure and glucose levels to recommended goals. Both the long-term and short-term goals include interventions to reduce metabolic risk factors and include weight loss, increased physical activity, and diet modification to low fat intake. Refer to the section on medical nutrition therapy for additional information (pages 103-105).

Blood pressure management including lifestyle changes are recommended for readings that range from 120 to 139 systolic and 80 to 90 mmHg diastolic. Readings higher than ≥ 140/90 should be considered for drug therapies according to current hypertension guidelines. When either diabetes or chronic renal disease is present, reducing blood pressure to < 120/80 mm Hg, with drugs if necessary, is recommended.
**Table 2: Medication Therapy**

<table>
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<th>Action of Drug</th>
<th>Drug Choices Commonly Used</th>
</tr>
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<tbody>
<tr>
<td><strong>ATHEROGENIC DYSLIPIDEMIA</strong></td>
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<tr>
<td><strong>Standard LDL-Lowering Drugs</strong></td>
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</tr>
<tr>
<td>Medication therapy for the treatment of atherogenic dyslipidemia is based on NCEP guidelines and target lowering the LDL-C and raising HDL-C.</td>
<td>Statins, exetimibe, and bile acid sequestrants (Recent research findings from the parent company Merck/Schering-Plough (2008) question the efficacy of exetimibe when combined with simvastatin (Vytorin)).</td>
</tr>
<tr>
<td><strong>Secondary Drugs</strong></td>
<td></td>
</tr>
<tr>
<td>Produce moderate reductions of LDL-C</td>
<td>Nicotinic acid and fibrates are considered to be secondary drugs to lower non-HDL-C and to raise HDL-C after LDL-C goals are achieved.</td>
</tr>
<tr>
<td><strong>Severe Hypertriglyceridemia</strong></td>
<td>The fibrates or nicotinic acid are first-line therapy for patients with severe hypertriglyceridemia for the purpose of preventing acute pancreatitis.</td>
</tr>
<tr>
<td><strong>CAUTION:</strong></td>
<td></td>
</tr>
<tr>
<td>Caution must be exercised in using fibrates (particularly gemfibrozil) with statins because of the accentuated risk for severe myopathy.</td>
<td></td>
</tr>
<tr>
<td><strong>Low Dose Aspirin</strong></td>
<td>Use of low-dose aspirin is recommended for individuals exhibiting the following:</td>
</tr>
<tr>
<td></td>
<td>1) prothrombotic states characterized by elevation of plasminogen activator inhibitor-1 and fibrinogen;</td>
</tr>
<tr>
<td></td>
<td>2) a 10-year risk for CHD ≥ 10%;</td>
</tr>
<tr>
<td></td>
<td>3) those with overt type 2 diabetes;</td>
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<tr>
<td></td>
<td>4) ASCVD; or</td>
</tr>
<tr>
<td></td>
<td>5) other high risk categories</td>
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<tr>
<td></td>
<td>In patients with ASCVD in whom aspirin is contraindicated, consideration should be given to use of clopidogrel.</td>
</tr>
<tr>
<td><strong>Treatment of IFG</strong></td>
<td>Drug therapy to reduce plasma glucose or insulin resistance is not recommended for patients with IFG. Once diabetes is diagnosed, drug therapy is indicated to achieve the recommended ADA goal for hemoglobin A1C of &lt; 7% (6.5% per AACE).</td>
</tr>
</tbody>
</table>
What are the therapeutic goals for long-term prevention of ASCVD? Refer to Table 3 for current therapeutic goals for the long-term prevention of ASCVD.

<table>
<thead>
<tr>
<th>Therapeutic Target</th>
<th>Goals of Therapy</th>
<th>Therapeutic Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal obesity</td>
<td>Reduce body weight by 7%-10% during first year of therapy</td>
<td>Consistently encourage weight maintenance/reduction through appropriate balance of physical activity, caloric intake, and formal behavioral programs when indicated to maintain/achieve waist circumference of &lt; 40 inches in men and &lt; 35 inches in women. Aim initially at slow reduction of and 7%-10% from baseline weight. Even small amounts of weight loss are associated with significant health benefits.</td>
</tr>
<tr>
<td></td>
<td>Continue weight loss thereafter to extent possible with goal to ultimately achieve desirable weight (BMI &lt; 25 kg/m2)</td>
<td></td>
</tr>
<tr>
<td>Physical inactivity</td>
<td>Regular moderate-intensity physical activity; at least 30 minutes of continuous/intermittent (preferably 60 minutes) 5 days/week, but preferably daily</td>
<td>In patients with established CVD, assess risk with detailed physical activity history and/or exercise test to guide prescription. Encourage 30 to 60 min of moderate-intensity aerobic activity (e.g., brisk walking), preferably daily, supplemented by an increase in daily lifestyle activities (e.g. pedometer step tracking, walking breaks at work, gardening, household work). Higher exercise times achieved by accumulating exercise throughout day. Encourage resistance training 2 d/wk. Advise medically supervised programs for high-risk patients (e.g. recent acute coronary syndrome or revascularization, CHF).</td>
</tr>
<tr>
<td>Atherogenic diet</td>
<td>Reduced intakes of saturated fat, transfat, cholesterol</td>
<td>Saturated fat &lt; 7% of total calories; reduce trans fat; dietary cholesterol &lt; 200 mg/d; total fat 25%-35% of total calories. Most dietary fat should be unsaturated, simple sugars should be limited.</td>
</tr>
</tbody>
</table>
References:
Gestational Diabetes Mellitus (GDM)

- The increase in gestational diabetes is consistent with the current national obesity trends and epidemic of type 2 diabetes, further it poses a significant public health risk of obesity and glucose intolerance in children.
- Prenatal screening for GDM is important; however, there is controversy about whether screening should be universal or selective.
- The ADA (2008) and the Society for Maternal Fetal Medicine recommend screening for GDM using risk factor analysis at the first prenatal visit and later at 24 to 28 weeks by use of an oral glucose tolerance test (OGTT).
- According to the ADA, women with GDM are at extremely high-risk for developing type 2 diabetes and should be screened for diabetes six to twelve weeks postpartum and every one to two years to check for the development of diabetes or pre-diabetes.
- Clinical studies show a correlation between GDM and the lifelong risk of type 2 diabetes related to progressive beta cell failure due to overcompensation by the body for ongoing insulin resistance.

What is gestational diabetes mellitus (GDM)?
Gestational diabetes mellitus (GDM) is defined as glucose intolerance that begins during pregnancy or is first recognized during pregnancy. The diagnosis is independent of whether management is limited to diet or requires insulin. It includes previously unrecognized glucose intolerance that predated pregnancy. Nationally, 7 percent of pregnancies are complicated by GDM. Current data suggests that the prevalence of GDM has increased over time, and parallels the increased prevalence of obesity nationwide. Approximately 700 cases of GDM occur each year in South Dakota.

GDM affects maternal-child health and is associated with a potential for preeclampsia, cesarean delivery, and type 2 diabetes in the mother, and with higher rates of perinatal mortality, macrosomia, birth trauma, hyperbilirubinemia, and neonatal hypoglycemia in the infant.

Who should be screened?
The American College of Obstetricians and Gynecologists (ACOG) continues to recommend universal screening. Both the ADA and the Society for Maternal Fetal Medicine recommend using risk factor analysis at the first prenatal visit and later at 24 to 28 weeks if indicated by use of an oral glucose tolerance test (OGTT).

The U.S. Preventive Services Task Force (2006) concluded there was insufficient evidence to recommend universal screening for GDM, but more than 90 percent of obstetric physicians report screening all patients. The SD Diabetes Prevention and Control Program and the SD Diabetes Advisory Council currently recommend universal screening. The American Diabetes Association (2008) recommends screening for GDM using risk factor analysis and, if appropriate, use of an OGTT.
Patients at high-risk for GDM should undergo glucose testing as soon after confirmation of pregnancy as feasible, and then be retested at 24 to 28 weeks if the initial test is normal. Women at average risk should be screened at 24 to 28 weeks of gestation. The ADA continues not to recommend testing for low-risk women. Refer to Table 4 below for 2008 screening and diagnosis criteria.

While there is no definitive answer to the question of whether universal or selective screening is optimal, many medical centers choose to employ universal screening due to the difficulty involved in adhering to a selective screening protocol in a busy practice. Universal screening is the more sensitive strategy, identifying nearly all women with GDM. Because of the high incidence of overt diabetes later in life, and the opportunity to provide counseling regarding lifestyle at an early stage, missing the diagnosis of GDM may have long-term adverse effects.

### Table 4: Screening for and Diagnosis of GDM (ADA, 2008 Standards of Medical Care)

<table>
<thead>
<tr>
<th>Risk Determination</th>
<th>Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very High Risk for GDM</strong></td>
<td>❖ Severe obesity&lt;br&gt;❖ Prior history of GDM or delivery of large-for-gestational age infant&lt;br&gt;❖ Presence of glycosuria&lt;br&gt;❖ Diagnosis of PCOS&lt;br&gt;❖ Strong family history of type 2 diabetes</td>
</tr>
<tr>
<td><strong>Screening:</strong></td>
<td></td>
</tr>
<tr>
<td>Screening should be conducted using standard diagnostic testing (<em>fasting plasma glucose, symptoms of hyperglycemia, a casual plasma glucose ≥ 200 mg/dl, or a 2-hour plasma glucose ≥ 200 mg/dl during an OGTT</em>) as soon as possible after confirmation of pregnancy at first prenatal visit</td>
<td></td>
</tr>
<tr>
<td><strong>Higher Than Low Risk:</strong></td>
<td>❖ &gt; 25 years old&lt;br&gt;❖ Abnormal weight before pregnancy&lt;br&gt;❖ High risk ethnic/racial heritage (Hispanic American, Native American, Asian American, African American, or Pacific Islander)&lt;br&gt;❖ Family history of either type 1 or type 2 diabetes in first-degree relatives&lt;br&gt;❖ History of abnormal glucose tolerance&lt;br&gt;❖ History of poor obstetric outcome&lt;br&gt;❖ History of fetal macrosomia (infant weight &gt; 4000 grams)</td>
</tr>
<tr>
<td><strong>Screening:</strong></td>
<td></td>
</tr>
<tr>
<td>Should undergo GDM testing at 24 to 28 weeks of gestation</td>
<td></td>
</tr>
<tr>
<td><strong>Low Risk Status:</strong></td>
<td>❖ Age &lt; 25 years old&lt;br&gt;❖ Weight normal before pregnancy (body mass index of 25 or less)&lt;br&gt;❖ Member of an ethnic group with a low prevalence of GDM&lt;br&gt;❖ No known diabetes in first-degree relatives&lt;br&gt;❖ No history of abnormal glucose tolerance&lt;br&gt;❖ No history of poor obstetric outcome</td>
</tr>
<tr>
<td><strong>Screening:</strong></td>
<td></td>
</tr>
<tr>
<td>Does not require GDM screening</td>
<td></td>
</tr>
</tbody>
</table>
What screening test result should be used as a threshold for subsequent diagnostic testing?
In the US, the current standard screening test is a 50-gram oral glucose load (either fasting or non-fasting) followed by a plasma glucose level one hour after the load. For those women who exceed the chosen threshold on a 50-gram screening, a diagnostic 100-gram OGTT may be performed on a separate day, if indicated.

In the recent past, the ADA recommended specifically that a screening result of 140 mg/dl warranted confirmation. In 2000 the ADA no longer recommended a specific threshold level, rather it suggested that a prudent threshold lies somewhere between 130 mg/dl and 140 mg/dl. A threshold of 140 mg/dl will miss 20 percent of women with GDM, whereas a threshold of 130 mg/dl will miss 10 percent of women with GDM. However, the more sensitive but less specific threshold of 130 mg/dl will result in more false positive results. For example, 25 percent of all patients will screen positive when a threshold of 130 is used and will require a three-hour oral glucose tolerance test.

The ADA suggests that administering a fasting 100-gram three-hour oral glucose tolerance test (OGTT) as an initial test may be appropriate in high-risk individuals or in high-risk populations. New data obtained from ACOG Fellows indicate that they are becoming more comfortable managing GDM and are following the universal screening with a 50-gram glucose one-hour test, medical nutrition therapy, exercise, and SBGM in patients identified with gestational diabetes. More than half of those surveyed indicated they evaluated their patients with the 75-gram, two-hour oral glucose tolerance test.

How is the diagnosis of GDM confirmed?
Confirmation of the diagnosis of GDM requires that two or more of the four plasma glucose values obtained during a fasting 100-gram three-hour oral glucose tolerance test (OGTT) be elevated. In 2000 the ADA adopted the Carpenter-Coustan definitions for the upper limits of normal for OGTT values (see table below).

<table>
<thead>
<tr>
<th>Upper limits of normal for OGTT</th>
<th>Carpenter-Coustan (UVM/DHMC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma glucose</td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>95 mg/dl</td>
</tr>
<tr>
<td>1-hour</td>
<td>180 mg/dl</td>
</tr>
<tr>
<td>2-hour</td>
<td>155 mg/dl</td>
</tr>
<tr>
<td>3-hour</td>
<td>140 mg/dl</td>
</tr>
</tbody>
</table>

What prenatal monitoring should be done in women with GDM?

Glycemia
Daily self-monitoring of blood glucose (SMBG) is superior to intermittent office monitoring of plasma glucose. For women treated with insulin, postprandial monitoring is superior to preprandial monitoring. Urine glucose monitoring is not useful.

Ketonemia
Urine ketone monitoring may be useful in detecting inadequate caloric or carbohydrate intake in women treated with calorie restriction.
Hypertensive disorders
Serial blood pressure measurement is recommended. Serial urine protein measurement is recommended if hypertension exists.

Fetal well-being
Increased monitoring of fetal well-being is indicated if fasting blood glucose levels are > 105 mg/dl or the pregnancy is post-term. The specific monitoring technique employed, the time of initiation of the monitoring, and the frequency of the monitoring are dependent on the uniqueness of each patient and the cumulative fetal risk from GDM and other medical/obstetric conditions.

Asymmetric fetal growth
Ultrasound measurement of fetal abdominal girth may be helpful in detecting women whose infants are at increased risk for macrosomia. Detection of asymmetrical growth, particularly during the third trimester, may identify fetuses that would benefit from maternal insulin therapy. Macrosomic fetuses are a risk factor for shoulder dystocia and cesarean section.

What treatment is prescribed for GDM?

Diet and exercise
All women with GDM should receive individualized medical nutrition therapy by a registered dietitian consistent with current ADA recommendations. Obese women (BMI > 30) whose caloric intake is reduced 30-33 percent (~ 25 kcal/kg actual weight per day) experience reduced hyperglycemia and lower triglyceride levels. Active lifestyles should be encouraged. Moderate exercise has been shown to lower maternal glycemia.

A previous 1998 study by Major et al. showed that restriction of carbohydrates to 35-40 percent of total calories decreased maternal glucose levels and improved maternal and fetal outcomes. It is important to note that caloric restriction can lead to ketonemia and ketonuria, which can affect the fetus. Therefore, it must be done with great caution.

Pharmacologic therapy
Insulin is the pharmacologic therapy that has most consistently been shown to reduce fetal morbidity when used in conjunction with medical nutrition therapy. The ADA recommends initiating pharmacologic therapy when medical nutrition therapy fails to keep fasting whole blood glucose levels < 95 mg/dl, one-hour postprandial whole blood glucose levels < 140 mg/dl, or two-hour postprandial whole blood glucose level < 120 mg/dl. The goal of therapy is to maintain maternal glycemia below the above cut-off levels. Medication doses should be determined by whole blood/plasma assay finger stick measurements. Postprandial whole blood finger stick measurements are superior to preprandial measurements.

Currently, oral glucose-lowering agents are not generally recommended for use during pregnancy. Glyburide is not FDA approved for the treatment of gestational diabetes. The ADA feels that further studies are needed to establish its safety. Recent evidence gathered from clinical trials has shown the efficacy and safety of oral agents during pregnancy and suggests the use of oral agents during pregnancy warrants further study. One author concluded that poorly controlled glycemia was responsible for development of fetal anomalies, not the oral agents used to control hyperglycemia.
Is postpartum screening recommended?
The ADA recommends that all women with GDM should be screened for glucose intolerance six to twelve weeks after delivery. Those women with a greater degree of glucose impairment during pregnancy have the greatest risk for persistence of glucose intolerance postpartum. All women with a history of gestational diabetes should be educated regarding lifestyle modifications and the risk of developing insulin resistance.

If postpartum glucose levels are normal, subsequent serial evaluation of glycemia should occur at a minimum of three-year intervals.

If the results at six weeks postpartum show impaired fasting glucose or impaired glucose tolerance, patients should be retested annually. All women with GDM should receive intensive medical nutrition therapy and prescribed individual exercise programs because of their very high risk of developing diabetes. Referral to practitioners with expertise in the education and care of adult diabetes is appropriate for women with postpartum impaired glucose levels.

Patients with abnormal postpartum glucose levels should be referred to practitioners with expertise in the management of diabetes.

What postpartum education is recommended?

Diet and exercise
Women should be encouraged to maintain a normal body weight with a regimen of medical nutrition therapy and exercise in an effort to reduce insulin resistance.

Medications
Medications that increase insulin resistance (e.g. glucocorticoids and nicotinic acid) should be avoided if possible. The use of low dose estrogen-progesterone oral contraceptives is not contraindicated in women previously diagnosed with GDM.

Symptoms of hyperglycemia
Women should be educated about the symptoms of hyperglycemia and encouraged to seek medical attention with the advent of symptoms.

Family planning and future pregnancies
Family planning should be encouraged to assure optimal glycemia monitoring and regulation in subsequent pregnancies.

Implications for offspring
Women should be advised of the need for their offspring to be monitored for the development of obesity and glucose intolerance.
References:
Obesity Treatment and Management of Type 2 Diabetes in Adults

- In persons with type 2 diabetes, obesity is associated with poor control of blood glucose, blood pressure, and cholesterol, and elevates risks of cardiovascular and microvascular disease.
- Intentional weight loss is associated with a decrease in mortality in overweight persons with type 2 diabetes.
- Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes.
- Weight loss and weight maintenance therapy should employ the combination of reduced-calorie diets, increased physical activity, and behavior therapy.
- During the past two decades, the prevalence of obesity in adults has risen sharply. South Dakota statistics parallel those of the nation.
- Healthy People 2010 goals for South Dakotans are to reduce overweight and obesity within state residents by promoting physical activity and healthy eating. Currently 64.2 percent of adults are overweight and 25.4 percent are classified as obese.

What is the definition of obesity?
Obesity is defined as a Body Mass Index (BMI) of > 30 kg/m² with overweight being a BMI of 25 to 29.9 kg/m². Elevated BMI is only one factor related to risk in overweight or obese individuals. The National Heart, Lung, and Blood Institute recommends the addition of the following guidelines:
- The individual’s waist circumference (because abdominal fat is a predictor of risk for obesity-related diseases).
- Other risk factors the individual has for diseases and conditions associated with obesity (e.g. hypertension or physical inactivity).

What is the relationship between obesity and type 2 diabetes?
As many as 90 percent of individuals with type 2 diabetes are overweight or obese. Not only is there a strong association between the presence of obesity and the development of type 2 diabetes, but obesity also complicates its management. The presence of obesity exacerbates the metabolic abnormalities of type 2 diabetes, including hyperglycemia, hyperinsulinemia, and dyslipidemia. Obesity also increases insulin resistance and glucose intolerance and ultimately may contribute to excessive morbidity and mortality, mostly as a result of cardiovascular comorbidities such as hypertension, dyslipidemia, and type 2 diabetes. Additionally, obesity can contribute to musculoskeletal disorders, cancer, psychological and psychosocial disturbances, and quality of life impairments. There is strong evidence that weight loss produced by lifestyle modification can reduce blood glucose and A1C levels in patients with type 2 diabetes.
What are the obesity treatment goals for people with type 2 diabetes?
Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Goals include:
- Reduce body weight by 10 percent from baseline through lifestyle modification (generally one to two pounds per week for a period of six months).
- Maintain a lower body weight over the long term.
- Prevent further weight gain.

What is lifestyle modification?
The components of an effective lifestyle modification program include dietary modification, physical activity, and behavior modification.

Can weight loss be maintained?
After successful weight loss, a program consisting of dietary therapy, physical activity, and behavior therapy, which should be continued indefinitely, enhances the likelihood of weight loss maintenance. A weight maintenance program should be a priority after the initial six months of weight loss therapy. Research suggests that increased contact between a patient and a practitioner is predictive of long-term weight loss maintenance.

Table 6: Weight Loss and Weight Maintenance Therapy

<table>
<thead>
<tr>
<th>Treatment Component</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Therapy</td>
<td>Low-calorie diets are recommended. Reducing dietary fat alone without reducing calories is not sufficient for weight loss. A diet that is individually planned to help create a deficit of 500 to 1000 kcal/day should be an integral part of any program aimed to achieve a weight loss of one to two pounds/week.</td>
</tr>
<tr>
<td>Physical Activity</td>
<td>Physical activity should be an integral part of weight loss therapy and weight maintenance. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days a week, should be encouraged with a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on 5 or more days a week.</td>
</tr>
<tr>
<td>Behavior Therapy</td>
<td>Practitioners need to assess the patient’s motivation to enter weight loss therapy, assess the readiness of the patient to implement the plan, and then take appropriate steps to motivate the patient for treatment. Behavior therapy strategies to promote diet and physical activity should be used routinely as they are helpful in achieving weight loss and weight maintenance.</td>
</tr>
</tbody>
</table>

References:
**Obesity in Children and Adolescents**

- The prevalence of overweight among children and adolescents has dramatically increased and is a significant public health concern.
- Overweight in children and adolescents can be linked to a variety of adverse health outcomes, including type 2 diabetes mellitus, obstructive sleep apnea, hypertension, dyslipidemia, and metabolic syndrome.
- A BMI percentile > 5th and < 85th is considered normal weight for height; the 85th to the 95th percentile is considered overweight and ≥ 95th percentile is defined as obesity.
- Data from the SD BRFSS study showed that 16.4 percent of 5 to 19 year olds are overweight and an additional 16.6 percent are at risk of being overweight (2004-2005 SD Height and Weight Report).

According to the CDC, since the mid 1970s, the prevalence of overweight and obesity has dramatically increased in both adults and children. Data from two NHANES surveys show increases in overweight among children and teens. For children aged 2 to 5 years, the prevalence of overweight increased from 5.0 percent to 13.9 percent; for those aged 6 to 11 years, prevalence increased from 6.5 percent to 18.8 percent; and for those ages 12 to 19 years, prevalence increased from 5.0 percent to 17.4 percent. These increasing rates of obesity and overweight have significant implications to the health care community due to the increase in long-term chronic health problems for all generations of people. Being overweight/obese increases the risk for hypertension, dyslipidemia, type 2 diabetes, coronary artery disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and increased risk for some types of cancers (endometrial, breast, and colon). Statistics from South Dakota mirror national trends with 13.9 percent of 2 to 5 years old listed as overweight (BMI-for-age 95th percentile and above) and an additional 18.1 percent are at risk of becoming overweight (BMI-for-age 85-94th percentile BMI-for-age).

**What contributes to overweight and obesity?**

There are a variety of factors that play a role in overweight/obesity.

- Overweight and obesity result from an energy imbalance that involves eating too many calories and not getting enough physical activity. This is directly related to large portion sizes of food and beverages, eating fast food, frequent snacking on high calorie, high fat foods, and consuming sugary beverages (soda, sweetened juices, sports drinks, etc.).
- Body weight is directly related to genetic tendencies, metabolism, behavior, environment, culture, and socioeconomic status.
- Behavior and environment play a large role in causing people to be overweight and obese, and are target areas for prevention and treatment activities.
- Lack of physical activity is another contributing factor to overweight/obese children and adolescents. Less than one-third of high school students (28 percent) currently meet recommended levels of physical activity. Children aged 8 to 18 years of age are more sedentary and spend over 3 hours per day watching television, playing video games, and other media devices.
- Home, childcare, school, and community environments can influence children’s behaviors related to food intake and physical activity. Over 80 percent of children over the age of 5 have working mothers and spend an average of 40 hours per week in childcare facilities. Community environments influence physical activity opportunities for children. Lack of sidewalks, safe bike paths, neighborhood parks, and access to
affordable, healthy food choices can be barriers to physical activity and purchasing healthy foods.

How is BMI used for screening for overweight and obesity in children?
Body Mass Index (BMI) is a practical measure to determine overweight, and is determined by measuring weight in relation to height to determine weight status. BMI is the most widely accepted method used to screen for overweight and obesity in children and adolescents, as it is relatively easy to obtain height and weight measurements. For children and adolescents (aged 2 to 19 years), the result is plotted on the CDC growth charts to determine the corresponding BMI-for-age percentile. Obesity is defined as a BMI at or above the 95th percentile for children of the same age and sex and is based on the 2000 CDC Growth Charts for the United States. A child’s weight status is determined based on an age and sex-specific percentile for BMI rather than by the BMI categories used for adults. Classifications of excess for children and adolescents are age and sex-specific because children’s body composition varies as they age and varies between boys and girls.

Figure 1: Universal Assessment of Obesity Risk and Steps to Prevention and Treatment

What efforts are currently in place to prevent obesity in South Dakota?
The South Dakota Department of Health has developed a statewide plan for Nutrition and Physical Activity to Prevent Obesity and Other Chronic Disease (January 2006). This plan targets healthy eating and increased physical activity in both adults and children to achieve a healthy Body Mass Index (BMI). Clinical toolkits to increase awareness of the overweight/obesity problem within the state are available to all healthcare providers through the
South Dakota Department of Health. Because South Dakotans depend upon their personal physicians and health care providers for health-related counseling, it is hoped that the clinical toolkits will serve as a valuable resource in fighting the epidemic of obesity within the state.

The American Medical Association, in collaboration with the Department of Health and Human Services, Health Resources and Services Administration, and the Centers for Disease Control and Prevention, convened an expert committee to develop recommendations on the assessment, prevention, and treatment of child and youth overweight and obesity. This expert panel representing fifteen professional organizations recently recommended changing the terms used to describe pediatric obesity.

If a child’s BMI-for-age is between the 85th and 94th percentile in the CDC reference population for children matched for age and gender, the term to describe the child is “overweight.” The previous term used was “at risk for overweight.” If a child is at or above the 95th percentile for children of that age and gender, the child is considered to be “obese” rather than the previous term “overweight.” The new terms overweight and obese provide continuity to adult definitions of overweight and obese and avoid confusion with the term “at risk of overweight.” Although the recommended cutoff points have not changed, these definition changes will not affect the prevalence rates of the BMI categories (Barlow et al, 2007).

What comorbidities are related to overweight and obesity in youth?
Overweight and obesity in children is associated with a number of comorbidities that may present during childhood and adolescence. Limited data is available regarding the detrimental effect of overweight, but it is suspected to be similar to that of adults. See Table 7 for adverse outcomes related to childhood obesity.

Table 7: Adverse Outcomes in Childhood Obesity

<table>
<thead>
<tr>
<th>Adverse Outcomes in Childhood Obesity</th>
<th>Psychological</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolic</td>
<td>Depression</td>
</tr>
<tr>
<td>❖ Type 2 diabetes mellitus</td>
<td>Poor quality of life</td>
</tr>
<tr>
<td>❖ Metabolic syndrome</td>
<td></td>
</tr>
<tr>
<td>Neurological</td>
<td>Hepatic</td>
</tr>
<tr>
<td>❖ Pseudomotor cerebri</td>
<td>Nonalcoholic fatty liver disease</td>
</tr>
<tr>
<td></td>
<td>Nonalcoholic steatohepatitis</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>Pulmonary</td>
</tr>
<tr>
<td>❖ Slipped capital femoral epiphysis</td>
<td>Obstructive sleep apnea</td>
</tr>
<tr>
<td>❖ Blount’s disease</td>
<td>Asthma (exacerbation)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Renal</td>
</tr>
<tr>
<td>❖ Dyslipidemia</td>
<td>Proteinuria</td>
</tr>
<tr>
<td>❖ Hypertension</td>
<td></td>
</tr>
<tr>
<td>❖ Left ventricular hypertrophy</td>
<td></td>
</tr>
<tr>
<td>❖ Atherosclerosis</td>
<td></td>
</tr>
</tbody>
</table>

What are the screening recommendations?
Children < 85th percentile with no other health risk factors should be screened (weight, height, and BMI percentile calculated and plotted) at every well child visit or at least annually. Identification of risk for overweight before adolescence is encouraged so that health habits can be improved at a stage of increased parental influence and control. See Table 8. Treatment of overweight should rarely be instituted before two years of age because of the rapid growth and
development that occurs during these early years and lower correlation with overweight in later years. Primary care providers should assess diet and activity habits at annual well child visits as part of the overall plan of care.

Family involvement is critical in the treatment of childhood overweight. If treatment is initiated when a family is not ready to support the program, then success is unlikely. The treatment planned should also take into consideration long-term management with the continued assessment of the child for adequate growth and development because overweight is a long-term problem. See Table 8.

**What are the guiding principles used in the treatment and management of overweight/obesity?**
The following five guiding principles provide an important framework for healthcare providers in the treatment of overweight/obese children and adolescents. Treatment should focus on a comprehensive multidisciplinary approach, targeting eating, activity, and behavior modification in a structured outpatient setting.

1. Establish individual treatment goals and approaches based on the child’s age, degree of overweight, and presence of co-morbidities.
2. Involve the family or major caregivers in the treatment.
5. Provide recommendations for dietary changes and increases in physical activity that can be implemented within the family environment and that foster optimal health, growth, and development. (American Heart Association, 2005)

**What is the 5-2-1-0 Healthy Behavior Method?**
The 5-2-1-0 Healthy Behavior Method is a prevention tactic that families can employ to get children to incorporate healthy lifestyle changes into their daily activities and manage overweight/obesity:

**Five:** Eat at least five servings of fruits and vegetables daily  
**Two:** Spend two hours or less of television/media activities daily  
**One:** Get at least one hour of physical activity every day  
**Zero:** Consume zero sugar-sweetened beverages daily, limit eating out

**What are some of the reasons for treatment failure?**
Physicians need to tailor their interventions to meet family needs, habits, culture, and risk factors. Physicians and office staff can learn the techniques and tools for utilizing motivational interviewing focusing on asking, listening, advising, and informing. Often patients are poorly motivated to make lifestyle or behavioral changes and feel a sense of futility and lack of empowerment in treatment of overweight/obesity. When treating overweight children and adolescents, parents need to be included in the plan of care and become motivated to achieve positive outcomes.
Table 8: Medical Screening According to BMI Category  
(Adapted from Barlow et al, 2007)

<table>
<thead>
<tr>
<th>BMI Percentile</th>
<th>Recent History</th>
<th>Medication Use</th>
<th>Review of Symptoms</th>
<th>Family History (1st &amp; 2nd degree relatives)</th>
<th>Physical Examination</th>
<th>Laboratory Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>5th-84th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (e.g. neuro-psychiatric)</td>
<td>Snoring/sleep, abdominal pain, menstrual irregularities, hip, knee, or leg pain, polyuria, thirst, depression</td>
<td>Obesity, type 2 DM, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff)</td>
<td></td>
</tr>
<tr>
<td>85th-94th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (e.g. neuro-psychiatric)</td>
<td>Snoring/sleep, abdominal pain, menstrual irregularities, hip, knee, or leg pain, polyuria, thirst, depression</td>
<td>Obesity, type 2 DM, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), Acanthosis Nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne, and hirsutism</td>
<td>Fasting lipid profile; if age 10 years and other risk factors, fasting glucose level biannually; ALT and AST levels biannually</td>
</tr>
<tr>
<td>95th-99th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (e.g. neuro-psychiatric)</td>
<td>Snoring/sleep, abdominal pain, menstrual irregularities, hip, knee, or leg pain, polyuria, thirst, depression</td>
<td>Obesity, type 2 DM, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), Acanthosis Nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne, and hirsutism</td>
<td>Fasting lipid profile; if age 10 years and other risk factors, fasting glucose level biannually; ALT and AST levels biannually</td>
</tr>
<tr>
<td>&gt; 99th</td>
<td>BMI change</td>
<td>Medications that may affect weight gain (e.g. neuro-psychiatric)</td>
<td>Snoring/sleep, abdominal pain, menstrual irregularities, hip, knee, or leg pain, polyuria, thirst, depression</td>
<td>Obesity, type 2 DM, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), Acanthosis Nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne, hirsutism, skin inflammation</td>
<td>Fasting lipid profile; if age 10 years and other risk factors, fasting glucose level biannually; ALT and AST levels biannually</td>
</tr>
</tbody>
</table>

References:
Pharmacologic Therapies for Glucose Management

- Medication therapy can involve oral agents, insulin, or a combination of the two therapies, and is an integral component of blood sugar control in conjunction with diet and exercise.
- Medication therapy is a therapeutic tool for use in lowering and maintaining blood glucose levels.

**Why is medication therapy used?**
Results from the United Kingdom Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complication Trial (DCCT) conclusively revealed that lowering blood glucose reduces the risk of developing complications. Medication therapy is a potential therapeutic tool for use in accomplishing blood glucose goals when used in conjunction with diet and exercise.

**Using medication/insulin therapy in practice.**
- Weight gain can occur with insulin therapy in addition to some oral agents. (Insulin Detemir is an exception.)
- The use of insulin secretagogues and insulin can pose the risk of hypoglycemia.
  1. This risk must be taken to achieve improved glycemic control; however, in some patients, such as the elderly, the risks may outweigh the benefits.
  2. Self-monitoring of blood sugars allows for better adjustment of therapy as well as better recognition and treatment of hypoglycemia.
  3. Ongoing communication between the patient and the diabetes care team is critical to reach glycemic goals.
  4. Diabetes education informs the patient about the interplay between medications, carbohydrate intake, exercise, stress, and illness. This allows for better glycemic control.
- Insulins glargine (Lantus) and detemir (Levemir) are basal insulins with 24-hour duration. In a randomized double blind study conducted by Heise et al (2004), comparing the glucose lowering effects of insulin detemir, glargine, and NPH in people with type 1 diabetes, results suggest that insulin detemir has a significantly more predictable glucose lowering effect than both NPH insulin and insulin glargine.
- Lente and Ultra Lente insulins have been taken off the market. Refer to the Eli Lilly website for additional information. [http://www.lilly.com/products/index.html](http://www.lilly.com/products/index.html)
- Insulin action (absorption and duration) may be variable for different people.
- The mixing of appropriate insulins and/or multiple daily injections can improve blood glucose levels. (Refer to section on intensive insulin therapy on page 51.)
- As a general rule, the mixed insulins should be of the same brand.
- Regular or analog (Lispro, aspart, and glulisine) insulins should be drawn up before the longer acting insulins to prevent contamination of the faster acting insulin, leading to dose variance. Detemir and glargine should not be diluted or mixed with any other insulin preparations or solutions.
- Refer to the chapter on gestational diabetes for indications during pregnancy.
- Care should be taken to not confuse clear insulins such as glargine and detemir with rapid acting insulins. Please refer to the table on page 48 for additional information on insulin.
- Refer to Figure 2 on the following page for the current algorithm for metabolic management of type 2 diabetes (Nathan et al, 2006).
Figure 2: Algorithm for the Metabolic Management of Type 2 Diabetes
## Overview of Current Pharmacologic Therapies for Glucose Management

<table>
<thead>
<tr>
<th>Medication</th>
<th>Action</th>
<th>Prescribing Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BIGUANIDES</strong></td>
<td><strong>Metformin</strong> <em>(Glucophage &amp; Glucophage XR, Riomet, and Glumetza)</em></td>
<td><strong>Metformin combined with lifestyle intervention should be initiated in newly diagnosed type 2 diabetes. Refer to <a href="http://dave.md/s/indexp.cfm?aid=998">http://dave.md/s/indexp.cfm?aid=998</a></strong></td>
</tr>
<tr>
<td></td>
<td>Increases peripheral glucose uptake and utilization.</td>
<td>Start at low dose, titrate up</td>
</tr>
<tr>
<td></td>
<td><em>Decreases gluconeogenesis, enhances insulin sensitivity by</em></td>
<td>GI symptoms: diarrhea, nausea, vomiting, abdominal bloating, flatulence, and anorexia</td>
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<tr>
<td></td>
<td><em>increasing peripheral glucose uptake and utilization.</em></td>
<td>most common side effects; these symptoms are generally transient and resolve spontaneously</td>
</tr>
<tr>
<td></td>
<td></td>
<td>during continued treatment; taking with food and/or temporarily reducing the dose may be</td>
</tr>
<tr>
<td></td>
<td></td>
<td>helpful</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May have positive effects on triglycerides, total cholesterol, and LDL</td>
</tr>
<tr>
<td></td>
<td>Refer to packaging label for additional prescribing considerations.</td>
<td>Contraindicated in:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>■ men with serum creatinine 1.5 or greater, and in females with 1.4 or greater</td>
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<tr>
<td></td>
<td></td>
<td>■ hepatic dysfunction and should not be used in patients with excessive alcohol use</td>
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<tr>
<td></td>
<td></td>
<td>■ acute or chronic lactic acidosis</td>
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<tr>
<td></td>
<td></td>
<td>■ may be contraindicated in patients with CHF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>■ use &gt; 80 years of age unless creatinine clearance is normal</td>
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<td></td>
<td></td>
<td>Generally not indicated during pregnancy, breastfeeding, or in children under 10 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of age; Glucophage XR indicated for use ≥ 17 years of age or older</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Should be temporarily withheld in situations of cardiovascular collapse, acute MI, acute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>exacerbation of CHF, use of iodinated contrast media, and a major surgical procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requires 2-11 weeks of use before determining effectiveness</td>
</tr>
</tbody>
</table>
THIAZOLIDINEDIONES (GLITAZONES)

**Medication Action Prescribing Considerations for THIAZOLIDINEDIONES (GLITAZONES)**

The FDA’s review of rosiglitazone’s possible increased risk of cardiovascular events is ongoing. Until further data is available, this drug now carries a “Black Box” warning from the FDA advising patients and physicians to be aware of signs of heart failure. Risk versus benefits regarding use of this drug should be evaluated on a case-by-case basis, with mutual decision-making between the physician and patient (Nissen, 2007). Black Box warning further indicates that thiazolidinediones are “not recommended in patients with symptomatic heart failure” (Avandia and Actos Product Information).

**Rosiglitazone has additional information in the “Black Box” warning regarding cardiac ischemia. A review of 42 studies (primarily comparing Rosiglitazone to placebo) found an increase in the occurrence of myocardial ischemic events. However, three studies comparing Rosiglitazone to other oral agents to treat diabetes have not yielded definitive results (Avandia Product Information).**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Action</th>
<th>Prescribing Considerations</th>
</tr>
</thead>
</table>
| Rosiglitazone (Avandia) | Improves insulin sensitivity within peripheral muscle and adipose sites; Inhibits hepatic gluconeogenesis. | • Requires 2-16 weeks of use before determining effectiveness  
• Liver enzymes should be checked prior to initiation of therapy with Rosiglitazone and periodically thereafter per clinical judgment of the healthcare provider  
• Rosiglitazone may increase HDL and LDL  
• Pioglitazone decreases triglycerides and increases HDL  
• May cause weight gain and fluid retention  
• Use with caution in patients with hepatic disease or with advanced heart disease  
• Generally not indicated during pregnancy, breastfeeding, or in children  
• Decreases oral contraception effectiveness and may cause resumption of ovulation in anovulatory women |
| Pioglitazone (Actos) | | |

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Action</th>
<th>Prescribing Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALPHA-GLUCOSIDASE INHIBITORS</strong></td>
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</tbody>
</table>
| Acarbose (Precose) | Delays digestion of carbohydrates, lowers rise in post-meal blood glucose. | • To be taken with first bite of food  
• GI symptoms are the most common reaction; the incidence of diarrhea and abdominal pain tend to diminish with continued treatment  
• Reduces bioavailability of Digoxin, Propanolol, Ranitidine, digestive enzymes  
• Avoid use in patients with GI disorders  
• Avoid use of Acarbose in patients with cirrhosis  
• Neither agent recommended in patients with creatinine clearance < 25 mL/min  
• Generally not indicated during pregnancy, breastfeeding, or in children  
• Must use dextrose (not sucrose) to correct hypoglycemia when taking Acarbose  
• Refer to packaging label for additional prescribing considerations |
<p>| Miglitol (Glyset) |                                                                 |                                                                                                                                                         |
| <strong>OTHERS</strong>                                                                                                             |                                                                                                                                                    |
| Glucovance       | Combination of Glyburide and Metformin                                | • See Glyburide and Metformin                                                                                                                           |
| Metaglip         | Combination of Glipizide and Metformin                                | • See Glyburide and Metformin                                                                                                                           |
| Avandamet        | Combination of Rosiglitazone and Metformin                            | • See Rosiglitazone and Metformin                                                                                                                       |
| Actos + Met      | Combination of Pioglitazone and Metformin                             | • See Pioglitazone and Metformin                                                                                                                        |
| Janumet          | Combination of Januvia and Metformin                                  | • See Januvia and Metformin                                                                                                                             |
| Avandaryl        | Avandia plus Glimepiride                                             | • See Avandia and Glimepiride                                                                                                                             |</p>
<table>
<thead>
<tr>
<th>Medication</th>
<th>Action</th>
<th>Length of Action</th>
<th>Prescribing Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SULFONYLUREAS</strong></td>
<td></td>
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</tr>
<tr>
<td>Chlorpropamide</td>
<td>Stimulates insulin release from the pancreas.</td>
<td>72 hours</td>
<td>• Hypoglycemia, gastrointestinal complaints and weight gain are most common side effects</td>
</tr>
<tr>
<td>(Diabinese)</td>
<td></td>
<td></td>
<td>• Contraindicated in patients with diabetic ketoacidosis, severe infection, surgery, or trauma</td>
</tr>
<tr>
<td>Tolazamide (Tolnase)</td>
<td></td>
<td>10-14 hours</td>
<td>• Avoid use in patients with significant alcohol consumption</td>
</tr>
<tr>
<td>Tolbutamide (Orinase)</td>
<td></td>
<td>6-12 hours</td>
<td>• Generally not indicated during pregnancy, breastfeeding, or in children</td>
</tr>
<tr>
<td>Glyburide (Diabeta)</td>
<td></td>
<td>12-24 hours</td>
<td>• Refer to packaging label for additional prescribing considerations</td>
</tr>
<tr>
<td>(Micronase) (Glynase)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Glipizide (Glucotrol)</td>
<td></td>
<td>12-16 hours</td>
<td></td>
</tr>
<tr>
<td>(Glucotrol XL)</td>
<td></td>
<td>24 hours</td>
<td></td>
</tr>
<tr>
<td>Glimepiride (Amaryl)</td>
<td></td>
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</tr>
<tr>
<td><strong>MEGLITINIDES</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Repaglinide (Prandin)</td>
<td>Stimulates insulin release from the pancreas.</td>
<td>2-3 hours</td>
<td>• Administer 15 to 30 minutes before meals</td>
</tr>
<tr>
<td></td>
<td>Insulin release is glucose dependent and diminishes at low glucose concentrations.</td>
<td></td>
<td>• Only works in the presence of glucose</td>
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<tr>
<td></td>
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<td></td>
<td>• Approved for combination use with Metformin and Thiazolidinediones</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Use Repaglinide cautiously in patients with hepatic impairment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Repaglinide contraindicated in patients with diabetic ketoacidosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Severe infection, surgery, or trauma</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Generally not indicated during pregnancy, breastfeeding, or in children</td>
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<td></td>
<td></td>
<td></td>
<td>• Refer to packaging label for additional prescribing considerations</td>
</tr>
<tr>
<td>Nateglinide (Starlix)</td>
<td></td>
<td>4 hours</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Action</td>
<td>Prescribing Considerations</td>
<td></td>
</tr>
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<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>INCRETIN MIMETIC INJECTION-SYNTHETIC PEPTIDE</td>
<td><strong>Exenatide (Byetta)</strong>&lt;br&gt;Onset of action is unknown. Time of peak is 2.1 hours. Indicated as adjunctive therapy to improve glycemic control by reducing fasting and postprandial glucose concentrations in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control. It enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying.</td>
<td>• Common side effects include mild nausea, vomiting, diarrhea, jittery feeling, dizziness, headache, and dyspepsia&lt;br&gt;• Contraindicated in patients with long-standing gastroparesis and end-stage renal disease&lt;br&gt;• May reduce appetite and cause weight loss&lt;br&gt;• Acute pancreatitis has been noted in 30 case reports; patients at risk include those with gallstones, extremely high triglycerides, or increased alcohol consumption; watch for severe abdominal pain&lt;br&gt;• Given subcutaneously; packaged in injectable pre-filled pens&lt;br&gt;• Store new, unused Byetta Pens in the refrigerator. DO NOT FREEZE. After first use, keep pen at room temperature not to exceed 77 degrees F. for up to 30 days; throw pen away after 30 days even if not completely used&lt;br&gt;• Administer BID within 60 minutes before morning and evening meals&lt;br&gt;• Refer to packaging label for additional prescribing considerations</td>
<td></td>
</tr>
</tbody>
</table>
Sitagliptin phosphate (Januvia)

Available in 25, 50, and 100 mg tablets

Creatinine Clearance:

>50cc/min=100mg/day
<50cc/min but>30cc/min=50mg/day
<30cc/min=25mg/day

DPP-4 inhibitor
(slowrs inactivation of incretion hormones)

Indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin or a PPAR agonist (e.g. thiazolidinediones) when the single agent alone, with diet and exercise, does not provide adequate glycemic control. Not indicated for patients with type 1 DM or to treat diabetes ketoacidosis.

- Improves insulin secretion
- Decreases glucagon secretion
- Peak plasma concentrations 1-4 hrs
- Drug half-life is 12 hrs

Common side effects are: upper respiratory infection, nasopharyngitis, and headache
- Administer BID within 60 minutes before morning and evening meals
- Contraindicated in patients with long-standing gastroparesis and end-stage renal disease
- May reduce appetite and cause weight loss
- Acute pancreatitis has been noted in 30 case reports; patients at risk include those with gallstones, extremely high triglycerides, or high alcohol use; watch for severe abdominal pain

Precautions: Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD; assess renal function prior to initiation of drug

- When used with a sulfonylurea, a lower dose of sulfonylurea may be required to reduce risk of hypoglycemia
- Serious allergic and hypersensitivity reactions such as anaphylaxis, angioedema, and exfoliative skin conditions such as Stevens-Johnson Syndrome have been associated with Januvia; promptly stop the drug, assess, monitor, and initiate alternate treatment for diabetes
- Not indicated for use in children under 18 years of age, pregnancy, or with lactation
- Refer to packaging label for additional prescribing considerations
<table>
<thead>
<tr>
<th><strong>Medication</strong></th>
<th><strong>Action</strong></th>
<th><strong>Prescribing Considerations</strong></th>
</tr>
</thead>
</table>
| **SYNTHETIC HUMAN AMYLIN ANALOG**<br>**(Pramlintide) Symlin** | *Onset of action is unknown. Drug half-life is 48 minutes.*<br><br>*Mimics 3 important actions of Amylin that impact glucose appearance:*<br>1. *Inhibits inappropriately high postprandial glucagon secretion*<br>2. *Slows gastric emptying*<br>3. *Promotes satiety and reduces caloric intake, decreases appetite, promotes weight loss* | • Given as a sub-Q injection  
• Do not mix with insulin – separate injection sites by at least 2 inches  
• Use U-100 insulin syringe  
• Inject before each major meal  
• Can be used as an adjunct treatment in patients with type 1 or type 2 DM who use mealtime insulin therapy and have failed to achieve desired glucose control despite optimal insulin therapy, with or without concurrent sulfonylurea agent and/or metformin  
• Warning: Pramlintide acetate is used with insulin and has been associated with an increased risk of insulin-induced severe hypoglycemia, particularly in patients with type 1 diabetes.  
• Generally not indicated during pregnancy, breastfeeding, or in children  
• Refer to package insert for additional prescribing considerations |
How do the insulins compare with one another?

<table>
<thead>
<tr>
<th>Insulin Type</th>
<th>Onset of Action</th>
<th>Time of Peak</th>
<th>Duration of action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rapid Acting Analogs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspart (Novolog)</td>
<td>5 - 15 minutes</td>
<td>½ - 1½ hours</td>
<td>3 - 5 hours</td>
</tr>
<tr>
<td>Lispro (Humalog)</td>
<td>10 - 15 minutes</td>
<td>½ - 1½ hours</td>
<td>3 - 4 hours</td>
</tr>
<tr>
<td>Glulisine (Apidra)</td>
<td>15 - 30 minutes</td>
<td>½ - 1½ hours</td>
<td>3 - 4 hours</td>
</tr>
<tr>
<td><strong>Short Acting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Regular</td>
<td>30 - 60 minutes</td>
<td>2 - 4 hours</td>
<td>8 - 12 hours</td>
</tr>
<tr>
<td><strong>Intermediate Acting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human NPH</td>
<td>1 ½ hours</td>
<td>4 - 12 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td>Human Lente</td>
<td>2 - 5 hours</td>
<td>7 - 15 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Basal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glargine (Lantus)</td>
<td>1 ½ hours</td>
<td>peakless</td>
<td>24 hours*</td>
</tr>
<tr>
<td>Detemir (Levemir)</td>
<td>0.8 - 2.0 hours</td>
<td>relatively flat</td>
<td>up to 24 hours*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*DO NOT MIX with other insulin</td>
</tr>
<tr>
<td><strong>Lente and Ultra Lente</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lente and Ultra Lente insulins have been taken off the market. Refer to the Eli Lilly website for additional information. <a href="http://www.lilly.com/products/index.html">http://www.lilly.com/products/index.html</a></td>
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<tr>
<td><strong>Pre-Mixed</strong></td>
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</tr>
<tr>
<td>Humalog Mix 75/25 (NPH/Lispro)</td>
<td>10 minutes</td>
<td>½ - 4 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td>Human 70/30 (NPH/R)</td>
<td>10 minutes</td>
<td>2 - 12 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td>Human 50/50 (NPH/R)</td>
<td>30 minutes</td>
<td>1 - 6 hours</td>
<td>14 hours</td>
</tr>
<tr>
<td>Novolog 70/30</td>
<td>10 minutes</td>
<td>2 - 12 hours</td>
<td>24 hours</td>
</tr>
</tbody>
</table>
References:
Intensive Insulin Management

- Candidates for Intensive Insulin Management must be motivated to improve glucose control and be able to assume responsibility for their day-to-day care.
- Use of Intensive Insulin Management should be initiated, monitored, and supported by a Comprehensive Diabetes Team.
- Aggressive management of glycemic treatment goals with insulin may reduce morbidity in patients with severe acute illness, following myocardial infarction, and in pregnancy to improve patient outcomes.
- Intensive Insulin Management is essential during pregnancy.
- The challenge of treating type 1 diabetes is to mimic physiologic insulin action. New insulins and new insulin delivery devices allow better basal and bolus insulin replacement than ever before.

What is Intensive Insulin Management?
Intensive Insulin Management is the strategy of making multiple adjustments in insulin dosage each day in order to achieve better glucose control with less hypoglycemia, less hyperglycemia, and more lifestyle flexibility. This strategy is used primarily by people with type 1 diabetes and is often the only means of achieving an ideal level of glucose control without excessive and unsafe episodes of hypoglycemia.

The major emphasis is on making frequent adjustments in short-acting insulin dosages with regular insulin, lispro insulin (Humalog), glulisine, or insulin aspart (Novalog). The dosage is typically altered based on the pre-meal blood glucose level, carbohydrate content of the meal, and sometimes also the anticipated level of physical activity. It is the preferred method of insulin dosing for most patients with type 1 diabetes and can be tailored to fit almost any lifestyle. The two types of insulin delivery for intensive insulin therapy are continuous subcutaneous insulin infusion (CSII) or an insulin pump, and multiple daily injections (MDI).

How is this different from conventional insulin management?
Conventional insulin regimens usually consist of only two insulin injections per day using a mixture of short-acting and intermediate-acting insulins (such as regular and NPH). The dose is usually identical every day, and requires patients to be very consistent about meal times, meal content, timing, and level of any strenuous activity. The use of a sliding scale is also considered conventional insulin management, as it reacts only to the current blood glucose level. Conventional insulin management rarely allows achievement of A1C goals, and requires the patient's lifestyle to revolve around his or her insulin schedule.

Learning how to adopt an Intensive Insulin Management plan is complex and ideally involves the instruction and support of a comprehensive diabetes team. This team often includes the following:
- Registered dietician, skilled in the teaching of carbohydrate counting, to accurately estimate meal content.
- Diabetes nurse educator who can instruct patients in proper self-monitoring of blood glucose, insulin administration, and other techniques.
- Endocrinologist or other physician skilled in the use and adjustment of intensive insulin regimens utilizing various combinations of insulin types, timing, and delivery devices such as insulin pumps.
What are some examples of Intensive Insulin Management?
The following are some examples of some common intensive insulin regimens.

Continuous Subcutaneous Insulin Infusion (CSII)
Patients utilizing this insulin strategy use a continuous subcutaneous insulin infusion pump worn 24 hours per day (it can be disconnected for short periods of time such as bathing).
- Utilization of exclusively rapid-acting insulin such as lispro insulin or insulin aspart.

Multiple Daily Injections (MDI)
This regimen consists of multiple injections of insulin, three or four times per day, using a combination of short-acting and either long-acting or intermediate-acting insulin. Two typical therapeutic regimes are:
- Glargine insulin (Lantus) or detemir insulin (Levemir) at bedtime or in the morning as a fixed dose in combination with lispro insulin, insulin aspart, Glulisine (Apidra), or regular insulin before each meal (variable dose as described above).
- NPH insulin at bedtime and in the morning as a fixed dose in combination with lispro insulin, insulin aspart, or Apidra insulin before each meal (variable dose as described above).

What are the benefits of insulin pump (CSII) therapy versus multiple daily injections (MDI)?
There are several reasons people with diabetes may find an insulin pump provides better outcomes and more lifestyle flexibility than multiple daily injections. Frequently reported benefits include:
- Less variation in insulin absorption (about 3 percent versus 25 percent) due to exclusive use of rapid acting insulin, single injection site, and eliminating subcutaneous depot of insulin.
- Fewer insulin injections (the subcutaneous catheter is replaced every two or three days rather than three to four injections each day).
- Can be programmed to more closely mimic normal pancreatic insulin secretion patterns (to accommodate working variable shifts, physical activity, nocturnal hypoglycemia, the “dawn phenomenon,” unpredictable lifestyle, high fat meals, etc.).
- The pump assists with calculation of insulin doses based on carbohydrates ingested and on the blood sugar.
- It can deliver insulin boluses accurately in 1/10 unit increments (rather than one or two unit increments as with conventional injections). This is particularly important in very insulin sensitive patients including young children.

What are the drawbacks to intensive therapy?
Highly motivated patients are able to overcome many of these problems and achieve success. However, there are drawbacks/limitations to intensive therapy including, but not limited to the following:
- A high learning curve is associated with pump therapy and continuous glucose monitoring.
- Individuals must be committed to adapt to use of the pump, frequent blood glucose testing, additional injections of insulin, and time to complete required cares.
- Many physicians and other healthcare providers are unfamiliar with pump therapy and may not be able to provide the necessary educational support to the patient.
- Technical equipment failure may occur.
There is an increased risk of ketosis when only rapid-acting or short-acting insulin is used.

Skin irritation or infections may occur at the needle insertion sites. Frequent site changes are required.

Expenses associated with intensive therapy may not be covered by insurance, and will incur additional out-of-pocket expenses.

Hypoglycemia may occur as a result of aggressive therapy.

**What role does intensive therapy play in type 2 diabetes?**

Through the natural disease progression of type 2 diabetes, the resultant loss of beta-cell function eventually leads to the initiation of insulin therapy. A number of different regimens have been studied and are currently available for use in type 2 diabetes to improve 24-hour glycemic control. Recent studies (DCCT and UKPDS) have shown that intensive therapy improves patient outcomes by reducing microvascular complications and reduced mortality rates of diabetes-related deaths.

New recommendations from the American Diabetes Association encourage early use of insulin in patients with type 2 diabetes. Previous insulin therapy was limited to NPH, lente, and ultralente insulin before the introduction of insulin analogs. Three rapid-acting insulin analogs—insulin lispro, insulin aspart, and apidra, along with two long-acting insulin analogs—insulin glargine and insulin detemir, are available and demonstrate consistent abilities to obtain target glucose levels and have a lower rate of hypoglycemia than NPH and regular insulin.

**Is intensive insulin therapy feasible or appropriate for all patients?**

As with any therapy, there are people for whom intensive insulin therapy is not a practical or appropriate strategy. This may include patients with limited insight and judgment, those who cannot do accurate self-monitoring of blood glucose or estimate carbohydrate content, and patients who are not likely to benefit from improved glucose control. Intensive insulin therapy may be unsafe in patients with hypoglycemia unawareness. In the DCCT, the most common side effects of intensive therapy were a three-fold increase in severe hypoglycemic reactions and weight gain. Many patients with type 2 diabetes are less prone to hypoglycemia and can achieve good glycemic control on less intensive insulin regimens.

A caveat to the increased incidence of hypoglycemia in the DCCT is that insulins used were less physiologic than the current insulin analogs. In addition, the increased hypoglycemia with the pump was cut in half as the trial progressed; suggesting that familiarity with management of tight glycemic control improved as the trial proceeded (Pickup & Keen, 2002).
References:
Hemoglobin A1C (A1C)

- A1C target goals have been lowered. The ADA suggests a target A1C < 7 percent. The American College of Endocrinology supports a target A1C < 6.5 percent.
- The ADA recommends re-evaluation and significant change in treatment for anyone with an A1C > 8 percent.
- Perform A1C testing at least two times a year in patients who are meeting treatment goals and who have stable glycemic control.
- Perform A1C testing quarterly in patients whose therapy has changed or who are not meeting glycemic goals.
- Use of point-of-care testing for A1C allows for timely decision-making regarding therapy changes, when indicated.
- Glycemic control is best determined by evaluating a combination of both the patient’s SMBG results and A1C results.
- In 2006, 91.6 percent of BRFSS respondents with diabetes stated a healthcare professional had checked their A1C at least once in the previous year.
- The *Healthy People 2010 Objective 5-12* is to increase the proportion of adults with diabetes who have an A1C measurement at least once a year.

What is A1C?
A1C is one of a group of stable minor hemoglobin components, glycated hemoglobin, formed slowly and nonenzymatically from hemoglobin and glucose. The rate of formation of A1C is directly proportional to the level of blood glucose. A single sample of hemoglobin contains red cells of various ages. Since the average life of a red cell is four months, a single A1C level reflects the blood sugar levels that red cells have been exposed to in the previous two to three months. Thus, A1C levels reflect the average of a person’s blood sugar levels in the past two to three months. Certain clinical situations, including frequent episodes of hypoglycemia, may alter the A1C level. Any clinical situation that increases erythrocyte turnover and increases the percentage of young circulating erythrocytes, such as a hemolytic anemia, will lower the measured A1C level. Other clinical situations may interfere with the assay methodology, e.g. hemoglobinopathies, chronic alcohol ingestion, salicylates, uremia, and sample storage effects.

How often should an A1C be obtained?
The A1C level should be measured at least every six months in all persons with diabetes. More frequent monitoring is appropriate if a person’s diabetes is not in control or if there are significant changes in management. A1C testing should be dependent on the clinical situation, the treatment regime used, and the judgment of the clinician (ADA, 2007).

What assay does my lab use?
There are several different types of assays for glycated hemoglobin. Some assays measure A1C directly; others actually measure total glycated hemoglobin and derive a calculated A1C result. The range of normal varies between assay types. Clinicians should be aware of the specific assay used in their laboratory and the range of normal values. If a patient changes the laboratory that measures their A1C, the clinician should consider that the results may vary from previous results because of a change in methodology and/or a new range of normal and not because of a change in the patient’s clinical status.
What is the goal for A1C?
The American Diabetes Association (ADA) recommends a goal A1C of < 7 percent. Practitioners should re-evaluate, and in most cases significantly change, the treatment regime for anyone with A1C levels consistently > 8 percent. The American College of Endocrinology (ACE) and the American Association of Diabetes Educators (AADE) are recommending a target A1C of 6.5 percent. This more rigorous target goal is consistent with goals currently in place in Europe. In patients without diabetes, an A1C of 4 to 6 percent is considered normal.

Glycemic control markedly reduces the progression of microvascular complications. In the type 1 patients followed in the landmark Diabetes Control and Complications Trial, there was a 45 percent lower rate of progressive retinopathy in persons with a mean A1C of 8.2 percent as compared to patients with a mean A1C of 9 percent. Patients with a mean A1C of 7.2 percent had a rate of progressive retinopathy 33 percent lower than patients with a mean A1C of 8 percent. Glycemic control also delayed the onset and progression of renal disease and diabetic neuropathy. More recent clinical trials continue to defend conclusions that improved glycemic control reduces risk of developing retinopathy and reduces cardiovascular disease events.

Individualized goal setting to attain a hemoglobin A1C level less than 7 percent is recommended in the majority of patients. However, less stringent treatment goals may be appropriate for patients who are frail, elderly, experience adverse effects related to tight control, and those who have a short life expectancy due to comorbid conditions.

Tight glycemic control benefits type 2 patients as well. The initial results of a major study of the effect of tight glycemic control in type 2 patients, the United Kingdom Prospective Diabetes Study (UKPDS), were published in 1998. The principal conclusions of that study to date are:
- Vigorous treatment of hyperglycemia decreases the morbidity and mortality of type 2 diabetes.
- Glycemic control reduces the risk of developing retinopathy, neuropathy, and nephropathy. The overall rate of microvascular complications was 25 percent lower in the intensive therapy group than in the conventionally treated group.
- The use of insulin, sulfonylureas, and metformin does not increase the risk of cardiovascular complications, thus there are no reasons not to treat glycemic levels aggressively.
- Control of blood pressure reduces the risk of both microvascular and macrovascular disease.
- The effects of glycemic control and blood pressure control are additive.
- The effect of tight glycemic control on reducing the risk of major cardiovascular events (myocardial infarction, stroke, amputation, and sudden death) did not reach statistical significance, though patients with the highest levels of glycemia experienced a greater incidence in major events.

What is the newest consensus statement of A1C measurement?
The American Diabetes Association, European Association for the Study of Diabetes, International Federation of Clinical Chemistry and Laboratory Medicine, and the International Diabetes Federation are calling for universal, worldwide standardization values for measurement of hemoglobin A1C. They have released a new equation and a new system for reporting blood glucose results. The new number will be reported as ADAG (A1C derived average glucose).
Knowledge gained from the American Association of Diabetes Glucose Trials (ADAG) indicated that elevated A1C values increase the chances of microvascular complications from diabetes. Clinicians worldwide are calling for a universal measurement to monitor glycated hemoglobin A1C levels, with reporting of test results in scientifically correct units such as mmol/L, as a percentage value is not a measure. Results from the American Association of Diabetes Glucose Trials (ADAG) have identified a new equation to make numerical assessments of glycemic control more accessible to patients. Refer to the website for additional information www.easd.org.

The equation: \( AG \text{ (average glucose in mmol/L)} = 1.583 \times HbA1C - 2.52 \). Where \( R^2 = 0.836 \text{ mmol/L} \). (Note that 1 mmol/L = 18mg/dl.) With this system, providers will have three numbers: the usual A1C percentage, the new IFCC version in mmol/L, and the new estimated average glucose.

*\( R^2 \) is defined as the root mean square error (the standard deviation of prediction error).

The implications are that patients will find it easier to integrate this information into their management behaviors and improve control because the average glucose scale matches that of glucose meters. Also, manufacturers of A1C equipment will need to update their software. Prior to this new information, the A1C was tied to the results of the DCCT, where a 6 percent was equal to 135 mg/dL. The change occurred as a result of checking and comparing values between A1Cs and values from over two thousand finger sticks and averaging them out. Thanks in part to new technology, data from thousands of finger sticks, and use of continuous blood glucose monitors, results are more accurate. Use of this equation yields a linear correlation with a wide range of A1C values. This means that a 6 percent A1C reading in no longer an average of 135 mg/dL. The new number values are as follows:

- 6% = 126mg/dl
- 7% = 155 mg/dl
- 8% = 182 mg/dl
- 9% = 211 mg/dl
- 10% = 239 mg/dl

Which measure is more important, the A1C or blood glucose? The ADAG trial showed no difference between LifeScan Monitor and CGM data. Conclusions from the study show that perhaps A1C is not the gold standard for correlating cardiovascular disease with glucose levels. Data presented at EASD showed that patients with the same A1C can have different “area under the curve” postprandial glucose (PPG). For these patients, high PPG values may be a better indicator of inflammation and CVD risk than A1C. It should be the combinations of data that will most help patients understand how the A1C and the average blood glucose are both important. (Reported at 2007 EASD Symposium)
References:
Retinopathy

- Treatment is available for patients diagnosed with diabetic retinopathy. Clinical research trials are underway and have identified new medications and treatment modalities to prevent loss of vision in patients with diabetes, in addition to laser therapy (panretinal photocoagulation). Early diagnosis and treatment through yearly comprehensive eye examination is essential to identify early disease progression.
- **Type 1 diabetes:**
  Schedule yearly complete dilated and comprehensive eye examinations starting three to five years after diagnosis and/or at ten years of age, whichever is later.
- **Type 2 diabetes:**
  Schedule yearly complete dilated and comprehensive eye examinations starting shortly after diagnosis.
- **Pregnant women with pre-existing type 1 or type 2 diabetes:**
  Schedule a first trimester examination with close follow-up during pregnancy and for one year postpartum.
- **Women with type 1 or type 2 diabetes who are planning pregnancies:**
  Schedule a complete dilated and comprehensive eye examination pre-conception, with counseling on the risk of development and/or progression of diabetic retinopathy.
- Cataracts and glaucoma are more common in people with diabetes.
- In 2006, 72.0 percent of BRFSS respondents stated they had reported receiving a dilated eye exam within the previous 12 months, as compared to 77.1 percent in 2000.
- *Healthy People 2010 Objective 5-13* is for 75 percent of adults with diabetes to receive a dilated eye exam annually.
- In 2006, 18.0 percent of respondents were told that diabetes had affected their eyes or that they had retinopathy, as compared to 23.7 percent in 2000.

Retinopathy
The prevalence of diabetic retinopathy is strongly correlated with the duration of the disease. After 20 years of diabetes, nearly all persons with type 1 diabetes and > 60 percent of persons with type 2 diabetes will have some retinopathy. Twenty-one percent of persons with type 2 diabetes will have retinopathy at the time of diagnosis. Diabetic retinopathy is the leading cause of new cases of legal blindness in Americans ages 20 to 64 years, despite effective treatments to prevent visual loss or to restore useful vision. Veteran’s Affair Diabetes Trial (VADT) studies conclude that improving glycemic control and normalizing blood pressure may reduce the ocular morbidity of diabetes, especially in African American and Hispanic patients.

Women who develop gestational diabetes are not at increased risk for diabetic retinopathy. However, if these women subsequently develop type 1 or type 2 disease, their retinopathy risk increases like anyone else with diabetes.

**What patients are at highest risk for developing retinopathy?**
Elevated A1C, as well as proteinuria, has been strongly correlated with increased risk for development of and progression of diabetic retinopathy. Poorly controlled systemic hypertension, proteinuria, and hyperlipidemia are all positively correlated with both the incidence and the rate of progression of retinopathy. Pregnancy and puberty may accelerate microvascular progression. Women with pre-existing diabetes who are planning a pregnancy should be counseled on the increased risk for development of and/or the progression of diabetic retinopathy.
Why is screening for retinopathy so important?
Diabetic retinopathy is often asymptomatic in its early stages. Screening provides a cost-effective method of detection and treatment of proliferative diabetic retinopathy and macular edema. Prevention and screening programs have the potential to bring significant savings to the Medicare/Medicaid programs and improve the long-term health of patients in today’s society. Because the retinal vascular complications of diabetes can result in permanent visual impairment, laser photocoagulation therapy can prevent loss of vision in most patients with severe nonproliferative and proliferative retinopathy.

What is the recommended screening exam for retinopathy?
Yearly dilated ophthalmoscopic examination is the best current approach to annual screening. Indirect opthalmoscopy with slit lamp examination and measurement of the intraocular pressure are essential. Stereo fundus photography is a sensitive method, but this modality has not been completely evaluated for efficacy as a screening method and is not in widespread use.

Who should perform the screening exam?
The American Diabetes Association suggests that an Ophthalmologist or Optometrist with knowledge and experience in the diagnosis and management of diabetic retinopathy should perform the screening.

What screening results necessitate a referral to a retinal specialist?
Persons with clinically significant macular edema, moderate to severe nonproliferative retinopathy, or any proliferative retinopathy require the prompt care of an Ophthalmologist knowledgeable and experienced in the care of diabetic retinopathy.

Cataracts and Glaucoma
People with diabetes are at increased risk for the development of cataracts and glaucoma compared to people without diabetes. A dilated and comprehensive eye examination is the best current approach to annual screening.
References:
Perform an annual comprehensive foot exam to provide foot self-care education and teach patients to identify risk factors that may be predictive of ulcers and amputation.

Foot exams can easily be performed in primary care settings and should include use of a monofilament, tuning fork, palpation, and visual examination of the feet and lower extremities.

A multidisciplinary approach is recommended for individuals having foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation.

Refer patients who use tobacco or with prior lower-extremity complications to foot specialists for comprehensive preventative care and to determine a plan for life long monitoring.

Initial screening for peripheral arterial disease (PAD) should include a claudication history and assessment of pedal pulses. Consider obtaining arterial Dopplers to obtain early diagnosis as many patients are asymptomatic.

Patients with significant claudication, abnormal Doppler studies, or positive ankle brachial index (ABI) should be referred to a vascular specialist for assessment and treatment with medications, exercise, and surgical options as indicated.

Identify patients with high-risk feet.

Closely monitor high-risk feet.

Consider peripheral vascular studies in patients with signs or symptoms of vascular compromise.

Ulcers should respond to treatment within a month.

Treat foot infections aggressively.

Patients with loss of sensation in feet and lower extremities require protective footgear - i.e. shoes and socks.

Foot ulceration is a precursor to 85 percent of lower extremity amputations in persons with diabetes.

In 2006, 74.9 percent of BRFSS respondents stated a health care professional had checked their feet for sores or irritations at least once in the previous year.

Healthy People 2010 Objective 5-14’s goal is for 75 percent of adults with diabetes to receive at least one foot examination annually.

What are risk factors for ulceration?
The first step in stopping limb loss is to identify those at risk. Risk factors for ulceration are distinguishable by general or systemic considerations versus those localized to the foot and its pathology.

**General or Systemic Contributions**
- Uncontrolled hyperglycemia
- Duration of diabetes
- Peripheral vascular disease
- Blindness or visual loss
- Chronic renal disease
- History of circulatory disorders
- Intermittent claudication

**Local Issues**
- Peripheral neuropathy
- Structural foot deformity
What is diabetic neuropathy?
Diabetic neuropathy refers to the presence of signs and symptoms of peripheral nerve dysfunction in people with diabetes after excluding other causes, and can be motor, sensory, or autonomic. Diagnosis should be made after a thorough examination of the lower limbs including vibratory testing and use of a 5.07 monofilament. Absence of symptoms should not be assumed to indicate absence of signs. Loss of the ability to feel vibration is often the first sensation lost by diabetic patients. Confirmation of diagnosis can be confirmed by quantitative electrophysiology, sensory, and autonomic function testing.

Diabetic neuropathies are heterogeneous and affect different parts of the nervous system, and can initially present with a plethora of diverse clinical manifestations of focal or diffuse nature. Sensorimotor distal symmetric polyneuropathy (DPN) and the autonomic neuropathies are most common. DPN is considered to be a diagnosis of exclusion. According to Boulton et al (2005), early diagnosis and treatment of diabetic neuropathy is important for the following reasons:

- Nondiabetic neuropathies can be present in patients with diabetes mellitus
- Currently a number of treatment options are available
- Approximately 50 percent of patients with DPN may be asymptomatic
- Patients are at great risk of insensate injury to their feet
- > 80 percent of amputations follow a foot ulcer or injury
- Treatment includes early recognition and provision of patient education
- Appropriate foot care may result in a reduction in the incidence of ulceration and ultimately prevent future amputation
- Autonomic neuropathy may involve every system in the body
- Autonomic neuropathy causes a substantial increase in morbidity and mortality, especially if cardiovascular autonomic neuropathy (CAN) is present

What are treatment options?
The first logical step in treatment is to normalize glucose control to acceptable limits of normal. Research suggests that neuropathic symptoms may improve with control of blood sugars and avoidance of erratic excursions of hyperglycemia. Currently, a number of non-pharmacological interventions such as topical preparations (Capsaicin, glyceryl trinitrate, spray, patches, etc.), acupuncture, and physical therapy may be beneficial. Medications of benefit to patients include use of tricyclic drugs, anticonvulsants, anti-depressants (Amitriptyline, Neurontin, Lyrica, and Cymbalta), and opioid or opioid-like drugs. Referral to pain clinics may offer some benefit. Aggressive control of blood glucose, A1C, blood pressure, lipids, and healthy lifestyle changes may result in reduced incidence of injury to the feet and lower extremities.

I. Annual Comprehensive Foot Examination with Risk Stratification
A. Steps for Preventing Diabetes Foot Problems
   1. Perform a comprehensive foot exam annually.
      - Examine skin, hair, toenails, musculoskeletal structure, and evaluate vascular status and protective sensation
      - Inspect footwear for proper fit, appropriate materials, foreign objects, torn linings, and proper cushioning
   2. Categorize your findings.

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>All of the following:</td>
<td>One or more of the following:</td>
</tr>
<tr>
<td>Intact protective sensation</td>
<td>Loss of protective sensation</td>
</tr>
<tr>
<td>Pedal pulses present</td>
<td>Absent pedal pulses</td>
</tr>
<tr>
<td>No foot deformity</td>
<td>Foot deformity</td>
</tr>
<tr>
<td>No history of foot ulcer</td>
<td>History of foot ulcer</td>
</tr>
<tr>
<td>No amputation</td>
<td>Prior amputation</td>
</tr>
</tbody>
</table>

3. Document your findings in the medical record.
4. Counsel your patients and/or refer to a diabetes educator.
   - Examine feet and lower extremities at each visit
   - Talk with your patients about their risk category
   - Demonstrate self-care techniques
   - Instruct patients to report injuries, trauma, or signs of infection
   - Prescribe appropriate footwear
   - Give positive feedback for proper foot care
   - Counsel about tobacco cessation if needed
   - Exercise
   - Reinforce the importance of blood glucose control to reduce the risk for foot problems and other complications (A1C reduction)
5. Follow up with low risk patients.
   - Visually inspect feet at every visit
   - Inspect footwear at every visit as warranted
6. Follow up with high risk patients.
   - Place a “high risk feet” sticker on medical record
   - Visually inspect feet at every visit
   - Inspect footwear at every visit
   - Prescribe special inserts and shoes as needed
   - Refer to specialist for a risk factor you cannot rectify
   - Use an interdisciplinary team approach to ensure positive patient outcomes (i.e. primary care physician, podiatry, surgeons, dietician, diabetes educator, home health, etc.)
   - Ensure that the elderly and blind have help for daily foot care

II. Vascular Evaluation of the Lower Extremity in a Patient with Diabetes
This section contains additional specific information on the evaluation of the arterial supply to the lower extremities.
   A. History
      The patient should be asked about:
- Calf, thigh, or buttock claudication
- Pain at rest in feet and toes (vascular rest pain is confined to the feet)
- Circulation to the extremities
- Previous sepsis
- Other co-morbid conditions, and
- Impaired renal function

B. Physical Examination

Identify:
- Decreased or absent peripheral pulses, i.e. femoral, popliteal, dorsalis pedis, posterior tibial
- Cool feet
- Dependent rubor
- Atrophy of subcutaneous tissues, and
- Hair loss

If there is any historical or physical suggestion of compromised blood supply to the forefoot or toes, even with palpable pedal pulses, non-invasive peripheral vascular testing should be ordered.

C. Non-Invasive Peripheral Vascular Testing

An objective assessment of the severity of peripheral arterial occlusion can be obtained by the use of one or more non-invasive diagnostic tests. Non-invasive testing is also helpful in patients with an equivocal history or physical exam. Typically, a professional with expertise in the subject will work in conjunction with the referring practitioner to determine which tests are appropriate given the specific clinical scenario.

**Segmental measurement of blood pressure and Ankle Brachial Index (ABI)**

Serial placement of a blood pressure cuff and Doppler auscultation allows measurement of blood pressure along the legs. Normally, blood pressures in the legs and arms are equal. In fact, ankle pressure may be slightly higher than arm pressure. The ABI is the ratio of the arterial pressure in the ankle to that in the arm. The ABI in normal individuals is > 1.0. The ABI in individuals with moderate to severe occlusive disease is < 0.7. Additionally, a drop in blood pressure of 20 mmHg or more between levels indicates disease in that arterial segment. One of the pitfalls in patients with diabetes is that calcified vessels may give falsely elevated pressures, therefore definite diagnosis via Doppler studies should be considered.

**Pulse-Volume Recording (PVR)**

Significant arterial occlusion decreases the normal volume displacement in the legs that occurs with each pulse and alters the waveform output of the test. Flat or barely pulsatile tracings at the ankle indicate moderately severe to severe ischemia.

**Doppler Flow Velocity Waveform Analyses**

The contour of the Doppler waveform is flattened with significant disease. This test gives similar information to the PVR. Monophasic flow on Doppler studies and non-healing/slow healing wounds may merit further study or referral to a specialist.

**Treadmill Testing**

Treadmill exercise testing allows assessment of functional limitation. Decline of the ABI after exercise supports the diagnosis of vascular occlusion if history and physical exam are equivocal. This test most frequently is used for patients with normal pulses who have symptoms of claudication to distinguish between vascular and neurogenic claudication.
D. Clinical Scenarios Using Non-Invasive Peripheral Vascular Testing
If there are any clinical signs or symptoms of peripheral vascular compromise, the patient should undergo non-invasive testing. An ABI of < 0.7 and flat or barely pulsatile PVR tracings at the ankle indicate moderately severe to severe ischemia. Treadmill testing may be helpful if initial results are normal at rest and the patient has a strong history of claudication.

If a patient is at high-risk for foot problems but does not have signs or symptoms of vascular occlusion, a non-invasive test is indicated to establish a baseline. Examples of high-risk foot conditions include the presence of abnormal foot structure or biomechanics, neuropathy, and employment that requires extensive walking or standing.

III. Management of Diabetic Foot Ulcers
Ulcers should heal. There are three core therapies of diabetic ulcers:
- Topical therapy
- Pressure reduction dressing
- Edema reduction dressing

Emerging technologies that may play a role include growth factors and artificial skin substitutes. Surgical interventions are sometimes necessary, e.g. debridement, bone resection, arthrodesis, tendon lengthening and rerouting, and skin flaps.

The presence of an ulcer or the history of a previous ulcer should stimulate an evaluation of the underlying cause and appropriate preventive management. Specific consideration should be given to the possibility of previously undetected vascular compromise.

IV. Management of Diabetic Foot Infections
All patients with diabetes should be proactively encouraged to seek early evaluation at the first suggestion of infection. Pain and tenderness are not consistent findings and should not be used to judge either the presence of infection or the progress of treatment.

A. Infection Classification
Severity of infection is based on clinical exam:
- Type I (mild) infections are characterized by mild erythema of skin, minimal edema, and only minor breaks in the skin, e.g. superficial ulcer, small laceration, blister. There is no osteomyelitis or systemic toxicity.
- Type II (moderate, limb threatening) infections usually surround a chronic ulcer. Ulceration extends to deep tissues but no bone is exposed. Edema may extend to the forefoot. Cellulitis is typically present. Purulent drainage and osteomyelitis may be present.
- Type III (severe, limb and life threatening) infections are typically odorous and draining purulent material. Erythema, cellulitis, and lymphatic streaking are typical. There may be gangrenous, wet, black soft tissue present. Bone or joint space may be exposed. Osteomyelitis may be present. Signs and symptoms of systemic toxicity may be present.
B. Diagnosis

Physical Exam*

- Probe bone for soft areas suggestive of osteomyelitis
- Probe wound for tracking and undermining
- Document wound area and depth
- Periodically evaluate wound size and volume to gauge response to therapy
- Pain and tenderness are not consistent findings

*Practitioners unfamiliar with wound probing should consult or refer to a physician with training and experience with this assessment.

Laboratory

- Culture purulent drainage, abscesses, and tissue from deep debridement
- Usually avoid culture of superficial lesions as these results are not particularly helpful
- Blood cultures are appropriate in serious infections
- CBC in Type II and III infections
- Renal and liver function tests if needed to guide antibiotic choice
- Sedimentation Rate (WESR) may be useful—if elevated, consider osteomyelitis

Radiology

- Acute osteomyelitis is not always identifiable by routine radiographs or CT scans, except in the late phases
- Plain radiographs may reveal soft tissue gas in deep infections
- Serial radiographs aid monitoring erosive changes in chronic lesions, and are the most useful
- Bone scans may not always be helpful in making the diagnosis of osteomyelitis (three phase is necessary)
- Bone scans are helpful in detecting a Charcot fracture, as the cause of an acutely swollen foot with no open lesion

C. Treatment

Type I infections with no evidence of peripheral vascular obstruction may be treated with outpatient oral antibiotics. The most likely organisms are Staphylococcus or Streptococcus. Patients should be seen again in 24 to 48 hours. If there is no improvement within 48 hours, hospital admission is indicated for bed rest, wound care, and intravenous antibiotics. If the patient has peripheral vascular disease, initial hospitalization and surgical consultation are recommended. Consultation with podiatry is appropriate if underlying deformity or altered biomechanics are present.

If there is no response to therapy or re-infection occurs, one should re-evaluate vascular supply, wound care, and antibiotic therapy. Consultation with an expert in the management of diabetic foot infection is also appropriate.

Type II infections necessitate in-hospital intravenous antibiotic therapy. Surgical consultation is indicated for drainage, debridement, and culture. Infectious disease consultation is appropriate. Type II and III infections are typically polymicrobial (gram negative rods, anaerobes, and enterococci).

Type III infections are a surgical emergency. Immediate surgical drainage and/or amputation is necessary. Infectious disease consultation is appropriate. Type II and III infections are typically polymicrobial (gram negative rods, anaerobes, and enterococci).

Please refer to Figures 3 and 4 and Table 10 on the following pages.
Figure 3: Diabetic Foot Ulceration Associated with Diabetes
Vascular disease, neuropathy, and mechanical trauma are common pathologies seen in patients with diabetes mellitus, and are responsible for complications such as ulceration and amputation.

Table 10: Lower Extremity Diabetic Foot Exam

Examination
- Palpation of pulses—common femoral, popliteal, dorsalis pedis, and posterior tibial
- Handheld Doppler examination
- Skin/limb color changes—cyanosis, erythema, elevation pallor, and dependent rubor
- Presence of edema
- Temperature gradient (ipsilateral and contralateral extremity)
- Dermal thermometry
- Integumentary changes—skin atrophy (thin, smooth, parchment-like skin), abnormal wrinkling, absence of hair growth, onychodystrophy
- Previous hospitalizations/surgery

Neurologic Examination
- Vibration perception—tuning fork 128 cps and measurement of vibration perception threshold (biothesiometer)
- Light pressure—Semmes-Weinstein 5.07 gram monofilament
- Light touch: cotton wool
- Two point discrimination
- Pain: pinprick (sterile needle)
- Temperature perception: hot and cold
- Deep tendon reflexes: patella, Achilles
- Clonus testing
- Babinski test
- Romberg test

Footwear Examination
- Type of shoe (athletic, oxford, comfort, etc.)
- Fit and depth of toe box
- Shoewear, patterns of wear
- Lining wear
- Foreign bodies
- Insole, orthoses

Dermatologic Examination
- Skin appearance—color, texture, turgor, quality, dry skin
- Calluses—discoloration/subcallus hemorrhage
- Fissures (especially posterior heels)
- Nail appearance—onychomycosis, dystrophic, gryphotic, atrophy or hypertrophy, paronychia
- Hair growth
- Ulceration, gangrene, infection—note location, size, depth, infection status, etc.
- Interdigital lesions
- Tinea pedis
- Markers of diabetes—shin spots (diabetic dermopathy), necrobiosis lipoidica diabeticorum, bullosum diabeticorum, granuloma annulare, Acanthosis Nigricans
Musculoskeletal Examination

- Biomechanical abnormalities
- Structural deformities—Hammertoe, bunion, tailor’s bunion; Hallux limitus/rigidus; flat or high-arched feet; Charcot deformities; and postsurgical deformities (amputations)
- Prior amputation
- Limited joint mobility
- Tendo-Achilles contractures/equinus
- Gait evaluation
- Muscle group strength testing—passive and active, non-weight bearing and weight bearing, foot drop, atrophy—intrinsic muscle atrophy
- Plant pressure assessment—computerized devices, Harris ink mat, pressure sensitive foot mat


References:
Blood Pressure

- Measure blood pressure at every visit.
- The goal for blood pressure is less than 130/80 mmHg.
- Patients with hypertension ≥ 140/90 should receive drug therapy, lifestyle, and behavioral therapy.
- Elevated blood pressure is a major risk factor for cardiovascular and renal diseases, including stroke, coronary heart disease, heart failure, and kidney failure.
- A recent National Health and Nutrition Examination Surveys (NHANES) survey indicated that 27 percent of adults have a systolic BP ≥ 140 mmHg, diastolic BP ≥ 90 mmHg, or currently take antihypertensive drugs. Another 31 percent have pre-hypertension and are not on medication.
- The lifetime risk of developing hypertension among adults > 50 years of age is 90 percent.

Why is control of blood pressure important?
Hypertension contributes to the development and progression of chronic diabetic complications. Control of hypertension reduces the rate of progression of diabetic nephropathy and reduces complications of hypertensive nephropathy, cerebrovascular and cardiovascular disease.

Antihypertensive treatment has been shown to decrease the rate of mortality from 43 percent to 9 percent in the first 16 years after the development of diabetic nephropathy. Need for dialysis and transplantation was reduced from 73 percent of patients to 31 percent of patients in the same period.

In type 1 diabetes, persistent hypertension is often a manifestation of diabetic nephropathy. In type 2 diabetes, hypertension often is part of a syndrome including glucose intolerance, insulin resistance, obesity, dyslipidemia, and coronary artery disease (also known as the metabolic syndrome). Isolated systolic hypertension may occur in both types of diabetes and is due, in part, to inelasticity of atherosclerotic large vessels.

What are appropriate treatments for high blood pressure in someone with diabetes?
Lifestyle Modifications
Lifestyle modifications are the first therapy to be employed to treat hypertension, unless the need to reduce the level of hypertension is emergent. Modifications include:
- weight loss
- exercise
- limiting of dietary sodium to 100 mmol (2,300 mg) of sodium per day
- limiting alcohol consumption to no more than 1-2 drinks per day
- tobacco cessation

Individualized goal setting to attain a blood pressure of < 130/80 is recommended in the majority of patients. However, less stringent treatment goals may be appropriate for patients who are frail, elderly, experience adverse effects related to tight control such as falls, and those who have a short life expectancy due to comorbid conditions.
ACEI (angiotensin converting enzyme inhibitors)/ARBs (angiotensin II receptor blockers)

In patients with microalbuminuria or clinical proteinuria, ACEI and ARBs are indicated as part of the initial treatment plan. ACEIs and ARBs have an additional benefit to patients with diabetes in that they decrease the rate of progression of renal disease beyond what would be predicted by controlling their hypertension.

**Additional Pharmacologic Treatment**

If after four to six weeks of initial treatment blood pressure goals have not been reached, additional pharmacological treatment is indicated. Medications should be added in a stepwise fashion.

Conclusions from recent clinical trials (Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial-ALLHAT) indicate the superiority of use of thiazide diuretics as first-line therapy in preventing cardiovascular disease and for their cost effectiveness. However, the presence of concomitant diseases (especially diabetes, vascular disease, fluid overload, etc.) should be considered when choosing medications. Information or advice about medications or treatment strategies for hypertension is available from a physician experienced in the care of patients with diabetes and renal disease.

ACEIs, ARBs, calcium channel blockers, and low dose diuretics are associated with fewer adverse effects on glycemic control, lipid profiles, and renal function than other anti-hypertension medications.

**What are treatment goals for isolated systolic blood pressure in someone with diabetes?**

For patients with isolated systolic blood pressure of > 180 mmHg, the goal is a blood pressure < 160 mmHg. For patients with systolic pressure between 160 and 179, the goal is a 20 mmHg reduction. Further lowering to 140 mmHg or less is appropriate if the initial reduction is tolerated.

**References:**
Renal Disease/Nephropathy

- Screen urine for evidence of renal disease every year in both type 1 and type 2 diabetes.
- For patients with nephropathy, the major goal is to maintain BP < 130/80 mmHg.
- Achieving target glucose goals reduces the risk and/or slows the progression of nephropathy.

When should screening occur for diabetic renal disease?
The first clinical evidence of diabetic nephropathy is the appearance of a small excess amount of albumin in the urine termed microalbuminuria (> 30 mg albumin excretion per day). Persons with microalbuminuria are referred to as having incipient nephropathy and are likely to progress to clinical proteinuria and decreasing renal function over a period of years.

Clinical proteinuria is defined as > 150 mg of protein excretion per day. Normally, small amounts of protein can be found in the urine, but usually this does not exceed 150 mg/24 hours, of which about 10 mg is albumin. When the level of albumin in the urine reaches 30 to 300 mg/day, it is considered low-level albuminuria or microalbuminuria. If the level is greater than 300 mg/day, it is termed macroalbuminuria. Persons with clinical proteinuria are referred to as having overt nephropathy. Once clinical proteinuria occurs, the risk of progression to end-stage renal disease (ESRD) is high in both type 1 and type 2 disease.

Additionally, microalbuminuria is a marker for increased cardiovascular risk, and, if present, is an indication for screening for vascular disease and aggressive intervention to reduce other cardiovascular risk factors, e.g., dyslipidemia, tobacco use, inactivity. In addition, there is some preliminary evidence to suggest that lowering of cholesterol may also reduce the level of proteinuria.

What is the glomerular filtration rate?
The glomerular filtration rate (GFR) is an estimate of the filtering capacity of the kidneys. It is usually expressed as milliliters (mL) per minute (min) and adjusted to a “standard” body size with a surface area of 1.73 meters². The normal GFR ranges between 95 to 120 mL/min/1.73m² but it varies depending on age, gender, and body size. GFR remains the most accurate index of kidney function, and is a key element of early management of chronic kidney disease. Refer to Table 11 to view the stages of chronic kidney disease.

Commonly Used Formulas (Cockroft-Gault):

**Female:**

\[
GFR[ml/min] = 0.85 \times \frac{(140 - age[y]) \cdot bodyweight[kg]}{72 \cdot serum creatinine [mg/dl]}
\]

**Male:**

\[
GFR[ml/min] = \frac{(140 - age[y]) \cdot bodyweight[kg]}{72 \cdot serum creatinine [mg/dl]}
\]
Web Links for GFR Calculation:

Refer to the dosage calculators at:
- National Kidney Foundation at:
  http://www.kidney.org/kidneydisease/ckd/knowGFR.cfm

To determine your patient’s glomerular filtration rate, scroll down on the page and click on “calculate your GFR rate.”

Table 11: Stages of Chronic Kidney Disease

<table>
<thead>
<tr>
<th>Stage</th>
<th>Degree of Damage</th>
<th>GFR (mL/min/1.73 m²)(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage with normal or increased GFR</td>
<td>≥ 90</td>
</tr>
<tr>
<td>2</td>
<td>Kidney damage with mildly decreased GFR</td>
<td>60–89</td>
</tr>
<tr>
<td>3</td>
<td>Moderately decreased GFR</td>
<td>30–59</td>
</tr>
<tr>
<td>4</td>
<td>Severely decreased GFR</td>
<td>15–29</td>
</tr>
<tr>
<td>5</td>
<td>Kidney failure</td>
<td>&lt; 15</td>
</tr>
</tbody>
</table>

GFR = glomerular filtration rate.

When should screening begin?
Because renal disease rarely develops in short duration type 1 diabetes, screening in persons with type 1 diabetes should start with the beginning of puberty or after five years from the initial diagnosis. Because of the difficulty in precise dating of the onset of type 2 diabetes, screening should start at the time of diagnosis.

What screening tests should be used?
The initial screening test in all adult patients is a routine urinalysis because some patients will already have clinical proteinuria (>150 mg/day), which is detectable by routine urinalysis. If the routine urinalysis is positive for protein, a quantitative measure of the amount of proteinuria is indicated. Such measures include spot or 24-hour collection for urinary protein/creatinine ratio.

If the urinalysis is negative, a test for the presence of microalbuminuria is indicated. Three screening methods are available:
1. Albumin/creatinine ratio in a single urine sample
2. 24-hour urine collection for albumin and creatinine
3. Timed collection (4 hour or overnight) for albumin and creatinine

First void or morning samples are preferred for the single urine sample technique. If this timing is not possible, all samples for a given individual should be collected at the same time of day to minimize the effect of normal diurnal variation in albumin excretion.

Specific assays are required to detect microalbuminuria as routine urinalysis and other standard assays for protein are not sufficiently sensitive. Screening with reagent tablets or dipsticks specific for microalbuminuria are 95 percent sensitive and 93 percent specific. However, because testing by reagent tablets or dipsticks is subject to error from alterations in urine concentration, all positive results should be confirmed by one of the three more specific methods mentioned.
above. Because there is day-to-day variability in albumin excretion, at least two of three collections done in a three to six month period should show elevated levels before designating a patient as having microalbuminuria. Refer to Figure 5 for algorithm of current recommendations for screening for renal disease.

Table 12: Categorization of Abnormalities in Albumin and Protein Excretion

<table>
<thead>
<tr>
<th>Category</th>
<th>Spot Collection</th>
<th>24-Hour Collection</th>
<th>Timed Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 30 ug albumin/mg creatinine</td>
<td>&lt; 30 mg albumin/24 hours</td>
<td>&lt; 20 ug albumin/minute</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>30 to 299 ug albumin/mg creatinine</td>
<td>30 to 150 mg albumin/24 hours</td>
<td>20 to 199 ug albumin/minute</td>
</tr>
<tr>
<td>Clinical proteinuria*</td>
<td>&gt; 300 ug protein/mg creatinine*</td>
<td>&gt; 150 mg protein/24 hours</td>
<td>&gt; 200 ug protein/minute</td>
</tr>
</tbody>
</table>

*Some nephrologists suggest that once clinical proteinuria is detected, teasing out that portion of total protein that is albumin adds no useful information.

What are treatment options and goals for patients with diabetic nephropathy?

Facts:
- Achieving normoglycemia will decrease the rate of progression to overt nephropathy.
- Lowering blood pressure will retard the development of overt nephropathy and decrease its rate of progression.
- Angiotension converting enzyme inhibitors (ACEIs) or Angiotensin II receptor blockers (ARBs) should decrease the level of albuminuria/proteinuria and the rate of progression to ESRD.

Options:
- ACE inhibitors or ARB use has been emphasized for nephropathy screening and treatment by the ADA (2008). ACE inhibitors are indicated in all type 1 patients with microalbuminuria even if they are normotensive. Use of ACE inhibitors in normotensive type 2 patients with microalbuminuria is less substantiated by studies. If a type 2 patient has progression in the amount of albuminuria or develops hypertension, ACE inhibitor or ARB treatment then becomes clearly indicated.
- Protein restriction to < 0.8 grams/kg/day is not recommended. Further restriction can be considered in patients with advancing renal dysfunction, symptomatic uremia, or in consultation with a physician experienced in the care of patients with renal disease.
- Tobacco cessation is beneficial for renal function in diabetic patients. There is substantial evidence for the adverse effect of smoking on renal functional deterioration in both type 1 and type 2 diabetes.

Goals:
- The major goal is to maintain BP < 120/80 mmHg.
- Serum creatinine and urinary protein excretion should be measured every three to six months until stable and then annually. (Urinary protein excretion should be measured as an albumin/creatinine ratio in a patient with incipient nephropathy and as a protein/creatinine ratio in a patient with overt nephropathy.)
Goals have not been established for the amount of albuminuria in patients with incipient nephropathy or the amount of proteinuria in patients with overt nephropathy. Expert opinion is that less albuminuria or proteinuria is better. The committee members suggest the following goals:

- For patients with incipient nephropathy (microalbuminuria), the goal of treatment is to stabilize or reduce the urinary albumin/creatinine ratio.
- For patients with overt nephropathy (clinical proteinuria), the goal of treatment is to maintain or reduce the urinary protein/creatinine ratio to < 1.

(Currently available therapy does not necessarily ensure that even these goals can be achieved.)

Figure 5 is listed after the reference page.

References:
1. Diabetic Retinopathy, Diabetes Care, Volume 25, Supplement 1, January 2002; pps S90-S93.
Screening for Renal Disease

Annual routine urinalysis for protein

Negative

Test for microalbumin

Negative

Both tests negative

Repeat test for microalbumin two times in the next six months to confirm the diagnosis

Positive*

One or two positive confirmatory tests

Incipient nephropathy
1. Begin treatment
2. Monitor serum creatinine and urinary protein

Positive*

Overt nephropathy
1. Quantitate proteinuria
2. Consider other renal diseases
3. Begin treatment
4. Monitor serum creatinine and urinary protein

Any patient testing positive for clinical proteinuria or microalbuminuria who has a physiologic condition that may cause a false positive result should be retested after the condition has resolved. Vigorous exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, and marked hypertension may elevate urinary albumin excretion over baseline values and invalidate test results.
Lipid Management for Adults

- Obtain an annual fasting lipid profile for both type 1 and type 2 diabetes, and more often if needed to achieve goals.
- The treatment goal for patients with diabetes is an LDL less than 100 mg/dl. For those patients with known significant high risk, as in macrovascular disease (CVD), the goal is an LDL less than 70 mg/dl.

**Why is control of lipid abnormalities important?**
Diabetes is one of the major risk factors for vascular disease, along with smoking, dyslipidemia, hypertension, and a family history of premature coronary heart disease. In type 2 diabetes there is an increased risk for obesity and lipid abnormalities that is independent of glycemic control. Because of the two to four fold increase in the prevalence of vascular disease in persons with diabetes, it is important to identify and manage all modifiable cardiovascular risk factors. The goal of lipid management is to prevent the development or progression of vascular disease.

**What is the relationship between blood lipid levels and coronary heart disease risk?**
Table 13 illustrates risk levels for coronary heart disease (CHD) with varying levels of LDL, HDL, and triglycerides in the general population. No clinical trial has been done on the effects of lipid-lowering agents on subsequent coronary heart disease in a diabetic population, though diabetic subjects have been included in some of the major trials such as the Scandinavian Simvastatin Survival Study (4S study), the Cholesterol and Recurrent Events Study (CARE Study), and the Helsinki Heart Study. The 4S and CARE studies provide evidence that pharmacologic therapy with statin drugs (HMG co-A reductase inhibitors) reduce CHD events (and mortality in 4S) in diabetic subjects with known CHD.

<table>
<thead>
<tr>
<th>CHD Risk</th>
<th>LDL (men and women)</th>
<th>HDL (men)</th>
<th>HDL (women)</th>
<th>Triglyceride (men and women)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>&gt; 130 mg/dl</td>
<td>&lt; 35 mg/dl</td>
<td>&lt; 45 mg/dl</td>
<td>&gt; 400 mg/dl</td>
</tr>
<tr>
<td>Intermediate</td>
<td>100 to 129 mg/dl</td>
<td>35 to 45 mg/dl</td>
<td>45 to 55 mg/dl</td>
<td>200 to 399 mg/dl</td>
</tr>
<tr>
<td>Low</td>
<td>&lt; 100 mg/dl</td>
<td>&gt; 45 mg/dl</td>
<td>&gt; 55 mg/dl</td>
<td>&lt; 150 mg/dl</td>
</tr>
</tbody>
</table>

**What diagnostic tests for hyperlipidemia are appropriate?**
Adult patients should be evaluated annually. Testing should include:
- fasting total cholesterol
- fasting triglyceride
- HDL cholesterol
- calculated LDL cholesterol

If all values are normal, less frequent testing may be appropriate. If the lipid profile is abnormal, consideration should be given to correctable secondary causes such as hypothyroidism (which has an increased prevalence in people with diabetes), poor glycemic control, medications (i.e. thiazides, steroids), and alcohol consumption.
What are the thresholds for initiating treatment for hyperlipidemia?
The 2001 Adult Treatment Panel (ATP III) of the National Cholesterol Education Program (NCEP) recognizes diabetes as a CHD risk equivalent. The recommendations for people with diabetes mirror those of a patient with either established CHD or a risk factor profile that would confer a 20 percent ten-year risk of a CHD event. Tools for the convenient calculation of a patient’s risk of CHD on a computer or personal digital assistant device may be downloaded from the NCEP\textsuperscript{2}. Consideration is not given to gender because it is felt that women and men with diabetes are at a similarly high risk.

What are the treatment goals for hyperlipidemia in persons with diabetes?
Table 14 illustrates hyperlipidemia treatment thresholds for people with CHD or a CHD risk equivalent.

<table>
<thead>
<tr>
<th>CHD or CHD Equivalent</th>
<th>LDL Goal</th>
<th>LDL level at which to initiate lifestyle Rx</th>
<th>LDL level at which to consider drug Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100 mg/dl</td>
<td>&gt; 100 mg/dl</td>
<td>&gt; 130 mg/dl (100 to 129 mg/dl)*</td>
<td></td>
</tr>
</tbody>
</table>

*Some authorities recommend use of LDL lowering drugs if goal LDL < 100 mg/dl cannot be achieved with lifestyle changes.
*Some authorities recommend treating to less than 70 mg/d if at high risk.

What are the priorities for management of lipid abnormalities in people with diabetes?
In general, all people with diabetes who have lipid abnormalities should have a trial of medical nutrition therapy, exercise, and optimization of glycemic control. Monitor for previous hepatitis history, obtain baseline liver function studies, and monitor follow-up as indicated. Refer to Table 15 for priorities and options for pharmacologic management of dyslipidemia.
### Priorities and Options for Pharmacologic Management of Dyslipidemia

<table>
<thead>
<tr>
<th>Priorities and Options for Pharmacologic Management of Dyslipidemia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First priority is to lower the LDL cholesterol.</strong></td>
</tr>
<tr>
<td>✷ First choice of pharmacologic treatment is a HMG CoA reductase inhibitor (statin).</td>
</tr>
<tr>
<td>✷ Second choice for treatment is a bile acid binding resin (resin), or fenofibrate.</td>
</tr>
<tr>
<td>✷ Improved glycemic control will decrease the LDL level but has a more pronounced effect on lowering elevated triglycerides than on lowering elevated LDL.</td>
</tr>
<tr>
<td><strong>Second priority is to raise the level of HDL cholesterol.</strong></td>
</tr>
<tr>
<td>✷ Behavioral interventions such as weight loss, increased physical activity, and tobacco cessation may be useful.</td>
</tr>
<tr>
<td>✷ Pharmacologic treatment is generally not very effective.</td>
</tr>
<tr>
<td>✷ Nicotinic acid may be used, but is relatively contraindicated due to its potential to worsen glycemic control.</td>
</tr>
<tr>
<td><strong>Third priority is to lower the triglyceride level.</strong></td>
</tr>
<tr>
<td>✷ The best method to lower the triglyceride level is to achieve glycemic control.</td>
</tr>
<tr>
<td>✷ Fibric acid derivative (gemfibrozil or fenofibrate) is the second management option.</td>
</tr>
<tr>
<td>✷ Treatment with statins is moderately effective at high dosages in hypertriglyceridemic subjects who also have high LDL cholesterol. Newer statin drugs such as atorvastatin may offer advantages for lowering triglycerides and raising HDL.</td>
</tr>
<tr>
<td><strong>If there is combined hyperlipidemia:</strong></td>
</tr>
<tr>
<td><em>First choice of therapy:</em></td>
</tr>
<tr>
<td>1. Improved glycemic control plus high dose statin</td>
</tr>
<tr>
<td><em>Second therapy choice:</em></td>
</tr>
<tr>
<td>1. Improved glycemic control plus statin plus fibric acid derivative (gemfibrozil, fenofibrate)</td>
</tr>
<tr>
<td><em>Third therapy choice:</em></td>
</tr>
<tr>
<td>1. Improved glycemic control plus resin plus fibric acid derivative, or</td>
</tr>
<tr>
<td>2. Improved glycemic control plus statin plus nicotinic acid†* (glycemic control must be monitored carefully)</td>
</tr>
</tbody>
</table>

†The combination of statins with nicotinic acid (niacin) and especially with gemfibrozil may carry an increased risk of myositis.

*Nicotinic acid must be used with caution because of a tendency to worsen glycemic control.
References:
1. Management of Dyslipidemia in Adults with Diabetes. (2002). *Diabetes Care*, 25 (Suppl 1), S74-77. Available at: [http://care.diabetesjournals.org/cgi/content/full/25/suppl_1/s74](http://care.diabetesjournals.org/cgi/content/full/25/suppl_1/s74).
Immunization Recommendations

- Annual influenza vaccine is recommended for all patients with diabetes ≥ 6 months of age.
- Pneumococcal vaccine is recommended for all patients with diabetes. Revaccination is recommended for individuals > 64 years previously immunized before age 65 if the vaccine was administered more than 5 years ago.
- Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, as following transplantation.
- In 2006, 80.4 percent of BRFSS respondents with diabetes reported receiving a flu shot in the previous 12 months.
- Also in 2006, 78.4 percent of BRFSS responders with diabetes report they had previously received a pneumococcal immunization.
- *Healthy People 2010 Objective 14-29’s* goal is for 60 percent of adults with diabetes to receive an influenza vaccination yearly, and for 60 percent of adults with diabetes to receive a pneumococcal vaccination.

Why are immunizations important for people with diabetes?
People with diabetes mellitus are six times more likely to be hospitalized during an influenza outbreak than those without diabetes. Pneumococcal infections cause 40,000 deaths annually in the United States; the highest mortality occurs among the elderly and patients with underlying medical conditions including diabetes. Many influenza and invasive pneumococcal infections are vaccine preventable.

What are the recommendations for receiving the influenza vaccine?
Annual vaccination is recommended in all patients with either type 1 or 2 diabetes. Split virus and whole virus vaccine preparations are available. The manufacturer’s package insert should be reviewed for current year dose recommendations. The optimal time for vaccination is late October through mid December, but vaccination at any time during the winter offers benefit. Overseas travel plans may necessitate adjusting the vaccination schedule. Women with diabetes who will be in at least the 14th week of gestation during influenza season (December to March in the U.S.) should receive an influenza vaccine.

Contraindications
Known anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine contraindicates vaccination, unless there is a high risk of complications from influenza infection and appropriate allergy evaluation and desensitization has occurred. Moderate to severe acute illness is also a contraindication until symptoms have abated. Mild illness with or without fever is not a contraindication. Vaccine manufacturer’s package insert should be reviewed for product specific cautions and contraindications.

Concomitant administration of other vaccines
Influenza vaccine may be administered at the same time, at a different site, or with other vaccines without increasing side effects or reducing efficacy. Specifically, influenza vaccine may be given at the same time as pneumococcal vaccine.
**Who can use the nasal-spray flu vaccine LAIV (FluMist®)?**

LAIV (FluMist®) is approved for use in healthy* people 2 to 49 years of age who are not pregnant. Breastfeeding is not a contraindication for FluMist®. The nasal-spray flu vaccine LAIV (FluMist®) can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered. FluMist® is contraindicated in people less than age 2 or 50 years of age or older, those with medical conditions at high risk for complications from influenza, including those with chronic heart or lung disease (asthma or reactive lung disease), diabetes, kidney failure, weakened immune systems, or those who take medications that can weaken the immune system, in children < 5 years of age with a history of recurrent wheezing, children or adolescents receiving aspirin therapy, history of Guillain-Barre syndrome, and people who have severe allergy to chicken eggs or nasal spray vaccine components. Please see [www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm) for a list of contraindications for FluMist®.

*On September 19, 2007, the U.S. Food and Drug Administration (FDA) approved use of the nasal influenza vaccine LAIV (FluMist®) for healthy children ages 2-4 years old (24 to 59 months old) without a history of recurrent wheezing, as well as for healthy persons ages 5 to 49 years who are not pregnant. Previously, approval was for healthy persons ages 5 to 49 years who were not pregnant.*

**Pneumococcal Vaccine**

Pneumococcal vaccine is recommended in all patients with type 1 or type 2 diabetes at the time of diagnosis. The 23 capsular polysaccharide antigens in the current vaccine represent the pneumococcal serotypes causing 85 to 90 percent of invasive disease and the 6 serotypes most frequently causing invasive drug-resistant infection. Consult the manufacturer’s package insert for dosage instructions

**Contraindications to pneumococcal vaccination**

There is no contraindication to a first dose of pneumococcal vaccine other than moderate or severe acute illness. Vaccine manufacturer’s package insert should be reviewed for product specific cautions and contraindications.

The safety of 23 valent polysaccharide vaccine for pregnant women has not been studied. It should generally not be given to healthy pregnant women. Women who are at high risk of pneumococcal disease and who are candidates for pneumococcal vaccine should be vaccinated before pregnancy.

**Revaccination**

Routine revaccination of young, immuno-competent adults is not presently recommended. A single revaccination five or more years after the initial vaccination should be considered in:

1. The elderly, and
2. For those people with co-morbid conditions that put them at very high risk for invasive infection including asplenia, transplant, immunosuppression, nephrotic syndrome, and chronic renal failure.
**Pediatric Patients**

**Influenza vaccination**

Infants with diabetes should not be immunized for influenza until they are > 6 months old. The manufacturer’s package insert should be reviewed for current year dose recommendations. See the section on FluMist® on the previous page for indications for pediatric patients.

**Pneumococcal vaccination**

The pneumococcal conjugate vaccine, PCV7 or Prevnar®, licensed in late 2000, is the first pneumococcal vaccine that can be used in children under the age of two years. However, pneumococcal vaccines for the prevention of disease among children and adults who are two years and older have been in use since 1977. Pneumovax® and Pnu-Immune® are 23 valent polysaccharide vaccines (PPV23) that are currently recommended for use in all adults who are older than 65 years of age and for persons who are 2 years and older and at high risk for disease (e.g., sickle cell disease, HIV infection, or other immunocompromising condition). (CDC, 2007)

All children with diabetes should receive a pneumococcal vaccine. Children who are < 24 months at the time of diagnosis should complete the initial series of the 7 valent conjugated pneumococcal vaccine if the series has not been completed. Children older than 24 months are potential candidates for both the 7 valent conjugated vaccine and the 23 valent polysaccharide vaccine. However, there is controversy over the sequencing and dosage for the two vaccines in this age group. Thus, it is advised that a physician with expertise in pediatric infectious disease be consulted about the best course of action. The overarching principle is that all children with diabetes should receive some form of pneumococcal vaccine.

**References:**

2. Centers for Disease Control (2000, October 6). Preventing pneumococcal diseases among infants and young children. *MMWR* 49(RR09), 1-38. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4909a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4909a1.htm).
6. Centers for Disease Control (2007, October 26). The nasal-spray flu vaccine (Live attenuated influenza vaccine [LAIV]). Available at [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov).
Dental and Periodontal Disease

- Diabetes is a risk factor for chronic periodontal disease.
- Periodontal disease is the most prevalent oral complication of diabetes.
- Periodontal infections may affect blood glucose control.
- Good blood glucose control is an effective tool in preventing periodontal disease.
- Data obtained from current studies indicated a link between periodontal disease and inflammation, and increased the risk factors for atherosclerosis.
- Early intervention with fluoride may be indicated in communities with un-fluoridated water and may be beneficial in infants and children. Refer to the most current guidelines at [http://www.cdc.gov/fluoridation/guidelines/tooth_decay.htm](http://www.cdc.gov/fluoridation/guidelines/tooth_decay.htm).
- Currently, the ADA offers no guidelines on dental examination beyond initial oral cavity examination. The Centers for Disease Control recommends individuals that have diabetes should see a dentist every six months and more often if periodontal disease is present.
- Current research shows individuals with diabetes are less likely to seek preventive dentistry than their non-diabetic counterparts.

What recommendations should healthcare providers and diabetes educators make to their patients regarding oral and dental hygiene?

Healthcare providers and diabetes educators should educate patients on the importance of maintaining good oral hygiene through regular dental exams every six to twelve months, brush teeth at least twice daily, floss regularly, and report any bleeding or sores on gums. Mouth infections and disorders of the gum are more prevalent when blood glucose levels are elevated. Compromised oral conditions related to periodontal disease such as missing teeth, dental caries, and oral infection can affect nutrition and glycemic control. At a minimum, patients and families should receive education on the following:

- Diabetes and oral health
- Maintaining glycemic control
- Cessation of smoking and tobacco use
- Healthy meal planning
- Proper brushing and flossing
- Dental examination, at least annually

How does periodontal disease occur?

Periodontal disease occurs when the periodontal ligament, which joins the root of the tooth to the alveolar bone (tooth socket), is destroyed by bacteria. Infection may develop as the tissue surrounding the tooth recedes. A periodontal pocket then develops, harboring an increasingly anaerobic environment. Normal brushing and flossing can no longer reach this area and a biofilm or plaque, consisting of communities of pathogenic bacteria, develops. These biofilms or plaques are resistant to normal body defenses and chemotherapeutics. The cells and molecules within this pocket are inflammatory and play a role in the pathogenesis of diseases. An increase in C-reactive protein, an inflammatory marker present in periodontal inflammation, is a risk factor for atherosclerosis. According to the American Heart Association, an elevation of the highly sensitive C-reactive protein can be a predictor for stroke and cardiovascular events.

The destruction that occurs with periodontal disease is caused by the body’s excessive inflammatory response to the periodontal pathogens and its inability to properly resolve this response. Diabetes, tobacco use, and genetic risk factors greatly affect how the body responds to the inflammatory response.
What is the treatment for periodontal disease?
Treatment for periodontal disease consists of debridement, usually with the addition of antibiotics following the procedure. Non-steroidal anti-inflammatory drugs (NSAIDS) can be used to slow or halt the inflammatory response but tend to also slow or halt the beneficial effects of the inflammatory response. Aspirin can also be used to modulate the inflammatory response. Prevention of periodontal disease in patients with diabetes requires an annual dental exam for gum and periodontal disease. Patients with significant periodontal disease require more frequent monitoring and treatment to control the periodontal disease.

What is the Scottsdale Project and what is its impact on patients with diabetes?
The Scottsdale Project Report data was released in September of 2007, and proposes that providers screen all patients for periodontal disease and refer as necessary. The report also suggested the following management plan for patients with diabetes (Grand Rounds in Oral-Systemic Medicine, 2007):

1. Patients with diabetes should be medically managed as recommended by the American Diabetes Association.
2. Patients with diabetes should have a dental exam at a minimum of twice a year, or more frequently if advised by the dental provider, and receive appropriate dental/periodontal care.
3. There should be close communication between the primary care physician and the dentist.
4. Medical providers should advise patients with periodontal disease that it is a chronic infection of the gums and a complication of diabetes.
5. Medical providers should also advise patients that periodontal disease has been associated with significant health problems, including worsening metabolic control and other complications of diabetes, coronary artery disease, and stroke.
6. Medical providers should advise the patient that periodontal disease can be treated by the dentist and dental hygienist, and in more severe case, refer to a periodontist (gum specialist).
7. If the patient has not seen a dentist within the last year, or if there are signs of periodontal disease, the patient should be advised to make an appointment to see a dental provider right away.
References:
## Self-Management Education

- Diabetes self-management education involves a continuum of services ranging from the teaching of survival skills to comprehensive self-management education programs to intensive management.
- Patients with diabetes must be able to comprehend, analyze, and apply diabetes self-management education, including self-blood glucose monitoring, medical nutrition therapy, and medication administration.
- Educational needs should be assessed at time of diagnosis and whenever there is poor clinical control or a major change in therapy.
- Health literacy and health numeracy play an important role in the health outcomes of patients with diabetes.
- At a minimum, a team consisting of a registered nurse and a registered dietitian, with advanced training and education in diabetes management, should provide patient self-management education.
- The individualized patient assessment and care plan should be documented in the medical record and shared with all members of the inter-disciplinary team.
- Self-management education enables the patient to participate in goal setting to normalize glucose levels and improve health outcomes.
- People with diabetes should increase preparedness by maintaining a waterproof, insulated disaster ready kit which contains items critical to self management, to include glucose testing materials and meter, medications (oral and injectable), syringes, glucose tablets, and glucagon kits.
- As of July 1, 1999, all health insurance carriers in South Dakota, including Medicaid, are required to provide coverage for self-management training and education for individuals with diabetes if prescribed by a health care professional legally authorized to prescribe such items under law.
- In 2006, 66.2 percent of BRFSS respondents with diabetes reported taking a course on how to manage their diabetes. Participation in self-management education classes has increased from 58.7 percent in 2000 to its current level.

### What are “survival skills”?

Survival skills should be offered to all persons with diabetes at the time of diagnosis. In order for patients to recognize the significance of diabetes, they should receive a comprehensive self-management education program. Those people unable to attend a comprehensive program should receive instruction in the following key areas:

1. Disease basics
2. Self-monitoring of blood glucose
3. Exercise and activity and weight control
4. Medication use
5. Hypoglycemia/Hyperglycemia
6. Nutrition

Survival skills should be taught by a licensed health care professional with specific training in diabetes and the education of people with diabetes. Specific training must be consistent with the prevailing state standards.
Why is it important for patients with diabetes to be prepared in the event of a natural or man-made disaster?

The 2007 ADA Standards encourage patients with diabetes to increase their preparedness by maintaining a “to go” kit in a waterproof, insulated bag. The bag should contain supplies essential to maintain glycemic control in a disaster situation, including blood glucose meter and testing strips, lancets, container for sharps disposal, oral medications, insulin, syringes, alcohol preps, glucose tablets, and glucagon kits.

Photocopies of relevant health information, medication lists, recent lab tests and procedures, and contact information of health care providers should be included. Prescription numbers should be noted, as pharmacy chains throughout the country may be able to refill medications based on the number alone in the event of relocation. Disaster kits should be checked and replenished at least twice yearly.

What is a comprehensive self-management education program?
A comprehensive self-management education program is an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). This process includes assessment of the individual’s specific education needs, identification of the individual’s personal goals, education, and behavioral interventions directed toward helping the individual achieve their goals. The National Standards for Diabetes Self-Management Education identify ten core educational content areas. Assessed needs of the individual will determine which areas listed below are delivered.

1. Describing the diabetes disease process and treatment options
2. Incorporating appropriate nutritional management
3. Incorporating physical activity into lifestyle
4. Utilizing medications (if applicable) for therapeutic effectiveness
5. Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control
6. Preventing, detecting, and treating acute complications (i.e. periodontal, nephropathy, etc.)
7. Preventing (through risk reduction behavior), detecting, and treating chronic complications
8. Goal setting to promote health and problem solving for daily living
9. Integrating psychosocial adjustment to daily life
10. Promoting preconception care, management during pregnancy, and gestational diabetes management (if applicable)

What are the requirements for comprehensive self-management program coordinators and program instructors?
A program coordinator who has familiarity with the lifelong process of managing a chronic disease (i.e. diabetes) and who is responsible for program planning, implementation, and evaluation shall be designated to manage the program. The coordinator role is filled by a healthcare professional with advanced education on a combination of diabetes management, educational strategies, behavioral interventions, and counseling skills in accordance with program requirements of the American Diabetes Association, the Indian Health Service, or the SD Department of Health. Requirements among these programs vary but are based on the National Standards for Diabetes Self-Management Education.
Program instructors must be licensed health care professionals with recent didactic and experiential preparation in diabetes education and management. DSME instructors who are collectively qualified to teach the required content areas must consist of at least a registered nurse and a registered dietitian/licensed nutritionist. Instructors must either be a CDE or have completed initial diabetes education and training as outlined in accordance with program requirements of the American Diabetes Association, the Indian Health Service, or the SD Department of Health.

All comprehensive program staff must obtain at least 6 hours of continuing education related to diabetes yearly. A list of comprehensive self-management education program recognized by the SD Department of Health, the American Diabetes Association and the Indian Health Service as meeting the national standards is at http://doh.sd.gov/Diabetes/SDDERP.aspx.

**What is health literacy?**

Health literacy is a person’s ability to read, understand, and use health information to make appropriate health care decisions and follow instructions for treatment.

According to the National Adult Literacy surveys conducted in 1993 and 2003, approximately 21 percent of American adults (40 to 44 million) are functionally illiterate and read at or below a 5th grade level and an additional 25 percent are marginally illiterate.

This is reflected in the 90 million adults who have difficulty understanding and using health information. Patients with lower health literacy levels are less apt to seek out preventive health care and to have a medical home. They are more apt to have increased use of emergency room services and have higher rates of hospitalization. They have more difficulty carrying out medical tests and treatment regimes. Reading and comprehending consent forms, insurance forms, or written instructions regarding their treatment plan may be beyond their reach.

**How should health literacy be assessed?**

Every patient should have a health literacy assessment done on admission to any healthcare center or comprehensive self-management education program. A tool that is free of charge and readily accessible is entitled “The Newest Vital Sign” and is available at http://www.newestvitalsign.org/nvs-resources.aspx. It can be administered in a three-minute period and will give the health care provider an estimate of the patient’s health literacy level. Information regarding health literacy level concerns should be communicated to other interdisciplinary team members to ensure continuity of care.

**Why is it necessary to assess cultural beliefs?**

It is important to assess a patient’s cultural beliefs as these beliefs may influence the manner in which the patient interprets and follows through with the treatment plan. There must be a mutual understanding between healthcare provider and patient that allows the patient to proceed with the plan from his/her own cultural reference.
What interventions can health care providers and educators implement to improve patient’s understanding?

According to the Clear Health Communication Initiative, there are six steps that can be used to improve patients’ understanding:

1. Limit the amount of information provided at each visit
2. Slow down
3. Use “living room” language, avoid medical jargon
4. Use pictures or models to explain important concepts
5. Assure understanding with the “show me” technique
6. Encourage patients to ask questions

Diabetes educators have been using the “show me” or “teach back” method for many years. It is the one way that an educator has to ensure that the patient can simultaneously describe and demonstrate the steps to a procedure such as insulin withdrawal and injection. However, educators must be careful to use pictures that demonstrate the steps to injection, or if written directions are given as take home reminders, they should be written at a 5th or 6th grade reading level. Readability calculators are available online that can be used to assess the reading level of printed materials to ensure they are at a level the patient can understand. (Available at http://www/harrymclaughlin.com/SMOG.htm.)

The health care provider must be extremely careful to be non-judgmental and avoid placing blame on the patient for not comprehending instructions. The health care provider can communicate ownership of ensuring that the patient understands by stating, “Just to be sure that I have taught you all you need to know, could you repeat back to me the instructions I have given you?”

How frequently should educational needs be assessed?

Educational needs should be assessed at the time of diagnosis and subsequently reassessed at least annually. Reassessment of educational needs should also occur whenever there is poor clinical control or a major change in therapy.

What is a comprehensive educational assessment?

Diabetes is a complex disease that affects nearly every aspect of a person’s life. A comprehensive assessment of a person’s educational needs is likewise complex. The American Association of Diabetes Educators has identified the following 12 components of a comprehensive educational assessment:

1. Health history
2. Medical history
3. Previous use of medication
4. Diet history
5. Current mental health status
6. Family and social supports
7. Previous diabetes education, actual knowledge, and skills
8. Current self-care management practices
9. Use of healthcare delivery systems
10. Lifestyle practices
A team consisting of a registered dietitian and a registered nurse should conduct the initial assessment and all reassessments. Both dietitian and nurse should be Certified Diabetes Educators (CDEs) or licensed health care professionals with specific training in diabetes and the education of people with diabetes.

**What is intensive management education?**
Intensive management education may be either individual or special group sessions designed for patients who are initiating continuous subcutaneous insulin infusion or multiple daily injection therapy combined with carbohydrate counting. A diabetes treatment team familiar with the use of the insulin pump and intensive management coordinates these sessions. This planned education is an integral component of care.

**Who is a Certified Diabetes Educator (CDE)?**
A Certified Diabetes Educator is a health care professional who is qualified by the National Certification Board for Diabetes Educators to teach people with diabetes how to manage their condition. To achieve certification, the individual must have accrued 1,000 hours in direct diabetes education and passed the certification exam of the National Certification Board for Diabetes Educators.

**What is Board Certified – Advanced Diabetes Management (BC-ADM)?**
According to the AADE, the Advanced Practitioner in Diabetes Management has an advanced degree and is able to:

- perform complete and/or focused assessments,
- recognize and prioritize complex data in order to identify needs of patients with diabetes across the life span; and
- provide therapeutic problem solving, counseling, and regimen adjustments

The scope of advanced clinical practice includes management skills such as medication adjustment, medical nutrition therapy, exercise planning, counseling for behavior management, and psychosocial issues. Attaining optimal metabolic control may include treatment and monitoring of acute and chronic complications. The depth of knowledge and competence in advanced clinical practice and diabetes skills affords an increased complexity of decision-making, which expands the traditional discipline specific practice. Research, publications, mentoring, and continuing professional development are expected skill sets.

**What is the differentiation between CDE and BC-ADM?**
BC-ADM certification differs from the CDE in that it is focused on advanced management of clinical diabetes problems and requires an advanced degree before sitting for the examination. A diabetes care professional with a BC-ADM credential may or may not be a CDE (a certification in diabetes education is not a pre-requisite). As diabetes education is an integral part of diabetes care and management, the professional with the BC-ADM credential necessarily incorporates aspects of diabetes self-management training (DSMT) into his or her practice, either directly or through referral to another qualified diabetes educator (AADE, 2008).
References:
Medical Nutrition Therapy (MNT)

- Medical Nutrition Therapy (MNT) is important in preventing diabetes, managing existing diabetes, and preventing, or at least slowing, the rate of development of diabetes complications. MNT continues to be an integral component of diabetes management and of diabetes self-management education (ADA, 2008).
- MNT should be individualized, based on the person’s metabolic needs, food preferences, and willingness to make lifestyle changes.
- A registered dietitian (RD), licensed in South Dakota, who is knowledgeable and skilled in implementing diabetes medical nutrition therapy should be the team member with primary responsibility for nutrition care and education.
- Weight loss is recommended for all overweight and obese individuals and should include structured programs emphasizing lifestyle changes, behavior modification, education, reduced energy and fat intake, and exercise.
- The ADA (2008) has revised its recommendations for weight loss to include either low-carbohydrate or low-fat calorie-restricted diets for short-term use of up to one year.
- For patients using low-carbohydrate diets, healthcare providers should monitor lipid profiles, renal function, and protein intake in patients with nephropathy, and adjust hypoglycemic therapy as needed (ADA, 2008).

What is Medical Nutrition Therapy?
MNT consists of nutrition assessment and the development of an individualized nutrition prescription based on treatment goals. MNT should be customized for each individual, taking into account age, cultural beliefs, weight, lifestyle, and other related medical, social, or psychological conditions. Nutrition counseling should be sensitive to the personal needs and willingness and abilities of the individual to make healthy lifestyle changes associated with diabetes or pre-diabetes.

To achieve nutrition-related goals, a coordinated team effort should include the person with diabetes and involve him or her in the decision-making process. A comprehensive assessment should include sensitivity to cultural, ethnic, and financial considerations, willingness to change, and ability of the individual to incorporate the lifestyle changes associated with a comprehensive self-management education program. Although it is recommended that a registered dietician be the team member who plays the leading role in providing nutrition care, it is important that all team members including physicians and nurses be knowledgeable about MNT and support its implementation.

What are the goals of Medical Nutrition Therapy?
According to the ADA (2008), the overall goals of MNT apply to individuals at risk for diabetes, those with pre-diabetes, and individuals with existing diabetes. Additionally, specific consideration should be given to the unique nutritional needs in the life cycle such as youth with type 1 diabetes, pregnant and lactating women, and older adults. The 2008 recommendations strive to make people with diabetes and healthcare providers aware of the beneficial interventions of MNT and include the latest scientific evidence-based practice recommendations.
**Prevention and Treatment**

1. Delay or halt the development of diabetes (primary prevention interventions).
2. Reduce the prevalence of obesity and pre-diabetes.
3. Decrease the risk of diabetes and cardiovascular disease (CVD) by promoting healthy food choices and physical activity leading to moderate, maintainable weight loss.
4. Manage existing diabetes and prevent or slow the rate of developing the long-term complications of diabetes such as renal disease, neuropathy, retinopathy, hypertension, and cardiovascular disease.
5. Achieve and maintain blood glucose levels in the normal range or as close to normal as is safely possible.
6. Maintain blood lipid levels that reduce the risk for macrovascular disease.
7. Maintain blood pressure levels in the normal range or as close to normal as is safely possible that reduce the risk for vascular disease.
8. Provide adequate calories for maintaining or attaining body weight goals, and for normal growth and development in children, during pregnancy and lactation, and older adults.
9. To maintain the pleasure of eating by only limiting food choices when indicated by scientific evidence.
10. Improve health through healthy food choices and physical activity while considering personal and cultural preferences and lifestyle, respectful of the individual’s wishes and willingness to make lifestyle changes.
11. For individuals treated with insulin or insulin secretagogues, to provide self-management training for the safe conduct of exercise, including the prevention and treatment of hypoglycemia, and diabetes treatment during acute illness.

**What are the components of a nutrition prescription/meal plan?**

1. Calories based on individual needs and weight management goals.
2. A dietary pattern that includes carbohydrates from fruits, vegetables, whole grains, legumes, and low-fat milk is recommended. Carbohydrate counting is an integral part of nutritional self-management.
3. Protein should provide 10 to 20 percent of total energy intake.
4. Saturated fat should be limited to < 10 percent of total energy intake.

**What is the recommended nutrition therapy for someone with type 1 diabetes?**

1. Follow the ADA protocols for medical nutrition therapy for type 1 diabetes.
2. In the first three months after diagnosis, three to four appointments with a registered dietitian.
3. Four routine follow-up visits per year with dietitian.

**What is the recommended nutrition therapy for someone with type 2 diabetes?**

1. Follow the ADA protocols for medical nutrition therapy for type 2 diabetes.
2. Up to four routine follow-up visits per year with a registered dietitian.
References:
Self-Monitored Blood Glucose Testing (SMBG)

- SMBG is important for all persons with diabetes in order to achieve glycemic control.
- SMBG is an essential management strategy in achieving tight glycemic control.
- The frequency of SMBG is influenced by mode of treatment, level of control, and treatment goals.
- In 2006, 64.0 percent of BRFSS respondents with diabetes reported checking their blood glucose at least once a day.

**Why is SMBG important?**
Self-monitoring of blood glucose allows persons with diabetes to achieve very specific glycemic goals. Maintenance of normal or near-normal blood glucose levels has major health benefits for persons with diabetes. Results of the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) indicate that there is a direct relationship between blood glucose level and the risk of future diabetes related complications (diabetic retinopathy, nephropathy, and neuropathy). Both the development and the progression of microvascular complications are slowed with improved glucose control.

**How many times a day should SMBG be done?**
Persons with type 1 diabetes should be encouraged to use SMBG for routine daily monitoring. For most persons with type 1 diabetes, SMBG is recommended three or more times a day; frequency and timing of SMBG should be determined by individual needs and goals.

The optimal frequency of SMBG in persons with stable diet-treated type 2 diabetes is not known but should be sufficient to facilitate attaining glycemic control goals. Times may include fasting, preprandial and postprandial. Varying the times may give a better picture of overall achievement of goals. The ADA recommends SMBG for all patients being treated with insulin or sulfonylureas, and for all patients who are not achieving their glycemic goals. Daily SMBG is especially important for patients treated with insulin or sulfonylureas to prevent asymptomatic hypoglycemia.

For both type 1 and type 2 diabetes, testing should occur more frequently when modifying therapy. It is the ADA’s recommendation that efforts should be made to substantially increase the appropriate use of SMBG. *(For recommendations for gestational diabetes see page 23.)*

**How accurate are SMBG measurements?**
Each patient’s ability to use monitoring equipment, along with their knowledge of instrument calibration, needs to be evaluated by health practitioners at regular intervals to assure accuracy. It is crucial that people with diabetes know whether their monitor and strips provide whole blood or plasma results. Plasma glucose values are 10 to 15 percent higher than whole blood glucose values. It is important that individuals understand what a “normal” blood glucose range is for them. A recent study found that forearm results were dramatically different from finger stick results and that finger stick measurements should always be used to confirm a forearm test that is not consistent with how the patient feels.

**What information do persons using SMBG need to know?**
Patients using SMBG should be taught how to adjust their medical nutrition regimens, exercise, and pharmacological therapy in response to results of SMBG. Patients also need to know when to call their health care team.
References:
Continuous Glucose Monitoring (CGM)

- Continuous glucose monitoring is a recent technological advance that provides real-time blood glucose data every one to five minutes, depending upon the model and mode of instrumentation.
- Data from ongoing clinical trials indicates great potential to improve glycemic control in adults and children with diabetes mellitus by: 1) providing capabilities with the monitoring device to alert the individual of high or low glucose values, and providing treatment to prevent hypo/hyperglycemia; 2) providing a means for real time insulin adjustments based on glucose values that may be rising, falling, or stable; and 3) allowing a retrospective review of glycemic excursions based upon time of day, activity level, and food intake that can be used to refine insulin adjustments.
- CGM technology is part of a futuristic approach leading to the development of an artificial pancreas that would provide an automated fully closed-loop insulin delivery system that mimics the way a real pancreas would act, by continuously monitoring blood glucose and constantly adjusting the level of insulin needed to keep glucose in an acceptable range.

What is continuous glucose monitoring (CGM)?
Continuous glucose monitoring is a recent technological advance that utilizes a minimally invasive device connected via a wire to a subcutaneous sensor that can be worn continuously up to 72 hours to monitor interstitial glucose levels, with capabilities to provide real-time blood glucose data every one to five minutes, depending upon the parameters of the model.

Continuous readings obtained create a trend line that can be used to understand how insulin, food, exercise, and other variables affect glucose values. Detailed information about blood glucose fluctuations trends the extent, duration, and frequency of elevations or drops in blood sugars. Data obtained during continuous monitoring highlights the relationships of excursions in blood glucose to certain activities or food, and helps predict or possibly prevent episodes of hypo or hyperglycemia.

How does the device work?
A small sensor is inserted under the skin via a needle mechanism that measures glucose in the interstitial fluid between the body’s cells. This means there is no blood involved. The sensor relays the glucose level to a device that displays the glucose reading, displayed with arrows that show upward or downward trends. The patient can then make adjustments in the insulin to keep glucose at an acceptable range.

When is continuous glucose monitoring used?
CGM can be utilized as an adjunct to therapy with certain insulin pumps or as a diagnostic tool device to facilitate adjustments in therapy to improve control. Health care providers may utilize CGM in either home or clinical settings for up to 72 hours as an assessment tool to obtain detailed information about blood glucose excursions and fluctuations.

This is accomplished by utilizing the same type of subcutaneous sensor attached to a small computer-like device that downloads and records information regarding blood glucose patterns over the 72-hour period it is worn. The report generated by the device allows the trained healthcare provider to analyze the data along with the patient’s records of food intake, activity, medication use, and to monitor adverse events such as hypoglycemia.
Data obtained from this test allows the healthcare provider to make adjustments in drug therapy, support suggested lifestyle modifications, monitor conditions where tighter control without hypoglycemia is needed (gestational diabetes, pediatric patients, and intensive care), and to diagnose and prevent hypoglycemic unawareness, hypoglycemia during sleep, and observe high or low post-prandial readings.

**What are the potential advantages of CGM?**
Recent clinical trials have indicated that use of continuous glucose monitoring has been associated with decreased time spent in hyper/hypoglycemic ranges, and an increased amount of time spent in a euglycemic range. Both adults and children achieved A1C reductions without additional hypoglycemia. In pediatric patients, use of CGM offers families’ new management approaches, the potential for improved glycemic control, and improved quality of life. An added benefit of close monitoring is fewer excursions in glucose levels < 70 mg/dl and > 190 mg/dl, yielding less glycemic instability and fewer swings that necessitate costly visits to the emergency room to treat severe hypoglycemia and DKA. Data can also be used to distinguish between the Dawn and Somogi phenomenons. Patients should confirm high or low monitor alarms with a finger stick before any corrective action is taken regarding additional food or insulin, due to the lag time difference between capillary and interstitial sites.

Patients experience better self-management and are able to see a correlation between diet, exercise, and medication and how they affect glucose levels. CGM allows patients to make changes in therapy earlier before preventive actions are not possible.

In actual practice settings, CGM has been implemented in the operating room preceding anesthesia induction, during the time of surgery, and in the post-operative period to reduce periods of hypo/hyperglycemia, decreased infection rates, and increased recovery time in patients with diabetes.

**Are there disadvantages to CGM?**
There are a number of disadvantages to continuous glucose monitoring and it is not indicated for all patients. Clinical trials are currently ongoing, and at this time clinicians have not yet developed implantation and dissemination tools and algorithms for optimized use and patient selection. Many challenges are involved with how to handle, manage, and trend the voluminous amount of data generated by the monitor without overwhelming both patients and practitioners.

Insulin pump therapy is generally covered by insurance. Due to its novelty, CGM is not always afforded reimbursement, but diagnostic 72-hour CGM through a healthcare provider may be covered by insurance with appropriate justification at time of submission. Costs incurred for transmitters and glucose sensors may be out-of-pocket expenses for patients. Because of the complex nature of the monitoring device, both providers and patients require training in sensor use and trend interpretation.
What effect will CGM have on the future of diabetes care?
Futuristic trends in diabetes technology would be the eventual development of an automated fully closed-loop insulin delivery system than would regulate blood sugar like the beta cells within the pancreas, i.e. an “artificial pancreas.” A limitation in the development of the artificial pancreas has been related to the lack of robust continuous glucose monitoring capabilities and mature control algorithms that are capable of driving the insulin delivery system.

Currently, the FDA has approved five continuous glucose monitoring devices, and a sixth is in the final stages of clinical trials. Great potential exists for improved glycemic control in adults and children with diabetes to enhance quality of life, increase management flexibility, and reduce the complications related to diabetes mellitus.

References:
Tobacco Use Status and Counseling

- Screen at time of diagnosis.
- Routine and thorough assessment of tobacco use is an important way to prevent smoking/chewing, prevent use relapse, and encourage cessation in patients of all ages.
- Providers should assess the level of nicotine dependence to assess probability of success in quitting versus relapse.
- Offer every tobacco user assistance in obtaining cessation treatment.
- > 20 percent of deaths from CVD can be directly linked to cigarette smoking.
- Smoking cessation can reduce risk of coronary death by 50 percent within 1 year.
- In 2006, 16.0 percent of BRFSS respondents with diabetes reported being current smokers while 5.7 percent reported using chewing/spit tobacco.

Tobacco use is the leading cause of preventable death in the United States, and is responsible for over 430,000 deaths each year. People with diabetes who use tobacco are at increased risk of both macrovascular and microvascular complications. Recent research has suggested that tobacco use may also increase the risk of developing type 2 diabetes mellitus.

Exposure to secondhand smoke puts non-smokers at risk for developing heart disease (25 to 30 percent), lung cancer (20 to 30 percent), sudden infant death syndrome (SIDS), respiratory problems, ear infections, and asthma attacks in infants and children. Findings from a recent U.S. Surgeon General’s report indicate second-hand smoke exposure is a major public health concern for non-smoking Americans, especially those with diabetes. One of the major ways to protect the general non-smoking public from dangerous chemicals emitted through secondhand smoke is to eliminate smoking in public places. Second-hand smoke is responsible for approximately 50,000 deaths per year, with one out of every eight of those deaths being children.

Tobacco cessation is one of the most modifiable life style behaviors that patients can incorporate to decrease the risk of premature death. Studies have established a link between cigarette smoking (tobacco use) and increased morbidity, premature death, and macrovascular complications.
What questions should be included in an assessment?

All patients should be assessed for tobacco use at the time of diagnosis (Figure 6) by using the five A’s from the Guideline for Treatment of Tobacco Use and Dependence from the U.S. Department of Health and Human Services:

- Ask if the patient uses tobacco
- Advise the patient to quit if they use tobacco
- Assess the willingness of the patient to quit tobacco
- Assist the patient in their quit attempt
- Arrange follow-up for the patient

Questions to consider in assessing the patient should include:

- How many cigarettes/dips are used daily?
- How soon after awakening does the patient use tobacco?
- Have attempts been made to quit or to reduce the amount of tobacco used?
- What are triggers for this patient to use tobacco?
- Does this patient have a plan in place for quitting? And if not, then the patient should be referred to tobacco cessation services for assistance.

Patients should be encouraged to quit using tobacco at each visit, and if the patient has quit, should be assessed for relapse or potential for relapse at each visit as well.

If not using tobacco:

- Assess risk for starting or relapse
- Congratulate and encourage continued abstinence

How can a healthcare provider help patients stop tobacco use?

Tobacco dependence is a chronic condition that often requires intervention. However, effective treatments exist that can produce long term or permanent abstinence. Every patient who uses tobacco should be offered one of these treatments, as outlined by the U.S. Department of Health and Human Services. Intervention is based on a patient’s willingness to quit. Patients willing to try to quit should be provided with assistance and offered effective pharmacotherapy (nicotine replacement therapy, Bupropion SR, or varenicline). (Table 16)

http://www.surgeongeneral.gov/tobacco/

What smoking cessation information and programs are available in South Dakota?

The South Dakota QuitLine (1-866-SD-QUITS or 1-866-737-8487) offers a range of services, from individual, pro-active telephone counseling to providing referrals to local cessation classes in the community. Tobacco users can also find out if they are eligible for cessation medication through the South Dakota Quitline. Information regarding the Quitline is available through the South Dakota Department of Health Tobacco Control Program’s website at http://doh.sd.gov/tobacco.
Figure 6: Screen for Tobacco Use

If Uses Tobacco
- Advise to quit
- Is patient willing to quit?
  - Yes
    - Willing to Quit
      Congratulate and assist with quit plan (STAR) or provide appropriate referral.
      - Set a quit date within 2 weeks
      - Tell family, friends and coworkers about quitting and request support
      - Anticipate challenges to planned quit attempt including nicotine withdrawal symptoms
      - Remove tobacco products from home and avoid smoking in places where they spend a lot of time (car, home, work)
      Recommend appropriate use of effective pharmacotherapy if smokes >10 cig/d and no contraindications
  - No
    - Not Willing to Quit
      Relevance: Ask the patient to identify why quitting is personally relevant
      Risks: Ask the patient to identify potential negative consequences of tobacco use
      Rewards: Ask the patient to identify potential benefits of stopping tobacco use
      Roadblocks: Ask the patient to identify barriers to quitting and note elements of treatment that could address barriers
      Repetition: Each time an unmotivated patient visits the clinic repeat the motivational interventions

If Not Using Tobacco
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Arrange Follow-up
<table>
<thead>
<tr>
<th>Type of NRT</th>
<th>Cautions</th>
<th>Adverse Effects</th>
<th>Dosing</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>All forms of NRT</td>
<td>• Concomitant tobacco use</td>
<td>• Jaw pain</td>
<td>• Nicotine gum 2mg (pt smokes &lt; 25 cigs/day) 1 piece q1-2 hr prn up to 12 weeks</td>
<td>• Chew slowly</td>
</tr>
<tr>
<td></td>
<td>• Less than 18 years old</td>
<td>• Dyspepsia, nausea</td>
<td>• Nicotine gum 4mg (pt smokes ≥25 cig/day) 1 piece q1-2 hr prn up to 12 weeks</td>
<td>• Once tingling sensation felt, park gum in between cheek and gum</td>
</tr>
<tr>
<td></td>
<td>• Active coronary artery disease including immediate post MI period, unstable angina</td>
<td>• Caution if TMJ syndrome or poor dentition</td>
<td></td>
<td>• Chew again when tingling goes away</td>
</tr>
<tr>
<td></td>
<td>• Life threatening arrhythmias</td>
<td></td>
<td></td>
<td>• No acidic beverages immediately before or after use</td>
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<td></td>
<td>• Pregnancy/nursing</td>
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<tr>
<td></td>
<td>• Stopping smoking can increase blood levels of medications (e.g. Theophylline, clozapine)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Check with pharmacy</td>
</tr>
<tr>
<td>Nicotine Gum</td>
<td></td>
<td>• Local irritation in mouth and throat</td>
<td>• 4mg (1 cartridge) 6-16 times a day prn up to 6 months</td>
<td>• Place plug in two-piece inhaler</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Caution if history of asthma</td>
<td></td>
<td>• Pt. inhales on mouthpiece as desired; one plug provides 80 inhalations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Use 6 to 16 plugs/day</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• No acidic beverages immediately before or after use</td>
</tr>
<tr>
<td>Nicotine Inhaler</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transdermal</td>
<td>• Skin sensitivity</td>
<td>• Initial nasal and throat irritation</td>
<td>• Nicoderm CQ 21 mg/d x 4 weeks, then 14 mg/d x 2 weeks, then 7 mg/d x 2 weeks</td>
<td>• Apply to area of skin without hair</td>
</tr>
<tr>
<td>Nicotine Patch</td>
<td>• Sleep disturbance (remove at night)</td>
<td>• rhinitis, sneezing, coughing</td>
<td>• Nicotrol 15 mg/16h x 8 wks</td>
<td>• If problems with sleep disturbance, remove at night and replace in morning</td>
</tr>
<tr>
<td>Nicotine Nasal</td>
<td>• Initial nasal and throat irritation, rhinitis, sneezing, coughing</td>
<td>• ? Dependence</td>
<td>• One dose = 1 spray each nostril</td>
<td>• Device similar to a nasal steroid spray delivers 1 mg of nicotine to nasal mucosa</td>
</tr>
<tr>
<td>Spray</td>
<td>• ? Dependence</td>
<td></td>
<td>• 8-40 doses/day prn for 3-6 months</td>
<td>• Rapid high serum levels may help highly dependent</td>
</tr>
</tbody>
</table>
### Contraindications and Cautions

<table>
<thead>
<tr>
<th>Type of NRT</th>
<th>Bupropion SR</th>
</tr>
</thead>
</table>
|             | • Patients with seizure disorders (contraindicated)  
|             | • Patients predisposed to seizures due to bulimia, anorexia nervosa (contraindicated)  
|             | • Concurrent therapy with MAIO’s, selected antidepressants  
|             | • With caution in hepatic dysfunction, end stage cirrhosis  
|             | • With caution in medical conditions that may increase seizure risk  
|             |   • Severe head trauma or CNS tumor  
|             |   • History of seizures  
|             |   • Abrupt withdrawal from alcohol, other sedatives  
|             |   • Opiate, cocaine, or stimulant addiction  
|             |   • Diabetics treated with oral hypoglycemics |

### Adverse Effects and Instructions

<table>
<thead>
<tr>
<th>Adverse Effects</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep disturbances</td>
<td>Begin one to two weeks before quit date</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>150 mg every day for 3 days then 150 mg BID for 7 to 12 weeks (average duration of therapy 8 weeks)</td>
</tr>
<tr>
<td>Type of NRT</td>
<td>Contraindications and Cautions</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
</tr>
</tbody>
</table>
| Chantix (varenicline) | • Not recommended for use in patients under 18  
• Has no clinically meaningful pharmacokinetic drug interactions  
• Use in pregnancy only if potential benefits justify potential risk to the fetus  
• Contraindicated in nursing mothers as drug may be transferred in breast milk  
• Physiologic changes resulting from smoking cessation with or without the use of Chantix may alter pharmacokinetics or pharmacodynamics of certain drugs—theophylline, warfarin, or insulin  
• Nicotine withdrawal may be associated with exacerbation of underlying psychiatric illness; symptoms may include emotional distress, anxiety, depression, irritability, restlessness |

<table>
<thead>
<tr>
<th>Common Side Effects</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| • Disturbances in attention, dizziness, sensory disturbance  
• Nausea, vomiting, sleep disturbance, constipation, flatulence  
• Polyuria  
• Menstrual disorders  
• Side effects can be minimized or reduced by titrating at a slower rate or leaving a patient at a lower dose, as 0.5 mg BID has still been shown to have a positive effect on tobacco cessation | The patient should set a date to stop smoking. Dosing should start 1 week before the date. Take after eating with a full glass of water.  
Recommended dose is 1mg BID following a one week titration:  
Day 1-3: 0.5mg once daily  
Day 4-7: 0.5 mg BID  
Day 8-end of treatment: 1mg BID  
Treatment is for 12 weeks. An additional 12 week course is recommended to further increase likelihood of long term abstinence. Patients who do not succeed or relapse can make another attempt once factors contributing to failure have been identified and addressed.  
A maximum of 0.5 mg BID should be utilized in patients with reduced kidney function as varenicline is largely excreted through the kidneys.  
As patients abstain from utilizing tobacco, the provider may need to adjust doses of medication such as warfarin that interacts with the P450 system, as nicotine is a potent P450 inhibitor and reduction or removal of nicotine will affect this system. |
References:
**Diabetes Mellitus and Exercise**

- A minimum of 30 minutes of moderate-intensity aerobic physical activity 5 days per week, or vigorous-intensity aerobic physical activity for 20 minutes 3 times per week is recommended for healthy adults aged 18 to 65. Physicians are encouraged to modify exercise guidelines to meet individual patient’s needs according to level of activity tolerated, comorbid conditions which may limit vigorous physical activity, or diabetes complications (retinopathy, neuropathy, amputation, etc.) which may limit physical activity.
- The goal of physical activity/exercise is to maintain near-normal blood glucose and lipid levels to prevent microvascular, macrovascular, and neural complications.
- Exercise is Medicine! It can lower blood pressure, decrease blood glucose, reduce weight, improve cholesterol, enhance sleep, maintain bone and heart health, and decrease the risk of cancer.
- Exercise programs should be individualized to maximize benefit and minimize risk.
- The ADA recommends that vigorous activity be avoided in the presence of hyperglycemia with ketosis. However, a patient with type 2 diabetes in the postprandial state who is well hydrated and non-ketotic should not have exercise postponed based solely on hyperglycemia.
- Depending on the level and duration, one occasion of aerobic exercise can increase insulin sensitivity for 24 to 72 hours.
- To improve glycemic control, assist with weight maintenance, and reduce CVD risk, at least 150 min/week (30 min/day – 5 days/week) of moderate intensity aerobic physical activity (40-70 percent of Vo2) is recommended. Individuals with type 2 diabetes should strive to achieve a minimum cumulative total of 1000 kcal/week from physical activities.
- Examination of the feet, with shoes and socks off, should be done on a daily basis by the patient and at each clinic visit by the physician.
- Resistance training preserves muscle mass, improves balance, increases functional capacity, increases metabolic rate, decreases adiposity, and increases insulin sensitivity at about the same rate as aerobic exercise.
- The benefit of exercise in lowering the hemoglobin A1C level is independent of associated weight loss.
- In 2006, 9.3 percent of BRFSS respondents with diabetes reported having no leisure time physical activity.

According to the Surgeon General, physical activity can be described as bodily movement produced by the contraction of skeletal muscle that requires energy expenditure in excess of resting energy expenditure. Exercise has been defined as physical activity and/or movement that is planned and structured with the intention to keep a person fit and healthy. Current opinion is that regular physical activity is an important therapeutic tool for people with diabetes. However, the benefits and risks for each individual need to be identified and exercise programs need to be individualized.

Prior to beginning an exercise program more vigorous than brisk walking, people with diabetes should be evaluated for the presence of conditions likely to increase CVD risk factors or predisposition to injury, such as uncontrolled hypertension, severe autonomic or peripheral neuropathy, pre-proliferative or proliferative retinopathy, or macular edema. The patient’s age and previous physical activity level should be evaluated.
Muscular-strengthening training (strengthening of muscles using equipment such as free weight, resistance bands, and weight machines) has recently been added to the activity plan for patients with diabetes based on a Canadian study conducted by Sigal et al. Study findings noted a 0.6 percent drop in hemoglobin A1C levels with both aerobic and resistance activity individually, but by combining both activities, a 1 percent absolute reduction in A1C readings was appreciated. This translates into about a 15 to 20 percent reduction in major cardiovascular events, and a 37 percent decrease in microvascular complications.

What are physical activity recommendations for people with diabetes?
Based on guidelines from the American College of Sports Medicine and American Heart Association, basic exercise recommendations for adults over age 65 (or adults 50 to 64 with chronic conditions such as arthritis) with diabetes are as follows:

1. Do moderate-intense aerobic activity 30 minutes a day, 5 or more days a week, or
2. Do vigorous-intensity aerobic exercise 20 minutes a day, 3 or more days a week, and
3. Do 8 to 10 strength-training exercises, 10 to 15 repetitions of each exercise twice to three times per week, and
4. If patient is at risk of falling, perform balance exercises, and
5. Have a physical activity plan.

Both aerobic and muscle-strengthening activities are critical for healthy aging. **Moderate-intensity aerobic exercise** means working hard at about level three intensity on a scale of ten. The patient should still be able to carry on a conversation during this physical activity and start to break a sweat.

Older adults or adults with chronic conditions should develop an **activity plan** with a health professional to manage risks and take therapeutic needs into account. This will maximize the benefits of physical activity and ensure safety.

It is recommended that patients who have an impaired glucose tolerance follow a program that includes a healthy diet with weight control and at least 150 min/week of moderate to vigorous physical activity.

**Evaluating risk and prescribing exercise to minimize risk.**

**Coronary Artery Disease**

All patients with diabetes participating in aerobic exercise should undergo a stress test to assess maximal heart rate, to assist in setting targets for maximum exercise intensity, to determine functional capacity, and to assess prognosis. Currently, there is no clinical evidence to guide practitioners on the need for stress testing prior to resistance training.

In patients who are sedentary, a graded exercise test with EKG monitoring should be considered before prescribing a physical activity greater than the energy needs of activities of daily living or more intense that brisk walking, or if the patient’s ten year risk of having a coronary event is greater than 10 percent. The free UKPDS Risk Engine located at [http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/](http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/) can assist in determining a patient’s risk factor for non-fatal and fatal coronary heart disease, fatal coronary heart disease, non-fatal and fatal stroke, and fatal stroke based on age, gender, ethnicity, duration of diabetes, smoking status, hemoglobin A1C level, systolic blood pressure, total cholesterol, HDL cholesterol, and absence or presence of atrial fibrillation.
Patients who should have the graded exercise test with EKG monitoring include any patient over the age of 30 who is sedentary with a history of tobacco use, hypertension, dyslipidemia, proliferative/preproliferative retinopathy or nephropathy (including microalbuminuria) with diabetes greater than 10 years duration, and a greater than 10 percent risk of a coronary event. Others who should have this exam include all patients, regardless of age, exhibiting complications of known or suspected CAD, CVD, peripheral vascular disease, autonomic neuropathy, or advanced nephropathy with renal failure.

Patients with coronary artery disease should undergo an evaluation of exercise tolerance supervised by a physician with expertise in stress testing. Recommendations about appropriate exercise are dependent on the interpretation of exercise stress testing.

**Peripheral Vascular Disease**
If peripheral vascular disease (PVD) has been diagnosed through a history and physical exam, a referral for consultation should be made with a physician experienced in the care of patients with significant peripheral vascular disease to design an appropriate exercise program.

**Retinopathy**
Annual dilated retinal exam is sufficient to identify patients with diabetic retinopathy. Since retinopathy is a risk factor for coronary artery disease, patients with proliferative or preproliferative retinopathy who intend to pursue moderate or intense exercise programs should undergo a graded cardiac exercise test with EKG monitoring.

Progression of nonproliferative diabetic retinopathy and macular edema do not seem to be affected by either resistance or aerobic exercise. However, if proliferative or severe non-proliferative retinopathy exists, vigorous aerobic or resistance activities may be contraindicated due to the risk of triggering vitreous hemorrhage or retinal detachment (e.g. lifting heavy objects or any contact sport). People with diabetes need to be cautioned about engaging in activities that cause blood pressure to increase dramatically, such as head-down or jarring activities or those with arms overhead.

**Nephropathy**
Annual urine screening for proteinuria and microalbuminuria is sufficient to identify patients with nephropathy. Currently, there is no clinical evidence to suggest that vigorous exercise increases the rate of progression of diabetic nephropathy. In fact, some studies have shown that aerobic exercise actually decreased urine protein excretion. Additionally, it has been demonstrated that resistance training may have a beneficial affect on muscle mass, nutritional status, functional capacity, and glomerular filtration rate. Therefore, the American Diabetes Association feels that there is no need to restrict exercise in patients with diabetic nephropathy.

Due to the fact that microalbuminuria and proteinuria are risk factors associated with cardiovascular disease, sedentary patients with these findings should have a graded exercise test with EKG monitoring before beginning anything more rigorous than their normal activities of daily living.
Peripheral Neuropathy
Peripheral neuropathy can be detected by physical examination. Decreased pain sensation in the extremities can result in increased risk of skin breakdown, infection, and Charcot joint destruction. Signs of peripheral neuropathy include impairments in: deep tendon reflexes, vibratory sense, position sense, and sensation to touch. The main consideration with exercise in patients with peripheral neuropathy is the loss of protective sensation in the legs and feet that can lead to musculoskeletal injuries and infection. Reinforce with patients the need for proper footwear and to check their feet after exercise. Significant peripheral neuropathy is a contraindication to weight bearing exercise. Examples of non-weight bearing activities include swimming, bicycling, rowing, and arm exercises.

Autonomic Neuropathy
History and physical examination can detect autonomic neuropathy. Autonomic neuropathy can increase the risk of exercise-induced injury by decreasing cardiac responsiveness to exercise. Symptoms of autonomic neuropathy include: gastrointestinal symptoms, urinary system symptoms, and defective thermoregulatory capacity. Signs of autonomic neuropathy include abnormalities of skin color and abnormalities of body temperature. Autonomic neuropathy may limit exercise capacity and may increase a patient’s risk of a cardiovascular complication during exercise. Patients may have defective thermoregulatory capacities, thus they should be advised to avoid exercising in extreme temperatures and be attentive to their hydration status. Patients may be predisposed to hypotensive or hypertensive episodes following exercise, thus patients should be encouraged to participate in lower intensity exercise to avoid dramatic change in heart rate and blood pressure. An active cool-down is important in preventing a post-exercise hypotensive response. Signs of cardiac autonomic neuropathy include resting tachycardia (> 100 beats per minute) and orthostasis (> 20 mmHg drop in systolic pressure on standing), thereby making traditional exercise prescriptions based on heart rate inaccurate. Cardiac autonomic neuropathy is associated with sudden death and silent myocardial ischemia. The Rate of Perceived Exertion (RPE) scale or %Vo2 Max can be used to determine exercise intensity. Patients with cardiac autonomic neuropathy should be evaluated by a cardiologist prior to initiating an exercise program. In fact, some advocate thallium scintigraphy for use in screening patients with this condition.

General recommendations about exercise programs.

Program intensity
Physical activity of low to moderate levels for patients with type 2 diabetes will minimize risks and maximize health benefits. Low to moderate intensity level exercise programs may be easier for patients to follow and maintain.

Pre-exercise preparation
- Exercise should be avoided at time of peak insulin activity.
- To prevent increased insulin absorption, injections should be administered in body areas not involved with activity, e.g. abdomen.
- Patients should check their blood glucose levels before and after exercise, as well as several hours following completion of exercise until they know the effect of physical activity on their blood glucose levels.
- In type 1 diabetes, vigorous activity should be avoided in the presence of ketosis and caution should be used with any physical activity/exercise for blood glucose levels > 300 mg/dl even if no ketosis is present. However, in type 2 diabetes, if the blood glucose is greater than 300 mg/dl without ketosis and the patient feels well and is well hydrated, exercise need not be postponed based on hyperglycemia.
Pre-exercise carbohydrate should definitely be taken to avoid hypoglycemia if pre-exercise glucose levels are < 100 mg/dl and the patient is taking insulin or a secretagogue, or the dosage of medication reduced before sessions of physical activity. However, patients who are not taking either insulin or secretagogues but are controlling their blood glucose levels with diet, metformin, α-glucosidase inhibitors, and/or thiazolidinediones usually will not need additional carbohydrates.

- Carbohydrate-based foods should be readily available during and after exercise.
- Proper warm-up and cool down period will decrease injuries.
- Diabetic ID bracelet or shoe tag should be worn.

**Hydration**

- Adequate hydration is necessary to maintain blood glucose levels and assure optimal cardiovascular function.
- Exercise in heat requires vigilant attention to hydration status.
- Pre-exercise hydration is particularly useful. For events lasting up to one hour, plain water is best. If activity is over one hour, fluids containing a 6 to 8 percent carbohydrate solution are best.

**Foot care**

- People with diabetes should be encouraged to take precautions to avoid injury to their feet.
- Silica gel or air mid-soles decrease impact.
- Polyester and cotton-polyester blend socks may be helpful in preventing blisters.
- Patients should be encouraged to change their socks before and after exercise.
- Properly fitting footwear is very important.
- Patients should know to examine their feet closely for blisters before and after exercise.

**Post-exercise routine**

- Patients should monitor their blood glucose levels after exercise in order to learn their metabolic response to different exercise conditions.
- Post exercise hypoglycemia may occur up to 30 hours later, especially after prolonged or vigorous exercise.
References:
Behavioral Changes/Healthy Lifestyle Changes

- Assess key psychosocial factors as part of the medical management of diabetes, including attitudes about diabetes diagnosis, expectations for care, affect/mood, quality of life, financial, social, and emotional support and resources, and psychiatric history.
- Patients should be screened for psychosocial problems such as depression, eating disorders, and cognitive impairment when poor adherence to medical regime is noted.
- Set realistic goals through collaboration with the patient.
- Identify community supports and make appropriate referrals

What does psychology have to do with diabetes care?
One of the biggest struggles for both patients and practitioners is identifying, addressing, and accomplishing the behavioral changes necessary to achieve the best possible diabetes management in their daily lives. Best medical practice requires practitioners to incorporate both the “science” and “art” of behavior change. There is a wealth of research in the behavioral science literature on factors that lead to best outcomes in diabetes management.

Diabetes interventions are predominantly “behavioral.” The delivery of successful medical care for individuals with diabetes ultimately depends on their ability to “self-manage.” Over time, the behavioral science literature reviews and position statements have consistently shown that:
- People of all ages have difficulty following diabetes regimens.
- People can do well with some aspects of their care while having extreme difficulty with other aspects.
- Children and adults living with diabetes have the most difficulty with the following, in order:
  1. Diet
  2. Exercise
- Timing and adjustment of diabetes medications is difficult and can result in adherence issues.
- Miscommunication between patients and providers on important aspects of diabetes care is an ongoing issue.

What are the key psychosocial factors affecting chronic care?
Best practice looks at assessing the “whole person” to assess where potential strengths and weaknesses with the diabetes regime are likely to occur. Assessment should include, but is not limited to, the following areas:

In child and adolescent patients:
- Developmental stage
- Temperament
- Parent-child issues
- Family dynamics
- Extended family/support
- Cognitive/school issues
- Psychiatric history (patient, family)
- Substance use/abuse
- Cultural issues
Overall “quality of life”
Weight history/genetics
Coping skills

In adult patients:
Personality
Natural/acquired coping skills/style
Role of significant others (helpful, hurtful)
Role of family of origin
Diabetes at work and play
Psychological factors/predictors of poor adjustment
Psychiatric history (patient, family)
Substance use/abuse
Cultural issues
Overall “quality of life”
Weight history/genetics

Treatment issues across the ages.
Depression is more common among people with diabetes than it is in the general public
1. may be more severe for people with diabetes
2. has an adverse effect on diabetes control and self-care
3. is often undiagnosed and untreated
4. can be treated with psychotherapy and/or psychopharmological agents
Anxiety
1. appears to be more prevalent in people with diabetes than the general population
2. can be treated with psychotherapy and/or psychopharmological agents
Eating disorders (anorexia nervosa and bulimia nervosa)
1. appear to be more common in people with diabetes than the general public
2. may be more severe for people with diabetes
3. have an adverse effect on diabetes control
Setting realistic goals: Collaboration is key
Diabetes team issues: When practitioners disagree on care
Team-family collaboration/conflict
Struggles with adherence
Meal planning
Exercise
Peer issues
Provider and patient burnout
Economic issues
Cultural factors

What behavioral strategies enhance diabetes management?
Adopt an educational model of patients as “continuous learners.”
Individualize treatment to fit strengths/weakness of patient/family, including assessing
individual patient “coping style.”
Incorporate “empowerment” approaches to enhance patient’s “self-efficacy” (i.e., patient
successfully targeting and accomplishing a particular goal).
Motivational interviewing (MI) is a technique that assists the patient in identifying feelings of ambivalence that exist when working to change a behavior. MI relies on the patient’s own inner strength and values rather than external threats and coercion. The patient assumes responsibility for their choices and the subsequent consequences (Rollnick and Miller, 2001).

Assess readiness for behavior change:
1. Precontemplation – not thinking about change
2. Contemplation – considering change in the foreseeable future
3. Preparation – seriously considering change in the near future
4. Action – in the process of change
5. Maintenance – continued change for an extended period

Verbally reinforce positive behaviors.
Avoid “punishing” and/or “shaming” patients for diabetes mismanagement. Arrange for other provider care when a bad ‘fit’ between patient and provider exists.
Practice a “problem solving” approach and teach patient and family members this as a strategy.
Practice good communication skills and advocate the same for communication between patient and family members.
Assess and enhance community supports (medical, school, work, social, religious) including, but not limited to, formal support groups specific to diabetes patients and families.
Identify and intervene with depression and other mental health risk behaviors early.

References:
# Diabetes Quick Reference Guide for Patients

Know your numbers – Track them on your wallet card. Keep a list of your medications.

<table>
<thead>
<tr>
<th>Office Visits</th>
<th>Test to be Performed</th>
<th>Frequency</th>
<th>Description/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood Pressure</td>
<td>Every visit</td>
<td>Goal is less than 130/80</td>
</tr>
<tr>
<td></td>
<td>Dilated Eye Exam</td>
<td>Once a year</td>
<td>Either ophthalmologist or optometrist (your medical provider will advise)</td>
</tr>
<tr>
<td></td>
<td>Dental Exam</td>
<td>Every 6 months</td>
<td>To identify periodontal disease</td>
</tr>
<tr>
<td></td>
<td>Brief Foot Exam</td>
<td>Every visit</td>
<td>Remove shoes and socks</td>
</tr>
<tr>
<td></td>
<td>Complete Foot Exam</td>
<td>Once a year</td>
<td>If at high risk may need a podiatrist referral</td>
</tr>
<tr>
<td></td>
<td>Flu Vaccine</td>
<td>Every fall</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pneumonia Vaccine</td>
<td>At time of diagnosis</td>
<td>Discuss re-vaccination with medical provider</td>
</tr>
<tr>
<td>Labs</td>
<td>Test to be Performed</td>
<td>Frequency</td>
<td>Description/Comments</td>
</tr>
<tr>
<td></td>
<td>Hemoglobin A1C</td>
<td>Every 3 to 6 months</td>
<td>Goal less than 7%</td>
</tr>
<tr>
<td></td>
<td>Triglycerides (fat)</td>
<td>Once a year</td>
<td>Goal less than 150 mg/dl</td>
</tr>
<tr>
<td></td>
<td>LDL (Bad) Cholesterol</td>
<td>Once a year</td>
<td>Goal less than 100 mg/dl, or less than 70 mg/dl if high risk for heart disease</td>
</tr>
<tr>
<td></td>
<td>HDL (Good) Cholesterol</td>
<td>Once a year</td>
<td>Goal greater than 40 for men; greater than 50 for women</td>
</tr>
<tr>
<td></td>
<td>Urine for microalbuminuria</td>
<td>Once a year</td>
<td>Goal less than 30 ug albumin/mg of creatinine</td>
</tr>
<tr>
<td>Self Management</td>
<td>Test to be Performed</td>
<td>Frequency</td>
<td>Description/Comments</td>
</tr>
<tr>
<td></td>
<td>Setting personal goals &amp;</td>
<td>Every visit</td>
<td>See diabetes educators. Attend diabetes education and other programs as advised.</td>
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<tr>
<td></td>
<td>discussing them with your</td>
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<td></td>
<td>medical providers</td>
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<tr>
<td></td>
<td>Wear diabetic identification</td>
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<tr>
<td></td>
<td>Checking Blood Sugar</td>
<td>As advised</td>
<td>Aim to reach personal goals and prescribed target range of 70-120 mg/dl.</td>
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<tr>
<td></td>
<td>If on hypoglycemic</td>
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<td></td>
<td>producing meds carry</td>
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<tr>
<td></td>
<td>glucose</td>
<td></td>
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<tr>
<td></td>
<td>Healthy Food Choices &amp;</td>
<td>As advised</td>
<td>Eat more whole grains, vegetables and fruits. Eat less butter, stick margarines,</td>
</tr>
<tr>
<td></td>
<td>Body Weight Management</td>
<td></td>
<td>fatty meats, and baked pastries. Talk to a dietician.</td>
</tr>
<tr>
<td></td>
<td>Physical Activity/Exercise</td>
<td>At least 30</td>
<td>Move more and try to have fun. Walk, swim, bike, dance, work in the garden, ski,</td>
</tr>
<tr>
<td></td>
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<td>minutes on 5 days</td>
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<td></td>
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<td>of the week</td>
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</tbody>
</table>

Adapted from the Vermont Department of Health Guide and the 2008 ADA Clinical Practice Recommendations. This document in not intended to replace the advice of your medical provider.