

# **Management of Diabetes**

**Federal Bureau of Prisons  
Clinical Practice Guidelines**

**June 2012**

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<http://www.bop.gov/news/medresources.jsp>.

## What's Been Changed in This Document?

*This document has been revised several times since September 2002: in February 2008, in April 2009, in November 2010, and now in June 2012.*

### June 2012 Revisions:

The June 2012 revisions, highlighted in yellow throughout the document, include the following:

- A new section on [Diabetic Periodontitis](#) has been added to *Section 11, Medical Management of Diabetic Complications*. Non-dentists should be aware of the bidirectional relationship between periodontal disease and glycemic control.
- Statistics from the CDC's 2011 *National Diabetes Fact Sheet* now introduces *Section 11* to highlight the [seriousness of diabetic complications](#).
- The importance of periodic finger sticks at Health Services is reinforced in [Section 9, Blood Glucose Monitoring](#).
- Under [Hypertension](#) in *Section 11*, the recommendation, "If targets are not achieved, a thiazide diuretic should be added," has been deleted.
- In [Appendix 2, Recommendations for Diabetes Chronic Care Monitoring](#), a note has been added regarding *screening for microalbuminuria*: "Abnormal results should be repeated at least 2–3 times over a 3–6 month period to appropriately diagnose, because of the potential for false positives."
- All technical information has been reviewed by BOP pharmacists, and the updates are highlighted in yellow.
- The nutritional information for diabetic inmates has been updated. The Diabetes Food Pyramid has been replaced; patients are counseled to choose from the heart-healthy food options on the BOP National Menu, and the BOP National Carbohydrate Counting Menu available on Sallyport. See *Food Selection* under [Lifestyle Intervention](#) in *Section 5*, and the new inmate handout in [Appendix 12, Eating to Manage Your Diabetes in the Bureau of Prisons](#).
- The three Inmate Handouts have been revised and grouped together as [Appendices 10–12](#).

### November 2010 Revisions:

The following BOP recommendations were changed to align with the American Diabetes Association's *Standards of Medical Care in Diabetes – 2010*.

- The recommendations for aspirin therapy in diabetic patients have been changed. See the discussion of [aspirin therapy](#) in *Section 11*.
- Criteria for diagnosing diabetes now includes hemoglobin A1C testing, with a cut point of  $\geq 6.5\%$ . An A1C of 5.7–6.4% is considered a sign of pre-diabetes (see [Table 1](#)). Based on the results of multiple randomized trials and correctional considerations, the BOP recommends A1C  $< 7.0$ –7.5% as a reasonable treatment goal for diabetic inmates (see [Section 6, Type 2 Diabetes Treatment](#)).

### April 2009 Revisions:

The April 2009 version of *Management of Diabetes* was a targeted update to make these guidelines consistent with the updated BOP guidelines on *Preventive Health Care*. Both guidelines were changed in 2009 to be in line with the following U.S. Preventive Services Task Force recommendation:

*There is only one group of asymptomatic, otherwise low-risk individuals for whom routine diabetes screening is warranted. Those with a blood pressure greater than 135/80 (treated or untreated) should be screened every 3 years.*

Otherwise, glucose screening should be performed as clinically indicated, i.e., in association with management of hyperlipidemia, cardiovascular disease, peripheral vascular disease, history of gestational diabetes, or history of polycystic ovary disease.

### February 2008 Revisions:

- The criteria for diagnosis of diabetes, *impaired fasting glucose (IFG)* and *impaired glucose tolerance (IGT)*, were revised ([Table 1](#)). A new term, “pre-diabetes,” was applied to IFG and IGT.
- The screening criteria for diabetes were revised ([Section 3](#)). Obtaining a capillary blood glucose from insulin dependent diabetics at intake is emphasized (in [Section 5](#)).
- Lifestyle interventions were recommended. The benefits of lifestyle intervention for inmates with IFG/IGT in preventing or delaying the onset of type 2 diabetes are emphasized. The role of exercise as a diabetes treatment intervention is more strongly emphasized. BOP institutions should consider implementing structured exercise programs for diabetic inmates. The American Diabetes Association “Food Pyramid” was included, but has now been replaced with more current information (see [Appendix 12](#)).
- Treatment goals were revised ([Appendix 3](#)), including an A1C goal of <7%.  
*Note: The 2008 A1C goal has been superseded by the November 2010 recommendations.*
- Early intervention for type 2 diabetes is emphasized. Recommendations for treatment of type 2 diabetes were changed ([Section 6](#)).
  - Drug treatment, in conjunction with lifestyle changes, is now recommended if the A1C is  $\geq 7\%$  (making adjustments at least every three months until the A1C <7%).  
*Note: The 2008 A1C goal has been superseded by the November 2010 recommendations*
  - A new approach to the management of type 2 diabetes is presented in [Appendix 4, BOP Treatment Algorithm for Type 2 Diabetes](#).
  - Initial therapy should generally consist of lifestyle intervention, plus metformin (unless contraindicated). See new recommendations for titration of metformin ([Table 3](#)).
  - Addition of insulin should not be delayed for type 2 diabetics who fail to meet glycemic goals on oral medication. Insulin should be initiated and adjusted according to the flow chart in [Appendix 5, Initiation/Adjustment of Insulin Regimens in Type 2 Diabetes](#).
- Recommendations for insulin were updated ([Section 8](#)). The use of intensive insulin regimens is emphasized. Evening doses of NPH insulin should optimally be administered at bedtime or as close to bedtime as feasible. Newly committed inmates who are on an insulin pump should generally be maintained on a pump. Specific instructions for drawing up Regular and NPH insulin in combination are provided.
- Infection control guidelines associated with diabetes management were summarized ([Appendix 8](#)). *Finger stick devices must be issued for individual use only.*
- Recommendations for blood glucose monitoring in the BOP were updated ([Section 9](#)). Criteria for self-monitoring of blood glucose are provided.
- A glomerular filtration rate (GFR) should be calculated for all diabetic inmates at baseline and at least annually. The calculation requires the following data: serum creatinine, age, sex, race. See GFR calculator at: [http://www.kidney.org/professionals/kdoqi/gfr\\_calculator.cfm](http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm).
- Recommendations for treatment of *diabetic neuropathy* were added (in [Section 11](#)).
- The following updated clinical tools were provided: [Appendix 1, Components of the Comprehensive Diabetes Evaluation](#), and [Appendix 2, Recommendations for Diabetes Clinic Chronic Care Monitoring](#).

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## 1. Purpose

The Federal Bureau of Prisons (BOP) Clinical Practice Guidelines for *Management of Diabetes* provides recommendations for the medical management of Federal inmates with diabetes mellitus.

## 2. Classification and Diagnosis

### Classification

Diabetes is classified into four general categories, as listed below.

→ *Despite the general differences listed below for types 1 and 2, it is sometimes difficult to determine whether an individual has type 1 or type 2 diabetes.*

**Type 1 diabetes** is a disease resulting from absolute insulin deficiency, usually caused by autoimmune destruction of pancreatic islet cells. The initial clinical presentation may be ketoacidosis with an acute illness, or a more gradual presentation with symptoms of hyperglycemia. Other autoimmune disorders may also be present such as Addison's disease, thyroiditis, and pernicious anemia. A small subset of patients with type 1 diabetes have a non-immune mediated disease process with a waxing and waning clinical course. This form of type 1 diabetes is strongly inherited and most commonly affects persons of African and Asian descent.

#### *The typical patient with type 1 diabetes:*

- Is often diagnosed as a child or young adult (although it can occur at any age).
- Is lean (i.e., BMI less than 25 kg/m<sup>2</sup>).
- Displays normal insulin sensitivity, i.e., insulin requirements do not exceed 0.7 units of insulin/kilogram body weight/24 hours.
- Displays evidence of anti-beta cell autoimmunity (i.e., anti-GAD, anti-IA-2, and/or anti-insulin antibodies).
- Is more "ketosis prone" than individuals with type 2 diabetes (i.e., if the individual has a history of repeated bouts of DKA, they are far more likely to have type 1).

**Type 2 diabetes** is a disease resulting from a relative, rather than an absolute, insulin deficiency with an underlying insulin resistance. Type 2 diabetes is associated with obesity, age, and physical inactivity. Patients with type 2 diabetes are not prone to ketoacidosis, frequently do not require insulin, and may be asymptomatic, despite being hyperglycemic for many years.

#### *The typical patient with type 2 diabetes:*

- Is more likely to be diagnosed as an adult.
- Is overweight or obese (i.e., BMI  $\geq$ 25 kg/m<sup>2</sup>, and often far exceeding that BMI).
- Is more likely to have a family history of diabetes (>90% of those with type 2 diabetes will have a first degree relative with the disease).
- If treated with insulin, is more likely to require very large doses to control the blood glucose (e.g., >0.7 units/kg/day) due to insulin resistance. Such individuals frequently

have characteristics associated with insulin resistance, including abdominal obesity, hypertension, lipid abnormalities, atherosclerosis, and hyperuricemia.

- Does not have evidence of anti-beta cell specific antibodies. Those who do have such circulating antibodies are sometimes referred to as having latent autoimmune diabetes of the adult (LADA). Such individuals seem to have a slowly progressive beta cell destructive process much like that occurring in children with typical type 1 diabetes, but the beta cell destruction occurs more slowly.
- Is much less likely to have a history of diabetic ketoacidosis (DKA), but may have a history of hyperosmolar coma.
- Is more likely to suffer other consequences of the “metabolic syndrome,” e.g. hypertension, hyperlipidemia.

**Gestational diabetes (GDM)** is diabetes or any degree of glucose intolerance that is diagnosed during pregnancy. Detection, diagnosis and treatment of gestational diabetes are discussed in [Section 10, Gestational Diabetes](#).

**Other** causes of diabetes that are not classified as either type 1 or type 2 include: genetic defects of islet cell function; genetic defects in insulin action; endocrinopathies such as Cushing’s disease or syndrome; drug- or chemical-induced hyperglycemia; infections; and insults to the pancreas from a variety of causes such as pancreatic cancer, cystic fibrosis, trauma, and pancreatitis.

## Diagnosis

Inmates with any of the following should be evaluated for diabetes: symptoms of hyperglycemia, symptoms that may represent complications of diabetes, or clinical presentations that include diabetes in the differential diagnosis.

The American Diabetes Association (ADA) criteria for the diagnosis of diabetes in non-pregnant adults are shown in *Table 1* below. In 2010, the ADA added the use of A1C to diagnose diabetes, with a cut point of  $\geq 6.5\%$ . The diagnostic cut-points recommended by the ADA are based on fasting *plasma* glucose values. Fasting serum glucose values run 10–15% lower than fasting plasma glucose values. The BOP recommends fasting *serum* glucose tests for initial screening and diagnosis. A fasting *plasma* glucose test should be obtained when fasting serum glucose values are borderline high, or if a patient has impaired glucose tolerance (**impaired fasting glucose—IFG, or impaired glucose tolerance—IGT**). (The BOP recommends the routine use of serum glucose testing because it does not require the special collection methods used in plasma glucose testing, i.e., a separate gray-top tube containing glycolytic inhibitor.)

The oral glucose tolerance test (OGTT) is *not* recommended for routine clinical use; however, it may be required when evaluating patients with **IFG**, or when diabetes is suspected despite a normal fasting *plasma* glucose test (as with postpartum evaluation of women with GDM). Unless unequivocal symptoms of hyperglycemia are present, diagnosis of diabetes requires that test results be confirmed by repeating the test on a subsequent day.



“Pre-diabetes” is the term that now encompasses IFG and IGT, i.e., hyperglycemia that does not meet the diagnostic criteria for diabetes. Both IFG and IGT, as well as an A1C range of 5.7–6.4%, are associated with a high risk for diabetes and cardiovascular disease.

**Table 1. ADA Diagnostic Criteria for Diabetes and Pre-Diabetes (Non-Pregnant Adults)**

Normal
<ol style="list-style-type: none"> <li>1. Fasting plasma glucose &lt;100 mg/dl.</li> <li style="text-align: center;"><i>or</i></li> <li>2. Oral glucose tolerance test (OGTT) 2-hr plasma glucose &lt;140 mg/dl.</li> </ol>
Pre-Diabetes
<ol style="list-style-type: none"> <li>1. A1C range of 5.7–6.4%.</li> <li style="text-align: center;"><i>or</i></li> <li>2. Impaired fasting glucose (IFG) = fasting plasma glucose of 100–125 mg/dl.</li> <li style="text-align: center;"><i>or</i></li> <li>3. Impaired glucose tolerance (IGT) = OGTT 2-hr plasma glucose of 140–199 mg/dl.</li> </ol>
Diabetes
<ol style="list-style-type: none"> <li>1. <b>A1C <math>\geq</math>6.5%.</b> The test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized to the Diabetes Control and Complications trial (DCCT) assay.</li> <li style="text-align: center;"><i>or</i></li> <li>2. <b>Fasting plasma glucose <math>\geq</math>126 mg/dl.</b> Fasting is defined as no caloric intake for at least eight hours.</li> <li style="text-align: center;"><i>or</i></li> <li>3. <b>2-h plasma glucose <math>\geq</math>200 mg/dl during an oral glucose tolerance test.</b> The test should be performed using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.</li> <li style="text-align: center;"><i>or</i></li> <li>4. <b>Symptoms of diabetes and a casual plasma glucose <math>\geq</math>200 mg/dl.</b> “Casual” is defined as any time of day, without regard to the time since the last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.</li> </ol>
<p><b>Notes:</b> Serum glucose values run 10–15% lower than plasma glucose values. The BOP recommends the use of serum glucose testing for initial screening and diagnosis. When <i>fasting serum glucose</i> values are borderline high, or for patients with impaired glucose tolerance (IFG or IGT), a <i>fasting plasma glucose</i> should be obtained. To diagnose diabetes, lab results must be confirmed on a second test performed on a subsequent day (unless there are unequivocal symptoms of hyperglycemia).</p>

### 3. Screening

#### Preventive Health

Diabetes screening in the BOP should be instituted as part of the facility’s preventive health care program. Utilize a fasting serum glucose test (confirming with a fasting plasma glucose test for values that are borderline high). Routine universal screening for diabetes is *not* recommended.

There is only one group of asymptomatic, otherwise low-risk individuals for whom routine diabetes screening is warranted. Those with a blood pressure greater than 135/80 (treated or untreated) should be screened every 3 years. Otherwise, glucose screening should be performed as clinically indicated, i.e., in association with management of hyperlipidemia, cardiovascular disease, peripheral vascular disease, history of gestational diabetes, or history of polycystic ovary disease.

## **Previously Identified IFG or IGT**

Inmates with impaired glucose homeostasis are at increased risk of developing diabetes. Approximately one third of patients with IFG or IGT will develop diabetes within five years. *Annual* screening by fasting *plasma* glucose is recommended for these patients.

## **Pregnancy**

Risk-based screening of pregnant women should be conducted in accordance with recommendations outlined in [Section 10](#) of these guidelines.

## **4. Prevention/Delay of Type 2 Diabetes**

Many studies have demonstrated that diabetes can be delayed, and sometimes prevented, in individuals at high risk for developing diabetes (those with IFG, IGT, or both). All inmates with IFG or IGT should be counseled on the importance of maintaining a healthy diet and a conscious approach to meal planning. Such inmates should be counseled about the benefits of modest weight loss and regular physical activity. They should be monitored annually for development of diabetes. Inmates with IFG or IGT should be assessed for other cardiovascular disease risk factors (e.g., hypertension and dyslipidemia) and provided treatment as indicated.

## **5. Baseline Evaluation and Initial Treatment Plan**

### **Intake Blood Glucose Screening of Diabetics**

It is essential to rapidly identify and evaluate insulin-treated inmates at intake to identify those at highest risk for hypo- and hyperglycemia, and diabetic ketoacidosis. Inmates who report being insulin-dependent at intake should have a capillary blood glucose (CBG) obtained upon admission.

### **Baseline Evaluation**

A complete medical evaluation should be performed to classify the patient, detect the presence or absence of diabetes complications, assist in formulating a management plan, and provide a basis for continuing care. If the diagnosis of diabetes has already been made, review the previous treatment plan in light of past and present degrees of glycemic control. Appropriate laboratory tests should be performed to evaluate the patient's general medical condition. The components of a comprehensive diabetes baseline evaluation are listed in [Appendix 1](#), *Components of the Comprehensive Diabetes Evaluation*, and [Appendix 2](#), *Recommendations for Diabetes Chronic Care Clinic Monitoring*.

## Initial Treatment Plan

The treating physician, with the assistance of other health care providers, should review the initial diabetic treatment plan with the inmate. Involvement of the diabetic inmate in the development of the treatment plan is pivotal to its success, including adequate training to empower the patient to prevent and treat hypoglycemia.

*The treatment plan should include the following basic components and recommendations:*

- Education on diabetes drug treatment options, self-monitoring, recognizing and treating severe hypoglycemic and hyperglycemic episodes, and identifying the signs of diabetic complications such as diseases of the eyes, kidneys, and nervous system.
- Instruction on the inmate's specific drug treatment regimen and methods for monitoring glucose.
- Necessary lifestyle modifications such as improving food selection, increasing physical exercise, and smoking cessation.
- Importance of annual eye exams (funduscopy) done by an optometrist or ophthalmologist.
- Need for daily self-examination of the feet.
- Need for daily self-examination of the skin, including insulin injection sites.
- Importance of regular dental examinations and treatment.
- Need for regular screenings: fasting blood glucose, A1C, lipid levels, and kidney monitoring (BUN, creatinine, glomerular filtration rate calculation).
- Need for daily aspirin therapy to prevent cardiovascular events.
- Need for annual influenza vaccinations and tuberculosis screening.

## Lifestyle Intervention

With rare exceptions, a lifestyle intervention program to increase activity levels and promote weight loss (as indicated) should be included as part of diabetes management. Overweight and lack of exercise are the most important environmental risk factors for type 2 diabetes. Losing weight and increasing exercise have been shown to have a beneficial effect on controlling glycemia in both type 1 and type 2 diabetics. Unfortunately, the high rate of weight regain has limited the effectiveness of lifestyle intervention as a long-term means of controlling glycemia.

## Food Selection

According to the American Diabetes Association *Position Statement on Diabetes Management in Correctional Institutions*, the easiest and most cost-effective means of facilitating good nutritional outcomes in patients with diabetes is by offering heart-healthy diet options as part of the master menu. Additionally, there should be consistent carbohydrate content at each meal—and a means for inmates to identify the amount of carbohydrates in each food item.

Nutrition counseling is considered essential in diabetes self-management, and diabetic inmates should receive nutrition counseling as needed to achieve their treatment goals. Nutrition education, conducted individually or in group settings, should help patients understand how their food and carbohydrate choices directly affect diabetes control. Diabetic inmates should be counseled to eat a reduced-calorie, low-sodium, and low-fat diet offered through the heart health food options on the BOP National Menu—as well as to strive for day-to-day consistency in mealtimes and in the amount of carbohydrates consumed. This information is available in the

*Eating to Manage Your Diabetes* handout in [Appendix 12](#) and in the BOP National Carbohydrate Counting Menu available on the Central Office Food Service Branch webpage ([http://sallyport.bop.gov/co/hsd/food\\_svc/National\\_Menu\\_Info.jsp](http://sallyport.bop.gov/co/hsd/food_svc/National_Menu_Info.jsp)).

The use of insulin or oral medication may necessitate snacks in order to avoid hypoglycemia in patients with a documented history of hypoglycemia. These snacks are a part of the medical treatment plans for these patients and should be prescribed by medical staff only as needed, on an individual basis.

### **Physical Activity**

Regular exercise can significantly improve glycemic control and contribute to weight reduction. All inmates with diabetes should be counseled on the benefits of increased physical activity, as well as the degree of exercise best suited to them. Sedentary diabetic inmates should be medically evaluated prior to undertaking aerobic physical activity that goes beyond the intensity of brisk walking. Institutions should consider implementing structured exercise programs for diabetic inmates. Aerobic exercise plans should be developed individually, based on the inmate's interests, co-morbid conditions, and physical limitations.

## **6. Type 2 Diabetes Treatment**

### **Goals and Principles**

*Based on the results of multiple randomized trials and correctional considerations, a reasonable A1C target for diabetic inmates is <7.0–7.5%. It is recognized, however, that very stringent goals may not be appropriate or practical for some patients. Clinical judgment, based on the potential benefits and risks of a more intensified regimen, should be applied for every patient. Factors such as life expectancy and risk for hypoglycemia need to be considered before intensifying a patient's therapeutic regimen.*

*Appendix 3* summarizes revised *Treatment Goals for Non-Pregnant Inmates with Diabetes*. Early treatment for diabetes (before blood glucose is significantly elevated) is associated with improved glycemic control and decreased diabetic complications. Further adjustments should be based on the A1C result, aiming for levels as close to the nondiabetic range as possible. Until glycemic goals are achieved, the patient should be seen at least monthly, and more frequently as indicated. An A1C should be obtained no more frequently than every three months. Medications should be adjusted according to blood glucose data, and the inmate should be counseled on diet and exercise. An A1C  $\geq 7.0$ –7.5% suggests the need for further intensification of diet, exercise, and medication management.

### **Medications for Type 2 Diabetes**

Selection of specific antihyperglycemic agents is based upon their effectiveness in lowering A1C levels, extraglycemic effects (reducing CVD risks), safety profiles, and tolerability. *Table 2* below outlines the advantages and disadvantages of the different antidiabetic interventions, when used as monotherapy, including the expected total decrease in A1C.

**Table 2. Summary of Antidiabetic Interventions as Monotherapy for Type 2 Diabetes**

Interventions	Expected total decrease in A1C (%)	Advantages	Disadvantages
<b>Step 1: Lifestyle intervention and metformin</b>			
Lifestyle to: ↓ weight & ↑ activity	1–2	Low cost, many benefits	Fails for most in the first year
Metformin	1.5	Weight-neutral, no hypoglycemia, inexpensive	GI side effects, rare lactic acidosis
<b>Step 2: Addition of a sulfonylurea or insulin</b>			
Insulin	1.5–2.5	No dose limit, inexpensive, improved lipid profile	Injections, requires frequent blood glucose self-monitoring, hypoglycemia, weight gain; <b>requires pill line</b>
Sulfonylureas	1.5	Inexpensive	Weight gain, hypoglycemia
<b>Alternative medications</b>			
Glitazones (TZDs–thiazolidinediones)	0.5–1.4	Improved lipid profile	Restricted use. Fluid retention, weight gain, expensive, increased risk of congestive heart failure
Alpha-glucosidase inhibitors	0.5–0.8	Weight-neutral	Frequent GI side effects, 3x/day dosing, expensive
Exenatide	0.5-1.0	Weight loss	Infections, 3x/day dosing, frequent GI side effects, expensive, little experience; <b>requires pill line</b>
Glinides (meglitinides)	1–1.5	Short duration	three times/day dosing, expensive
Pramlintide	0.5–1.0	Weight loss	Infections, 3x/day dosing, frequent GI side effects, expensive, little experience; <b>requires pill line</b>
Adapted from: Nathan DM, Buse JB, Davidson MB, et al. Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. <i>Diabetes Care</i> 2006;29(8):1964.			

For specific recommendations, see the [BOP Treatment Algorithm for Type 2 Diabetes](#), later in this section, as well as the flow chart in [Appendix 4](#).

The classes of medication used to treat type 2 diabetes are summarized below and in [Appendix 6, Oral Agents for the Treatment of Type 2 Diabetes](#). Refer to the BOP National Formulary for the formulary status and non-formulary use criteria for specific medications.

### Metformin

Metformin is the only biguanide available in most of the world. It reduces hepatic glucose production in the presence of insulin and reduces hyperglycemia through other poorly defined mechanisms. Metformin reduces A1C levels by 1–2%. In contrast to sulfonylureas, metformin is associated with weight loss or no weight gain, and has a lower risk of hypoglycemia. *Unless contraindicated, metformin in combination with lifestyle changes is recommended as initial treatment for type 2 diabetes* (see [Appendix 4](#)). Metformin can also be used in combination with insulin, sulfonylureas, glitazones, and glinides. See [Appendix 6](#) for general dosing recommendations. See [Table 3](#) below (under [BOP Treatment Algorithm for Type 2 Diabetes](#)) for recommendations for titrating metformin.

#### **Clinical Precautions for Metformin:**

- 1) *Metformin should be discontinued during acute illnesses where dehydration is a significant risk or where respiratory acidosis is possible, since metformin use in these situations may result in life-threatening lactic acidosis. Inmates with acute myocardial infarction, with septicemia, on hunger*

*strikes, on a prolonged fast, or with any significant decrease in caloric intake are at risk of this complication.*

- 2) ***Metformin is not recommended in the elderly (age >80) unless renal sufficiency is proven with a direct measure of GFR or for individuals with renal dysfunction (creatinine level >1.5 mg/dl in men or >1.4 mg/dl in women), liver dysfunction, congestive heart failure, severe infection, or alcohol abuse.***
- 3) ***Metformin should be withheld 48 hours before and after surgery or IV contrast radiograph studies; the inmate should be well hydrated both before and after these procedures. Before resuming metformin, normal renal function should be confirmed by measuring serum creatinine 24–48 hours after the procedure.***
- 4) ***Metformin can cause vitamin B12 deficiency with an associated anemia and neuropathy. The neuropathy may be misdiagnosed as a diabetic neuropathy.***

## **Insulin**

Insulin is the oldest of the currently available medications and, thereby, the one with the most clinical experience. Although initially developed to treat insulin-deficient type 1 diabetes, it has long been used to treat insulin-resistant type 2 diabetes. It is the most effective drug to decrease glycemia. In adequate doses, insulin can decrease any level of elevated A1C to meet a therapeutic goal. See [Section 8, Insulin and Insulin Administration](#), for a more thorough discussion of insulin. See [Appendix 5, Initiation/Adjustment of Insulin Regimens in Type 2 Diabetes](#), for a recommended approach to insulin management in type 2 diabetics.

Unlike the other blood glucose-lowering medications, there is no maximum dose of insulin beyond which a therapeutic effect will not occur. To overcome the insulin resistance of type 2 diabetes and lower the A1C to goal, relatively large doses of insulin (>1 unit/kg) may be required. Initial therapy is aimed at increasing basal insulin supply. Patients may also require pre-meal, regular insulin, as well. Insulin therapy has beneficial effects on triglyceride and HDL cholesterol levels, but is associated with weight gain of about 2–4 kg. As with sulfonylurea therapy, the weight gain may have an adverse effect on cardiovascular risk. Insulin therapy for type 2 diabetes is also associated with hypoglycemia, albeit much less frequently than in type 1 diabetes.

## **Sulfonylureas (SUs)**

Sulfonylureas stimulate insulin secretion and are most effective in treating non-obese, type 2 diabetics. The various sulfonylureas have equivalent efficacy, reducing A1C by 1–2%. Second-generation sulfonylureas, such as **glyburide**, **glipizide**, and **glimepiride**, have more favorable side effect profiles and fewer drug interactions than first-generation sulfonylureas, such as chlorpropamide, tolazamide, and tolbutamide.

Sulfonylureas can be prescribed as monotherapy, or they can be combined with other oral agents or with insulin. (To achieve glycemic control with a sulfonylurea plus insulin, there must be residual endogenous insulin production.) Sulfonylureas should not be used in combination with the non-sulfonylurea secretagogues (repaglinide and nateglinide), due to the similarity in their mechanisms of action.

Hypoglycemia (particularly in the elderly and in patients with renal insufficiency) and weight gain are the two most common adverse effects of sulfonylurea therapy. All sulfonylureas are metabolized by the liver and excreted in the urine; therefore, they should be used with caution in inmates who suffer from either renal or hepatic insufficiency. Note that glipizide has less renal toxicity than the other sulfonylureas and can be used in patients with renal insufficiency, only if the creatinine clearance is  $\geq 10$  ml/min. Glyburide can only be used if the creatinine clearance is  $\geq 50$  ml/min.

Sulfonylureas have a relatively high secondary failure rate (5–10% per year), most likely due to the gradual decline of endogenous insulin production over time. Therefore, clinicians should expect eventual loss of glycemic control with sulfonylureas and should counsel the inmate about the eventual need to add another oral agent or insulin to the treatment regimen.

→ See [Appendix 6](#) for general dosing recommendations for sulfonylureas.

#### **Clinical Precaution for SUs:**

*Hypoglycemia caused by sulfonylureas can be prolonged or recurrent, due to the drugs' long duration of action. Symptomatic hypoglycemia that cannot be managed with frequent feedings over a 24-hour period should be treated in a hospital setting.*

#### **Alternative Medications**

Other available medications to treat type 2 diabetes are all less effective than metformin, insulin, and the sulfonylureas. [Appendix 6](#) and [Appendix 7](#) provide an overview of these medications, including dosing information. In the BOP, their use should only be considered under special circumstances, e.g., drug intolerance or contraindications.

#### **BOP Treatment Algorithm for Type 2 Diabetes**

Treatment should generally be initiated when the A1C is  $\geq 7.0$ – $7.5\%$ . Except in rare circumstances, hospitalization is not required to initiate or adjust therapy for type 2 diabetes. Until glycemic goals are achieved, the patient should be seen at least monthly to adjust medications, based on serum glucose data, and to counsel the inmate on diet and exercise. In order to achieve glycemic goals, medications should be adjusted as frequently as titration allows (i.e., as often as every 3 to 4 days for insulin and every one to two weeks for metformin).

The A1C should not be obtained more frequently than every three months. An A1C level of  $\geq 7.0$ – $7.5\%$  suggests the need for further intensification of diet, exercise, and medication management.

→ [Appendix 4](#), *BOP Treatment Algorithm for Type 2 Diabetes*, presents a flow chart of recommended steps in the management of type 2 diabetes.

#### **Definite Indications for Insulin as Initial Therapy**

Insulin therapy in combination with lifestyle interventions is the initial treatment of choice for *severely uncontrolled diabetes* (i.e., plasma glucose levels  $>250$  mg/dl, random glucose levels consistently  $>300$  mg/dl, A1C  $>10\%$ , or the presence of ketonuria or symptomatic diabetes with

polyuria, polydipsia, and weight loss). Some patients with these characteristics have unrecognized type 1 diabetes; others have type 2 diabetes with severe insulin deficiency. Insulin can be titrated often and is the drug most likely to rapidly bring glucose down to target levels. After symptoms are relieved, oral agents can often be added and it may be possible to withdraw insulin. In addition, type 2 diabetics with significant renal or liver dysfunction often require insulin because they cannot take most oral agents.

### **Step 1: Use lifestyle intervention and metformin.**

Throughout management of type 2 diabetes, lifestyle interventions (outlined in [Section 5](#) above) should be an underlying theme. However, lifestyle interventions alone rarely result in long-term achievement of glycemic goals. Therefore it is recommended that drug treatment be initiated along with lifestyle interventions at the time of type 2 diabetes diagnosis. Presuming there are no contraindications, metformin is the initial drug of choice for the following reasons: effective glycemic control, absence of weight gain, absence of hypoglycemia, low level of side effects, and high level of acceptance.

Metformin should not be given to elderly patients (over age 80), unless renal sufficiency is proven with a direct measure of GFR; to patients who have renal, hepatic, or cardiac disease; or to patients who drink excess alcohol. If metformin is contraindicated, it is recommended that either insulin or a sulfonylurea be used as the initial drug.

Careful titration of metformin is critical to minimize gastrointestinal side effects. See [Table 3](#) below.

**Table 3. Titration of Metformin**

<ol style="list-style-type: none"><li>1. Begin with low-dose metformin (500 mg) once or twice daily with meals (breakfast and/or dinner).</li><li>2. After 5–7 days (if GI side effects have not occurred), advance dose to 850 or 1,000 mg before breakfast and dinner.</li><li>3. If GI side effects appear as doses are increased, decrease to previous lower dose and try to advance dose at a later time.</li><li>4. The most efficacious dose is usually 850 mg twice per day. Modest improvements in effectiveness can be achieved with doses up to a maximum daily dose of 2550 mg (administered 850 mg three times a day or other combination). GI side effects are dose-related and may limit therapy.</li></ol> <p>Adapted from: Nathan DM, Buse JB, Davidson MB, et al. Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. <i>Diabetes Care</i> 2006;29(8):1969.</p>
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### **Step 2: Add a sulfonylurea or insulin.**

If lifestyle interventions plus a maximally tolerated dose of metformin fail to achieve or sustain glycemic goals within two to three months, another medication should be added. Addition of either a sulfonylurea or insulin is generally recommended. The A1C level will determine, in part, which agent should be selected next.

Insulin should be initiated for inmates with A1C >8.5%, or who have symptoms of hyperglycemia. See [Appendix 5, Initiation/Adjustment of Insulin Regimens in Type 2 Diabetes](#), for suggested initial insulin regimens. Insulin is considered a fundamental tool for treating type 2 diabetes; initiation of insulin should *not* be delayed in patients who fail to meet glycemic goals.



### **Step 3: Add or intensify insulin.**

If lifestyle interventions plus metformin and a second medication fail to achieve glycemic goals, the next step is to start or intensify insulin therapy. *Usually, there is no benefit to prescribing three oral agents.* If plasma glucose and A1C goals are not met in a compliant patient on two oral agents, i.e., metformin and a sulfonylurea, the most effective next step is to add NPH insulin.

Intensification of insulin therapy usually consists of additional injections, often including regular insulin prior to selected meals to reduce postprandial glucose excursions. In general, once insulin has been started, sulfonylureas are discontinued.

### **Rationale in Selecting Specific Combinations**

The majority of patients with type 2 diabetes will require multiple medications over time. This is because type 2 diabetics have both insulin resistance at the tissue level and declining pancreatic insulin production. Drug selection should be based on glucose-lowering effectiveness, mechanism of action, side effect profile, and other factors that may reduce diabetes complications, e.g., weight loss or improvement in lipid profile. When adding antihyperglycemic medications, the synergy of particular combinations and other interactions should be considered. As a rule, antihyperglycemic drugs with different mechanisms of action will have the greatest synergy.

The first-line oral agents utilized within the BOP are metformin and the sulfonylureas. If metformin and/or sulfonylureas are contraindicated or not tolerated, the use of other oral hypoglycemic agents should be considered on a case-by-case basis. Consult the National BOP Formulary for non-formulary use criteria.

## **7. Treatment of Type 1 Diabetes**

Type 1 diabetics generally present with both acute diabetes symptoms and significantly elevated blood glucose levels. Given the acute onset of symptoms, type 1 diabetes is usually detected soon after symptoms develop. Treatment goals for type 1 diabetes are the same as those for type 2 (see [Appendix 3](#)). The A1C goal for type 1 diabetes is <7.0–7.5%.

For patients with type 1 diabetes, it has been clearly demonstrated that intensive insulin therapy (outlined in *Section 8* below) results in both improved glycemic control and reduction in diabetes-related complications (including nephropathy, retinopathy, neuropathy, and cardiovascular morbidity and mortality).

## **8. Insulin and Insulin Administration**

### **Intensive vs. Conventional Insulin Therapy**

*Conventional insulin therapy* involves single daily injections or two injections per day (usually twice-daily administration of a combination of short-acting and NPH insulins).

*Intensive insulin therapy* describes treatment with three or more injections per day, including both basal and pre-meal insulin. Intensive therapy can also be accomplished with continuous infusion of insulin via a pump. Intensive insulin therapy aims to provide a more physiologic

profile of insulin; it is now recommended for the majority of patients with type 1 diabetes and some type 2 diabetics. See **Table 4** below for examples of intensive insulin therapy regimens.

**Table 4. Examples of Intensive Insulin Therapy Regimens**

Regimen	Breakfast	Lunch	Dinner	Bedtime
1	Reg	Reg	Reg	NPH
2	Reg + NPH	—	Reg	NPH
3	Reg + Glargine	Reg	Reg	—
4	Reg	Reg	Reg	Glargine

➔ *When NPH is used as part of either a conventional or an intensive insulin regimen, evening doses should be administered at bedtime or as close to bedtime as feasible.*

*Although research findings strongly support the use of intensive insulin therapy, there are associated drawbacks:*

- Greater effort is required on the part of the inmate to coordinate diet, activity, insulin administration, and glucose monitoring.
- Greater effort is required to assure that insulin and mealtimes are coordinated.
- There is up to a three-fold increase in the incidence of hypoglycemia (a significant concern for correctional facilities).
- Weight gain is more likely, sometimes limiting patient compliance.

## Insulin and Insulin Analogues

The recent introduction of insulin analogues has expanded options for management of diabetes. The long-acting and rapid-acting insulin analogues are reviewed below.

➔ *In general, rapid-acting insulin is not utilized in the BOP because of the risks of hypoglycemia.*

**Long-acting insulins** (insulin glargine and insulin detemir) are frequently utilized in the community (i.e., outside the correctional setting) in place of **intermediate-acting insulin** (NPH). Insulin glargine (Lantus) has virtually no peak and can often be administered once daily. A disadvantage of insulin glargine is that it cannot be mixed with other insulins and thus requires a separate injection. Insulin detemir has a shorter duration of action than that of insulin glargine, but longer than NPH. Detemir is generally administered twice daily.

Studies comparing glargine and detemir with NPH have shown that the two longer acting agents have no superiority over NPH in terms of glycemic control; A1C values are no lower with long-acting insulins than they are with NPH insulin. It is important to note that evening doses of NPH insulin should be given at bedtime or as close to bedtime as feasible.

**Rapid-acting insulins** are often utilized in the community instead of **short-acting (regular) insulin**. The advantages of rapid-acting insulin, over regular insulin, include a reduction in the postprandial rise in blood glucose concentration and modest reductions in hypoglycemia. Rapid-acting insulin must be injected *immediately* before or after meals (a potential advantage in the community, but a disadvantage in the correctional setting). It may be necessary to increase the dose of basal insulin when a patient is switched from regular to rapid-acting insulin. Rapid-acting insulin can be especially useful in situations where unexpectedly high blood glucose levels are encountered, i.e., in

stressful situations or between meals, because it quickly lowers glucose levels without a prolonged effect.

In terms of glycemic control, clinical trials have shown only minor benefits of rapid-acting insulin over regular insulin. There is little difference in A1C values for patients on rapid-acting insulin, as compared to regular insulin.

Recognizing that many diabetic inmates may have used insulin analogues prior to incarceration, the action profiles of commonly utilized insulin analogues are outlined below in *Table 5*:

**Table 5. Onset and Peak of Commonly Used Insulin Preparations**

Insulin or Insulin Analogue	Action Profile	
	Onset	Peak
<b>Ultra-rapid-acting</b>		
Insulin lispro (Humalog)	12–30 min	30 min–2 hrs
Insulin aspart (Novolog)	12–30 min	30 min–2 hrs
Insulin glulisine (Apidra)	12–30 min	30 min–2 hrs
<b>Short-acting</b>		
Regular (human) Humulin R/Novolin R	30 min–1 hr	2–3 hrs
<b>Intermediate-acting</b>		
NPH (human) Humulin N/Novolin N	1.5–4 hrs	4–10 hrs
<b>Long-acting</b>		
Insulin glargine (Lantus)	1–3 hrs	No peak
Insulin detemir (Levemir)	1–3 hrs	9 hrs–unknown

Adapted from: Mooradian AD, Bernbaum M, Albert S. Narrative review: a rational approach to starting insulin therapy. *Ann Intern Med.* 2006;145:125-134.

## Designing a Multiple-Dose Insulin Regimen

Newly diagnosed type 1 diabetics ordinarily can be started on a total daily dose of 0.2 to 0.4 units of insulin per kg per day; most will eventually require 0.6 to 0.7 units per kg per day.

- **NPH:** *Approximately half the total dose should be NPH insulin, administered twice daily.* In general, two-thirds of the total NPH dose should be given in the morning and one-third at bedtime (or as close to bedtime as feasible).
- **Regular:** *The second half of the total daily insulin dose should usually consist of pre-meal, regular insulin.* The dosing of pre-meal insulin is based upon the usual meal size and calorie count. Nutritional consistency is critical for maintaining adequate glycemic control. The sliding scale for regular insulin is generally based upon the meal carbohydrate content and the pre-meal blood glucose levels. When NPH insulin is utilized as part of the regimen, a pre-lunch bolus of regular insulin may not be necessary.

### *Clinical Precautions for Multiple-Dose Insulin Regimens:*

- 1) *A disadvantage of glargine insulin (Lantus) is that it cannot be mixed with any other insulins.*
- 2) *Fixed-dose insulin combinations (e.g., 70/30 insulin preparations), are generally not suitable for insulin-dependent diabetics who need to achieve target A1C levels. Fixed-dose insulin formulations are not flexible enough to match changes in caloric intake with appropriate doses of short-acting and long-acting insulin.*

- 3) *Type 1 diabetics, and any type 2 diabetics who require short-acting insulin, must have access to glucose monitoring on an as-needed basis (typically before each dose of short-acting insulin), in order to achieve optimal control and to avoid hypoglycemia.*
  - 4) *Rapid-acting insulin (lispro and aspart) should be avoided in most circumstances; the benefit versus risk of using these agents within the correctional environment needs to be carefully assessed and appropriately justified on a case-by-case basis.* Anything that keeps the inmate from eating within 20–30 minutes after a rapid-acting insulin injection is very likely to induce symptomatic hypoglycemia.
- *If the rapid-acting insulin dose is not high enough to cause at least some symptoms of hypoglycemia in the absence of food, then it is also not high enough to provide adequate glucose control.*

## Insulin Administration

Diabetic inmates who require insulin should be educated on the appropriate and safe administration of insulin.

- **Administration:** **Directly observed** self-administration of insulin is recommended whenever feasible. Insulin should be administered subcutaneously at a 45-to-90 degree angle at a clean injection site, using clean hands. Absorption is fastest from injections into the abdominal wall (>2 inches from the umbilicus), making this site preferable for pre-meal (regular) insulin therapy. Injections into the leg or buttock result in slower absorption and are thereby appropriate for the evening dose of intermediate-acting (NPH) insulin. Rotating injection sites is recommended to prevent lipodystrophy.
- **Mixing Regular and NPH Insulin:** The following procedure should be utilized when mixing Regular and NPH insulin. Regular insulin should be drawn up first, followed by the NPH (being careful not to inject the Regular insulin into the NPH vial). Administer the mixture of Regular/NPH insulin within 15 minutes of drawing them up.
- **Infection Control Issues:** *Insulin syringes should be used only once; they should never be used on more than one patient or reused in the same patient.* Infection control procedures should be established to prevent the recapping of insulin needles, or the handling of contaminated syringes by other inmates or health care providers, following injections. Used insulin syringes should be promptly disposed of in puncture-resistant containers. Measures should be taken to avoid contamination of insulin solution when using multi-dose vials. Individual (single-person) use of multi-dose vials can be considered when inmates are permitted to draw up their own insulin. Multi-dose vials should be discarded if their sterility has been compromised. See infection control recommendations outlined in [Appendix 8, Infection Control for Diabetes Care Procedures](#).
- **Insulin pumps** are rarely necessary for type 2 diabetics. Newly incarcerated type 1 diabetics who are already on insulin pumps should usually be maintained on the pump. A physician with expertise in treating diabetes should be consulted before initiating long-term use of an insulin pump.
- **Inhaled Insulin** (Exubra) was approved by the FDA in 2006 as an alternative to subcutaneous rapid-acting insulin. The clinical indications are being evaluated. Given its higher cost, constraints in dosage flexibility, and questionable efficacy in achieving tight glycemic control, inhaled insulin is not indicated as a first-line treatment.

## Coordination of Insulin and Food Intake

The correctional environment poses challenges for coordinating insulin administration with food intake, particularly for inmates on short-acting (regular) insulin. The consequences of insulin/food mismatch are, at best, suboptimal control of hyperglycemia; at worst, the result is frequent and potentially severe hypoglycemic episodes. Because of the many factors in a correctional environment that can interfere with the optimal timing of insulin and food, the insulin regimen should be as “forgiving” as possible. The shorter the onset and peak of the insulin, the more critical it is to coordinate food intake with insulin administration. ***For this reason, rapid-acting insulin is generally not utilized within the BOP.***

Short-acting (regular) insulin is typically administered two-to-three times per day; ideally, it should be administered prior to a meal to allow some absorption of insulin prior to the rise in blood glucose that occurs during a meal. ***However, if the timing of meals is uncertain, regular insulin can be administered immediately after eating (rather than before).*** Although the inmate will have a short period of postprandial hyperglycemia, this approach causes fewer long-term consequences and good diabetic control can still be achieved.

***Below are questions to consider when planning for optimal insulin/food coordination in BOP facilities:***

- *Depending on the size of the dining hall, the size of the inmate population, and the type of meal being served, it may take anywhere from one-to-three hours to serve a meal. Is the pill line open during this entire meal period to administer insulin?*
- *Do inmates have free movement to go to the pill line before they go to the dining hall?*
- *If insulin is given prior to a meal, and then an institution recall occurs (a lockdown, an emergency count, a fog line, a severe weather incident, etc.), which of these situations would prevent inmates from eating?*
- *Are there contingency plans to provide food to prevent hypoglycemia?*
- *Are correctional staff trained to appropriately identify and respond to hypoglycemic episodes in insulin-dependent inmates?*
- *How quickly could a sack lunch or a snack be provided to inmates who had received their insulin, but were then prevented from eating their usual meal?*

## 9. Blood Glucose Monitoring

Glycemic control is the fundamental goal for managing patients with diabetes. Frequent monitoring of blood glucose (three times per day) is optimal for most patients with type 1 diabetes, type 2 diabetics who are on insulin, and pregnant women taking insulin. The optimal frequency of glucose monitoring for other patients with type 2 diabetes is uncertain and should be determined on a case-by-case basis. Type 2 diabetics who are well-controlled on oral agents, and are not taking insulin, generally have no need for a personal glucose monitor.

In the correctional setting, the methods and frequency of glucose monitoring must be determined in light of the institution’s security concerns, as well as the relevant patient factors. The following strategies permit adequate monitoring of blood or plasma glucose in inmates with diabetes. Self-monitoring of blood glucose is the preferred method for assessing glycemic control for most diabetic inmates who require insulin.

***The following criteria should be used to determine if a diabetic inmate should be issued a glucometer:***

- The inmate requires insulin on a chronic basis;
- The inmate has arrived at his designated facility;
- The inmate is highly motivated to monitor his or her blood glucose values; and
- The inmate has no cognitive or sensory impairments that would prevent accurate and safe self-monitoring.

Glucometers should be provided to inmates in accordance with the periodic guidance from the Medical Director that addresses security, logistical, and infection control concerns.

→ ***Periodic finger sticks at Health Services are still recommended so that reliable data can be collected to monitor the patient's response to treatment.***

Outbreaks of hepatitis B have been reported related to sharing of finger stick devices and glucose monitors. ***Finger stick devices must be issued for individual use only.*** Glucometers generally should be issued for individual use, as well. However, if a glucometer must be used by more than one patient, it should be cleaned and disinfected after each use. See infection control recommendations outlined in [Appendix 8](#).

## 10. Gestational Diabetes (GDM)

### Detection and Diagnosis

All pregnant inmates should be assessed for risk for GDM at the first prenatal visit, according to the risk categories outlined in *Table 6* below.

**Table 6. Gestational Diabetes Risk Categories and Related Screening Recommendations**

Risk Category	Screening Recommendations	
	As soon as possible	At 24–28 weeks gestation
<p><b>HIGH-RISK</b></p> <p><b>If any of the following are true:</b></p> <ul style="list-style-type: none"> <li>• Overweight/obese before pregnancy (BMI <math>\geq</math>25)</li> <li>• Personal history of GDM</li> <li>• Delivery of a previous large-for-gestation-age infant</li> <li>• Glycosuria</li> <li>• Polycystic ovary syndrome</li> <li>• Strong family history of diabetes</li> </ul>	<p>Perform 50-g glucose load. If threshold values exceed 140 mg/dl, perform 100-g oral glucose tolerance test.*</p>	<p>Repeat testing for women not found to have GDM on initial testing.</p>
<p><b>NOT HIGH-RISK</b></p>		<p>Perform 50-g glucose load. If threshold values exceed 140 mg/dl, perform 100-g oral glucose tolerance test.*</p>
<p>* Perform an initial screening by measuring plasma or serum glucose concentration 1 hour after a 50-g oral glucose load (glucose challenge test); for the subset of women who exceed the glucose threshold value (140 mg/dl) on the glucose challenge test, perform a diagnostic 100-g oral glucose tolerance test (OGTT).</p>		

The diagnostic criteria for gestational diabetes mellitus are outlined in *Table 7* below.

**Table 7. Diagnostic Criteria Gestational Diabetes Mellitus**

Oral Glucose Tolerance Test (OGTT)
<p>Two or more of the plasma glucose values must be exceeded for a positive diagnosis:</p> <ul style="list-style-type: none"> <li>&gt;95 mg/dl fasting</li> <li>&gt;180 mg/dl at 1 hr</li> <li>&gt;155 mg/dl at 2 hr</li> <li>&gt;140 mg/dl at 3 hr</li> </ul> <p><b>Note:</b> To confirm diagnosis of GDM, confirm these results as soon as possible on a subsequent day.</p>

## Potential Complications of GDM

Gestational diabetes (GDM) affects approximately 7% of all pregnant women. It is crucial that women with GDM be monitored closely because the fetuses of mothers with hyperglycemia are at greater risk for intrauterine death or neonatal mortality. GDM is also associated with fetal macrosomia, as well as neonatal hypoglycemia, hypocalcemia, polycythemia, and hyperbilirubinemia.

## Monitoring and Treatment During Pregnancy

The following guidelines should be considered when managing inmates with GDM:

- Close surveillance of the mother and fetus must be maintained throughout the pregnancy. Self-monitoring of blood glucose should be done on a frequent (daily) basis. Use of post-prandial monitoring is preferred. Monitoring of urinary glucose is not an adequate measure.
- Screening for hypertension should include measurement of blood pressure and urine protein.
- Clinical estimation of fetal size and asymmetric growth via serial ultrasounds, especially early in the third trimester, may identify large infants who would benefit from maternal insulin therapy.
- All inmates with GDM should receive dietary counseling and be provided with adequate calories and nutrients during pregnancy.
- Insulin therapy should be considered if dietary management does not result in:
  - (1) the fasting whole blood glucose  $\leq$ 95 mg/dL, *or*
  - (2) the fasting plasma glucose  $\leq$ 105 mg/dL, *or*
  - (3) the two-hour postprandial whole blood glucose  $\leq$ 120 mg/dL, *or*
  - (4) the two hour postprandial plasma glucose  $\leq$ 130 mg/dL.
- Oral hypoglycemic agents should be considered in lieu of insulin on a case-by-case basis, but only after careful consultation with an obstetrician; their efficacy and safety are still being investigated.
- Breast feeding should be encouraged in women with gestational diabetes mellitus.
- Whenever possible, care should be coordinated with an obstetrician experienced in the treatment of women with gestational diabetes.

## Postpartum Monitoring

Women with GDM are at an increased risk for developing diabetes later in life and should be educated on the importance of maintaining normal body weight, good nutrition, and physical activity. If postpartum glucose levels are normal, a fasting serum glucose screening should be obtained every three years in asymptomatic inmates. Inmates should be taught to recognize symptoms of hyperglycemia so that they readily seek medical attention at the onset of diabetes. Inmates with IFG or IGT (“pre-diabetes”) should be screened annually for diabetes with a fasting plasma glucose test; at that time, they should also be counseled regarding diet and a plan for aerobic exercise or increased physical activity.

## 11. Medical Management of Diabetic Complications

### The Seriousness of Diabetic Complications

According to the *National Diabetes Fact Sheet*, issued by the Centers for Disease Control and Prevention (CDC) in 2011 (see listing under [References](#)), diabetes affects 8.3% of the U.S. population. As reported in the Fact Sheet, the complications of diabetes are serious and numerous, for example:

- Sixty percent of non-traumatic lower-limb amputations occur in patients with diabetes.
- Diabetes is the leading cause of kidney failure, accounting for 44% of all new cases of kidney failure in 2008.
- Diabetes is the leading cause of new blindness in adults 20–74 years of age.
- Diabetic adults have heart disease death rates 2 to 4 times higher than non-diabetics, and their risk of stroke is 2 to 4 times greater than non-diabetics.
- Pre-diabetes affects 35% of adults aged 20 years or older, and 50% of adults aged 65 years or older.
- Women with gestational diabetes have a 35–60% chance of developing diabetes within 10–20 years.
- Diabetes remains the seventh leading cause of death.
- Medical expenses for people with diabetes are more than two times higher than for people without diabetes. In 2007, the direct medical costs of diabetes in the U.S. were estimated at \$116 billion, with indirect costs (e.g., disability, early mortality, work loss) of \$58 billion.

Management of diabetic complications is further discussed in this section.

### Hypertension

Diabetic patients with hypertension should have their blood pressure (BP) lowered to targeted levels, since serious microvascular and macrovascular diabetic complications are strongly linked to hypertension. The optimal treatment goal for non-pregnant diabetics over age 18 is a systolic BP of <130 and a diastolic <80 mmHg.



Patients with a systolic BP  $\geq 140$  or a diastolic BP  $\geq 90$  mmHg should receive drug therapy in addition to recommended lifestyle interventions. Those with a systolic pressure of 130–139 or a diastolic of 80–89 mmHg should be prescribed lifestyle interventions for up to three months. If the inmate fails to achieve a systolic BP  $< 130$  or a diastolic BP  $< 80$  mmHg within three months, drug therapy should be prescribed.

**All diabetics with hypertension should ordinarily be treated with an ACE inhibitor.** If an ACE inhibitor is contraindicated, consider using an angiotensin receptor blocker (ARB).

→ **ACE inhibitor therapy should also be considered for diabetic inmates, with or without hypertension, who have other cardiovascular risk factors.**

## Dyslipidemia

Type 1 and type 2 diabetes are considered coronary heart disease (CHD) risk equivalents, due to the strong association of diabetes and serious cardiovascular disease. Type 2 diabetes is associated with other CHD risk factors such as elevated LDL cholesterol, low HDL cholesterol, and elevated triglycerides. Lipid disorders should be managed aggressively in diabetic patients to reduce the risk of serious cardiovascular events. The therapeutic LDL goal for diabetic patients is  $< 100$  mg/dL; for diabetics with diagnosed CHD, an optional goal of  $< 70$  mg/dL should be considered. If drug treated patients do not reach targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of  $\sim 40\%$  of baseline is an alternative therapeutic goal. Monitoring and treatment strategies for lipid disorders should be pursued in accordance with the *BOP Clinical Practice Guideline on Management of Lipid Disorders*, which can be accessed at <http://www.bop.gov/news/medresources.jsp>.

## Cardiovascular Events: Aspirin Therapy as Intervention

Clinical trials have demonstrated that aspirin therapy is a cheap and effective intervention for preventing serious cardiovascular events such as myocardial infarctions and stroke among diabetics. The following recommendations are adapted from the American Diabetes Association's *Standards of Medical Care in Diabetes—2010 (Executive Summary)*:

- Consider aspirin therapy with enteric coated aspirin (75–162 mg/day) as a primary prevention strategy in patients with type 1 or type 2 diabetes who are at increased cardiovascular risk (10-year risk  $> 10\%$ ). This includes men  $> 50$  years of age and women  $> 60$  years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).
- There is not sufficient evidence to recommend aspirin for primary prevention in lower-risk individuals, such as men  $< 50$  years of age and women  $< 60$  years of age who do not have other major risk factors. For patients in these age-groups who have multiple other risk factors, clinical judgment is required.
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in diabetic patients who have a history of CVD.
- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used.
- Combination therapy with ASA (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome.

Other antiplatelet agents may offer reasonable alternatives for patients who are high-risk, but have conditions that contraindicate aspirin therapy such as an aspirin allergy, undergoing anticoagulant therapy, a bleeding tendency, recent gastrointestinal bleeding, or clinically active hepatic disease.

**Clinical Precaution for Aspirin Therapy:**

*Do not routinely use aspirin in inmates <21 years of age, due to the increased risk of Reye’s syndrome.*

**Diabetic Nephropathy**

Microalbuminuria (30–300 mg/24 hour), the earliest stage of kidney disease associated with diabetes, often progresses to clinical albuminuria (greater than 300 mg/24 hours) with a subsequent decline in renal function over a period of years. Hypertension usually develops during the onset of microalbuminuria and, if left untreated, can hasten progression of renal disease. Prevention and treatment recommendations for diabetic nephropathy include:

- **Maximize glycemic control** to delay onset of microalbuminuria.
- **Annually screen for microalbuminuria** in all type 2 diabetics, in type 1 diabetics beginning five years after diagnosis, and for gestational diabetes. The recommended method for screening for microalbuminuria in the BOP is by measurement of the albumin-to-creatinine ratio in a random spot collection. Clinical microalbuminuria is defined as the occurrence of elevated albumin-to-creatinine ratio for two of three tests within a six-month period. Measurement of spot urine for albumin only is *not* recommended.
- **Measure serum creatinine annually to calculate a glomerular filtration rate (GFR).** Serum creatinine alone is *not* an adequate measure of kidney function. Studies have found a decreased GFR in the absence of increased urine albumin excretion in a substantial percentage of adults with diabetes. All diabetic inmates should have a GFR calculated at baseline and annually. The GFR can be calculated utilizing an internet calculator from the National Kidney Foundation: [http://www.kidney.org/professionals/kdoqi/gfr\\_calculator.cfm](http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm).
- The stages of chronic kidney disease based on GFR are outlined in *Table 8* below. A nephrologist should be consulted if the GFR is <30 ml/min per 1.73 m<sup>2</sup>.

**Table 8. Stages of Chronic Kidney Disease**

Stage	Description	GFR (mL/min/1.73 m <sup>2</sup> )
1	Kidney damage with normal or elevated GFR	≥90
2	Kidney damage with mildly decreased GFR	60–89
3	Moderately decreased GFR	30–59
4	Severely decreased GFR	15–29
5	Kidney failure	<15 (or dialysis)

Chronic kidney disease is defined as either kidney damage or GFR <60 mL/min/1.73 m<sup>2</sup> for 3 months or more. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in composition of blood or urine tests or abnormalities in imaging tests.

- **Regardless of blood pressure status, treat diabetics with microalbuminuria with ACE inhibitors** (unless medically contraindicated). An ARB should be considered if ACE inhibitors cannot be tolerated or are contraindicated. Monitor for hyperkalemia.
- **Lower blood pressure to <130/80**, using multi-drug therapy if necessary.
- **Restrict protein intake for diabetic inmates with the onset of nephropathy.**
- **Avoid metformin in patients with elevated creatinine levels** (>1.5 mg/dl in men, or >1.4 mg/dl in women) because of increased risk of acidosis.

## Diabetic Retinopathy

Patients with type 1 diabetes do not usually have vision-threatening retinopathy in the first five years of their disease. Over the next 20 years, however, nearly all type 1 diabetics develop some retinopathy. A significant percentage of patients with type 2 diabetes have retinopathy at the time of diagnosis, and many will develop some degree of retinopathy over subsequent years. Retinopathy progresses in a predictable manner, advancing from mild background abnormalities to pre-proliferative retinopathy, and then to proliferative retinopathy. Vision loss occurs when macular edema or capillary non-perfusion cause the loss of central vision, or from proliferative retinopathy, which can lead to retinal detachment and irreversible vision loss. The proliferative vessels may also bleed, leading to pre-retinal or vitreous hemorrhage. Prevention and treatment recommendations for diabetic retinopathy include the following:

- **Maximize glycemic control**, since this reduces the risk of progression to clinically significant retinopathy.
- **Maximize blood pressure control.**
- **Annual funduscopic eye exam.** Screen diabetic patients for retinopathy, since proliferative retinopathy and macular edema may occur in completely asymptomatic patients,
- **Monitor pregnant diabetic patients closely**, since pregnancy may aggravate retinopathy.
- **Continue aspirin therapy.** It neither prevents retinopathy nor increases the risk of retinal hemorrhage.
- **Refer patients for laser photocoagulation surgery when indicated.** Photocoagulation reduces the risk of further vision loss in patients with retinopathy, but does not ordinarily reverse established vision loss.

## Diabetic Neuropathy

Peripheral diabetic neuropathy may result in pain, loss of sensation, and muscle weakness. Autonomic neuropathy may involve the gastrointestinal, cardiovascular, and genitourinary systems, resulting in related symptoms and complications. Diabetic neuropathy is treated by maximizing glycemic control and addressing related symptoms.

Pain related to diabetic neuropathy is treated with tricyclic amines and anticonvulsant medications. Titrated doses of nortryptline or carbamazepine are most effective in treating chronic nerve pain associated with diabetic neuropathy. Opioid therapy is not recommended as

it is an acute pain management therapy, and NSAIDS (ibuprofen) have no therapeutic benefit with neuropathic pain.

Foot ulcers and amputations are complications of diabetes that are frequently related to neuropathy. The risk of amputation is associated with the following conditions: peripheral neuropathy with a loss of sensation, evidence of increased pressure (erythema, hemorrhage under a callus), peripheral vascular disease (absent distal pulses), severe nail disease, and a history of foot ulcers.

Screening for diabetic neuropathy should include monofilament testing. For a thorough description of how to conduct a diabetes foot screen including monofilament testing, consult the following website: Department of Health and Human Services, Health Resources and Services Administration, Lower Extremity Amputation Prevention (LEAP) Program:  
<http://www.hrsa.gov/leap/>.

***Footwear recommendations for diabetic inmates should consider the following:***

- The current version of the BOP standard-issue work shoe addresses most concerns of diabetic and non-diabetic inmates.
- The institution is required to provide an inmate with a properly fitting work shoe. Tennis shoes and other recreational footwear are solely the responsibility of the inmate.
- Inmates with severe neuropathy are best served with protective footwear, such as steel-toed work shoes or boots, that minimize the chance of an incidental foot trauma that could cause a diabetic ulcer. Extra-wide, extra-deep toe boxes will reduce the risk of irritation to feet with deformities and/or impaired sensation. Only rarely will a tennis shoe be the most appropriate choice for a diabetic inmate.
- Medically ordered footwear should be considered in certain circumstances, including the following:
  - Inmates with symptomatic foot deformities (e.g., large bunions, pronounced hammertoes, etc.) where regular-issue shoes of the appropriate size and width are causing significant skin irritation or ulceration.
  - Inmates with Risk Category 2 or 3 (as determined by the LEAP Diabetes Foot Screen). This includes those with a loss of protective sensation with either high pressure (callous/deformity), or poor circulation; or history of plantar ulceration, neuropathic fracture (Charcot foot) or amputation.
  - Inmates with significant vascular disease as suggested by claudication, absent dorsalis pedis or tibialis posterior pulses, or other studies.

## Diabetic Periodontitis

Periodontal disease is the most common oral health complication associated with diabetic patients. Many patients with uncontrolled diabetes suffer from chronic inflammatory oral diseases and related premature tooth loss. The loss of tissue attachment and osseous destruction often correspond to poor glycemic control.

Non-dentists should be aware of the bidirectional relationship between periodontal disease and glycemic control. While it is known that patients with diabetes have an increased risk for periodontal disease, *it also has been shown that active periodontal disease can contribute to the progression of diabetes.* Studies have demonstrated that periodontal therapy can lower the blood sugars of diabetic patients.

An oral evaluation may reveal the periodontium (teeth and supporting gums and bone) as a possible focus of infection and a contributing factor in poor glycemic control. Healthcare providers should examine the oral cavity for *cardinal signs* of overt periodontal disease (see *Table 9* below). Incipient changes to gingival tissue may present as gingivitis (gum inflammation). Advanced periodontitis will present as gum inflammation, bone loss, and tooth mobility.

**Table 9. Cardinal Signs of Periodontitis**

<b>1</b>	<b>Bleeding gums</b>	Patients report frequent bleeding, even though they brush and floss consistently; the bleeding is related to inflammatory changes in the gums.
<b>2</b>	<b>Red swollen gums</b>	Gums are inflamed, and may be stippled. (Healthy gum tissue is pink and well-adapted to the underlying osseous architecture.)
<b>3</b>	<b>Gums that have pulled away from the teeth</b>	Root surfaces are exposed, giving the appearance that the teeth are actually longer.
<b>4</b>	<b>Infection or abscesses</b>	Exudate (pus) can be expressed at the gingival crevice by slightly pressing on the tissue.
<b>5</b>	<b>Fetid odor</b>	Bad breath often accompanies active oral infection.
<b>6</b>	<b>Mobile teeth</b>	Teeth are loose. Patients also may complain of gaps and spaces, which have resulted from bone loss and the teeth moving away from each other.
<b>7</b>	<b>Occlusal changes</b>	Patients complain that their bite has changed, a result of bone loss and inflammatory changes.
<b>8</b>	<b>Changes in the fit of prosthetics</b>	Dentures no longer fit or feel comfortable, due to unstable periodontium.
<b>9</b>	<b>Tooth loss</b>	Teeth are lost as a result of progressive bone loss around teeth.

Just as patients are advised about retinopathy, neuropathy, nephropathy, macrovascular disease, and altered wound healing, they need to be made aware of the oral health complications (periodontal disease) associated with diabetes. A comprehensive approach to diabetic management should include the oral health team. Long-term treatment often includes patient education, routine hygiene appointments, and antibiotic therapy.

## Dental Care

Diabetes is associated with an increase in the incidence and severity of gingival inflammation, periodontal abscesses, and chronic periodontal disease. The increased prevalence of dental caries in young diabetic patients is related to reduced salivary flow. Individuals with uncontrolled diabetes often heal more slowly from oral surgery, making them more susceptible to infection. The primary concern for diabetic inmates requiring dental treatment is the need to avoid metabolic imbalances during treatment interventions.

### Dental Procedures

Dental practitioners should confirm that diabetic inmates have eaten breakfast and have received morning medications before they provide dental care. Special attention should be given to patients with severe periodontal disease, since this may be an indicator of poor glycemic control. If possible, the inmate's blood glucose should be assessed the day of the dental appointment through glucometer testing or another available method. Adequately controlled diabetic inmates can receive dental care much the same as non-diabetic patients.

Dental care should be provided to diabetic inmates early in the day. Blood glucose and endogenous corticosteroid levels are usually higher in the morning, resulting in improved patient outcomes. Patient encounters should be brief. If the dental procedure extends into a scheduled meal, clinicians should provide a break for an appropriate snack. If this is not feasible, patient care should be concluded and continued at another appointment.

Clinicians should make sure that the dental staff are aware of an inmate's diabetic condition, and the inmate should be instructed to tell dental staff when they feel the onset of an insulin reaction. Dental practitioners should always be prepared for a hypoglycemic episode. A source of sucrose (or glucose/glucagon, if the inmate is taking acarbose) should be kept in the dental clinic for such emergencies.

Prior to performing invasive procedures (e.g., surgery or exodontia), dentists should consider antibiotic coverage for patients with poorly controlled diabetes. Patients with uncontrolled hyperglycemia are susceptible to post-operative infections and associated sequelae. The administration of antibiotics may improve post-operative healing.

After *all* dental procedures, diabetic patients should be screened carefully for occult dental infections. Special attention should be given to the post-surgery dietary needs of patients undergoing extensive periodontal or oral surgical procedures. The inmate's primary physician should be consulted for dietary recommendations.

### Oral Complications of Diabetes

Oral pathology in patients with uncontrolled diabetes mellitus is caused by a combination of factors: excessive loss of fluids, an altered response to infections, microvascular changes, and possibly the increase in salivary glucose concentrations. The combined effect of hyperglycemia and the related polyuria is to deplete extracellular fluids and reduce salivary secretion, causing a dry mouth (xerostomia). Oral complications most commonly associated with diabetes are xerostomia, oral lesions, burning and/or enlargement of the tongue, denture sore mouth,

candidiasis, cheilosis, and periodontal disease; as well as orofacial neurosensory disorders manifesting as hypogeusia (taste impairment), stomatopyrosis, glossodynia, and dysesthesia.

Diabetes is associated with an increase in the incidence and severity of dental caries, gingival inflammation, periodontal abscesses, and chronic periodontal disease. Individuals with uncontrolled diabetes often heal more slowly from oral surgery, making them more susceptible to infection.

***Dentists should consider the following when treating diabetic inmates with periodontitis:***

- Informing the inmate's physician about the presence of periodontal infection and the proposed treatment.
- Providing periodontal therapy and motivating the inmate to establish and maintain periodontal health.
- Prescribing systemic antibiotics in conjunction with mechanical therapy.
- Educating the inmate regarding the possible impact of periodontal infection on glycemic control.

**Medical Decompensation (Hospitalization Criteria)**

The decision to admit inmates to an inpatient hospital unit should be made on a case-by-case basis, but the following indications generally warrant hospitalization for diabetics:

- Diabetic ketoacidosis that is characterized by a plasma glucose  $>300$  mg/dL with an arterial pH  $<7.30$ , an increased anion gap, and serum bicarbonate level  $<15$  mEq/L, along with moderate ketones in the urine or blood. Low sodium, elevated potassium, and elevated BUN may also occur. Total body intracellular potassium may be significantly depleted, regardless of serum potassium levels.
- Hyperglycemic hyperosmolar state that is characterized by an elevated serum osmolality ( $>320$  mOsm/kg), usually with severe hyperglycemia (plasma glucose  $>600$  mg/dL) and associated with an altered mental status that may progress to coma.
- Severe hypoglycemia with a blood glucose  $<50$  mg/dL and an altered mental status that does not readily improve with treatment or is associated with neurologic deficits. Hypoglycemia caused by sulfonylureas can be prolonged or recurrent due to the drugs' long duration of action. Symptomatic hypoglycemia that cannot be managed with frequent feedings over a 24-hour period should be treated in a hospital setting.
- Uncontrolled hyperglycemia diagnosed during pregnancy.
- Moderate to severe hyperglycemia that is unresponsive to standard therapies or is associated with an acute illness.
- Severe complications of diabetes that warrant inpatient evaluation and treatment.

## 12. Periodic Evaluations

### Overview

Diabetes management requires dedicated clinicians, as well as the expertise of other treatment professionals, including pharmacists, nurses, optometrists or ophthalmologists, **dentists**, dietitians, physical therapists, and recreation specialists. Inmate treatment plans should be individualized, have measurable goals, and emphasize self-management. Regularly scheduled evaluations help maximize glycemic control, reduce diabetic complications, and enhance educational efforts. A one-page summary of recommended periodic evaluations is attached in [Appendix 2, Recommendations for Diabetic Chronic Care Clinic Monitoring](#).

The frequency of chronic care clinic visits for diabetic inmates should be individualized, depending on a number of factors: the degree of glycemic control, the complexity of the medication regimen, the frequency of changes to the regimen, the presence of complications of diabetes and co-morbid conditions, and the inmate's understanding of the disease and his or her self-motivation. Inmates with uncomplicated diabetes that is controlled by diet and exercise alone can be monitored predominantly by mid-level providers. Inmates with poorly controlled diabetes or with other serious complications such as heart or kidney disease should be monitored closely by a physician, along with the patient's mid-level provider(s). Weekly or monthly clinician evaluations may be necessary for brittle diabetics.

Inmates with IFG or IGT ("pre-diabetes") should be monitored for the development of diabetes with annual fasting *plasma* glucose measurements. One-third of these patients will be diagnosed with diabetes within five years.

### Medical History

The periodic patient interview should target the following concerns:

- Results of glucose monitoring and review of medication and/or insulin compliance.
- Frequency, causes, and severity of any hypoglycemic symptoms experienced since the last visit.
- Changes in the treatment regimen or any lifestyle changes made by the inmate between clinic visits (including level of participation in exercise, diet, and smoking cessation programs).
- Symptoms of concurrent illnesses such as untreated infections (e.g., tinea pedis, tinea cruris, ear infections, and urinary tract infections).
- Symptoms that suggest evolving complications such as paresthesias, weakness, angina, visual disturbances, skin infections, or foot problems.



## Physical Examination

The periodic examination should target the following (a more comprehensive physical should be conducted annually and whenever clinically necessary):

- Vital signs and weight.
- Foot exam (inspection, palpation of pulses, and an annual sensory exam--using a monofilament and documented on Diabetes Foot Screen form obtained from: <http://www.hrsa.gov/leap/>).
- Focused exam of organ systems, triggered by positive responses to questions on the interim history or the presence of diabetic complications.

## Glucose Monitoring

- Diabetic inmates should have their fasting or random glucose (by finger stick or venipuncture) evaluated frequently by the clinicians, nurses, and pharmacists they encounter, with notation as to the number of hours the sample is obtained postprandially. (If recent laboratory data are not available, at the very minimum, a random finger stick glucose should be measured as an indication of the degree of glucose control.)
- Inmates initiating insulin therapy, or making a major change in their insulin program, may need to be seen by a health care provider as frequently as daily until glucose control is achieved, the risk of hypoglycemia is low, and the inmate is competent and comfortable implementing the treatment plan.
- Inmates beginning treatment by diet or with oral glucose-lowering agents may need to be seen as often as weekly until reasonable glucose control is achieved, and the inmate is competent to conduct the treatment program.
- The frequency of blood glucose monitoring by the clinic should be based on factors that affect glycemic control:
  - Whether or not the inmate is self-monitoring.
  - Variations and degree of glycemic control, as documented by A1C levels.
  - Whether the inmate is being treated with insulin or oral agents.
  - Frequency of symptoms of hypoglycemia.
  - Frequency of prior adjustments in therapy.
  - Inmate motivation for self-care and the presence of limitations such as language barriers or mental illness.
  - Presence of diabetic complications. For example, diabetic inmates with retinopathy should be more closely monitored to protect them from wide fluctuations in blood glucose, which is thought to accelerate proliferative retinopathy.
- At minimum, a fasting or random glucose should be obtained at all routine patient encounters with diabetic inmates, along with routine vital signs.
- Periodic measurement of A1C levels is essential for assessing glucose control and compliance with therapy. Quarterly measurements are recommended if treatment changes are made or if glucose goals are not met; otherwise, measurements two times per year are ordinarily adequate. ***A1C measurements should be obtained just prior to a scheduled***

***appointment to review glycemic control. Medication adjustments should never be made based on A1C levels that were obtained more than 30 days prior to the appointment.***

- Urine glucose monitoring has limited value; it should only be considered as an alternative assessment of glucose control if inmates are unable or unwilling to perform blood glucose testing.

## **Monitoring for Diabetic Complications**

Inmates should receive the following evaluations to screen for diabetic complications:

- Annual serum electrolytes.
- Annual creatinine used to calculate a GFR.
- An annual screening test for microalbuminuria (for inmates who have had type 1 diabetes for more than five years and all inmates with type 2 diabetes), unless proteinuria has already developed).
- An annual fasting lipid profile to screen for hypercholesterolemia.
- An annual, comprehensive, dilated-eye and vision examination, by an ophthalmologist or optometrist (for all type 1 diabetics who have had the disease for five or more years and all inmates with type 2 diabetes). If an optometrist identifies ocular complications of diabetes or other serious problems, he or she should refer the inmate to an ophthalmologist.
- At each periodic visit, conduct a foot examination (inspection and palpation) to identify risk factors for amputation. Assess sensory loss through monofilament testing annually.

## **Inmate Education**

All inmates with diabetes should receive education from a health care provider at the time of diagnosis, and then periodically during subsequent evaluations and treatments. Inmates should be counseled on a range of issues related to their disease: the symptoms of hyperglycemia and hypoglycemia, how complications of diabetes progress, the importance of glycemic control, the benefits of healthy dietary selections and regular exercise, the importance of modifying heart disease risk factors, and the benefits and side effects of different medications. Inmates with poor glycemic control require more intensive educational efforts, either one-on-one or in groups.

Educational materials (revised in June 2012) are attached in [Appendix 10, Fact Sheet on Diabetes](#), [Appendix 11, The Three Keys to Controlling Your Diabetes](#), and [Appendix 12, Eating to Manage Your Diabetes in the Bureau of Prisons](#).

## **Documentation**

Periodic clinician evaluations should be documented in the inmate's medical record. The *Chronic Care Flow Sheet for Diabetes (BP S670.060)* is recommended for inmates who will be monitored for more than one year.

## **13. Health Care Provider Resources**

Provider resources for managing diabetes are listed in [Appendix 9, Resources for Information on Diabetes](#).

## Definitions

**Clinician** is a physician, mid-level provider, or an appropriately credentialed pharmacist.

**Conventional insulin therapy** describes the more simple insulin regimens, such as single injections of regular insulin given once daily, or two injections per day of regular and NPH insulin mixed together in fixed amounts in the same syringe (see [intensive insulin therapy](#) below).

**Diabetes mellitus** is a group of metabolic diseases characterized by hyperglycemia that results from defects in insulin secretion, insulin action, or both.

**Fasting plasma glucose** is a blood glucose that is obtained after no caloric intake for at least eight hours. It should be collected in a grey-top tube with glycolytic inhibitor and submitted for no other testing.

**HbA1C or A1C (glycated hemoglobin)** reflects the mean glycemia over the preceding two to three months. Values are free of day-to-day glucose fluctuations and are unaffected by exercise or recent food ingestion. The interpretation of this test depends on the red blood cells having a normal life span, the average being 120 days. Persons with hemolytic disease, or other conditions with a shortened red blood cell survival, exhibit a significant reduction in A1C. A1C can still be used to monitor inmates with such conditions, but the values must be compared with previous values from the same inmate, not from published reference values. High A1C levels have been reported in iron deficiency anemia, probably due to the high proportion of old, circulating erythrocytes.

**Gestational diabetes mellitus (GDM)** is any degree of glucose intolerance identified during pregnancy.

**Impaired glucose tolerance (IGT)** and **impaired fasting glucose (IFG)** are intermediate stages between normal glucose homeostasis and diabetes, which have recently been termed “[pre-diabetes](#).” Persons with either IGT or IFG are at risk for future diabetes and cardiovascular disease.

**Intensive insulin therapy** describes more complex regimens that provide basal insulin delivery (given as one or two daily injections of intermediate- or long-acting insulin) together with superimposed doses of short-, rapid-, or very rapid-acting insulin, three or more times daily.

**Lower Extremity Amputation Prevention (LEAP) Program** is a screening tool for peripheral neuropathy designed by the Hansen’s Disease Center; it uses a 10-gram monofilament to assess sensation of the soles of the feet. Refer to: <http://www.hrsa.gov/leap/>.

**Oral glucose tolerance test (OGTT)** is a supplemental test for diagnosing diabetes in certain patients. It involves an overnight fast after consuming an unrestricted diet for three days; then, an oral glucose load, followed by serial measurements of plasma glucose concentrations.

**Pre-diabetes** is a term applied to both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). IFG and IGT are each risk factors for future diabetes and cardiovascular disease.

**Type 1 diabetes** is caused by a deficiency of insulin secretion that is due to pancreatic islet  $\beta$ -cell destruction, which is frequently associated with pancreatic autoantibodies. Individuals with type 1 diabetes are usually dependent on exogenous insulin and are at risk for ketoacidosis.

**Type 2 diabetes** is caused by insulin resistance with a relative, but not absolute, deficiency of insulin. The etiology of type 2 diabetes is uncertain. Individuals with type 2 diabetes are not prone to ketoacidosis and may be asymptomatic.

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## Appendix 1: Components of the Comprehensive Diabetes Evaluation

<b>Medical History</b>	
<ul style="list-style-type: none"> <li>• Age and characteristics of onset of diabetes (e.g., diabetes ketoacidosis, routine screening)</li> <li>• Prior A1C records</li> <li>• Symptom review</li> <li>• Eating patterns, nutritional status, weight history; exercise history</li> <li>• Diabetes education history</li> <li>• Review of previous diabetes treatment</li> <li>• Current treatment of diabetes: medications, meal plan, results of glucose monitoring</li> <li>• Hypoglycemic episodes (any severe hypoglycemia – frequency, severity, cause)</li> <li>• History of diabetes-related complications: <ul style="list-style-type: none"> <li>• Microvascular (eye, kidney, nerve)</li> <li>• Macrovascular (CHD, PAD)</li> <li>• Other (sexual dysfunction, gastroparesis)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Diabetic ketoacidosis: frequency, severity, cause</li> <li>• Risk factors for atherosclerosis, i.e., smoking, hypertension, obesity, dyslipidemia, family history</li> <li>• Review of concurrent medications that may affect blood glucose levels or precipitate diabetes, i.e., HIV protease inhibitors, atypical antipsychotic agents, corticosteroids, pentamidine, high-dose thiazide diuretics</li> <li>• Review of prior/current infections, particularly of the skin, feet, dentition, genitourinary system</li> <li>• Female patients: gestational history including hyperglycemia, delivery of infant weighing more than 9 lbs., toxemia, stillbirth, polyhydramnios, or otherwise complicated pregnancy</li> <li>• Tuberculin (TST) skin test history and history of treatment of latent TB infection (LTBI)</li> </ul>
<b>Immunization History</b>	
<ul style="list-style-type: none"> <li>• Influenza vaccine (indicated annually for diabetic inmates, unless contraindicated)</li> <li>• Pneumococcal vaccine (at diagnosis; or at age 65, one-time revaccination if <math>\geq 5</math> yrs since initial vaccine)</li> </ul>	
<b>Physical Examination</b>	
<ul style="list-style-type: none"> <li>• Vital signs: height, weight, blood pressure (including orthostatic)</li> <li>• Funduscopic examination (preferably with pupillary dilation)</li> <li>• Thyroid palpation (Type 1 diabetes)</li> <li>• Skin examination (insulin injection site)</li> <li>• Oral exam</li> <li>• Hand and finger examination</li> <li>• Abdominal examination to rule out hepatomegaly, bruits, or enlargement of the abdominal aorta</li> <li>• Examination of the feet for infections or skin breakdown; testing for neuropathy</li> </ul>	<ul style="list-style-type: none"> <li>• Cardiac exam; auscultation/palpation of DP and PT pulses</li> <li>• Presence/absence of patellar and Achilles reflexes</li> <li>• Determination of proprioception, vibration, and monofilament sensation</li> <li>• Signs of other conditions that can cause secondary diabetes: bronzed skin color with hemochromatosis; GI malignancy (acanthosis nigricans); and endocrine disorders such as acromegaly, Addison's disease, pheochromocytoma, and Cushing's syndrome</li> </ul>
<b>Laboratory Examination</b>	
<ul style="list-style-type: none"> <li>• Fasting plasma or serum glucose (if not already obtained)</li> <li>• Hemoglobin A1C (HbA1C or A1C)</li> <li>• Fasting lipid profile (including total, LDL and HDL cholesterol, triglycerides)</li> <li>• Liver function tests</li> <li>• Urinalysis, as clinically warranted</li> <li>• Serum creatinine and calculated glomerular filtration rate (GFR)</li> <li>• Thyroid stimulating hormone</li> <li>• Screening for celiac disease in type 1 diabetes and as indicated in type 2 diabetes</li> </ul>	<p>Testing for microalbuminuria in type 1 diabetic inmates who have had the disease at least five years, and in all type 2 diabetics. (If routine urinalysis on two or more occasions detects protein, and other causes such as infection and menses are ruled out, then microalbumin determinations are <i>not</i> necessary because the nephropathy has already progressed to overt proteinuria.)</p> <ul style="list-style-type: none"> <li>• Urine culture, if symptoms of a urinary tract infection are present</li> <li>• Electrocardiogram (ECG) – baseline</li> <li>• TST (if not previously tested)</li> </ul>
<b>Referrals</b>	
<ul style="list-style-type: none"> <li>• Baseline optometry or ophthalmology exam</li> <li>• Dental care (including hard/soft tissue exam, periodontal assessment, and follow-up exam if indicated)</li> <li>• Diabetes education and medical nutrition therapy</li> </ul>	

## Appendix 2: Recommendations for Diabetes Chronic Care Clinic Monitoring

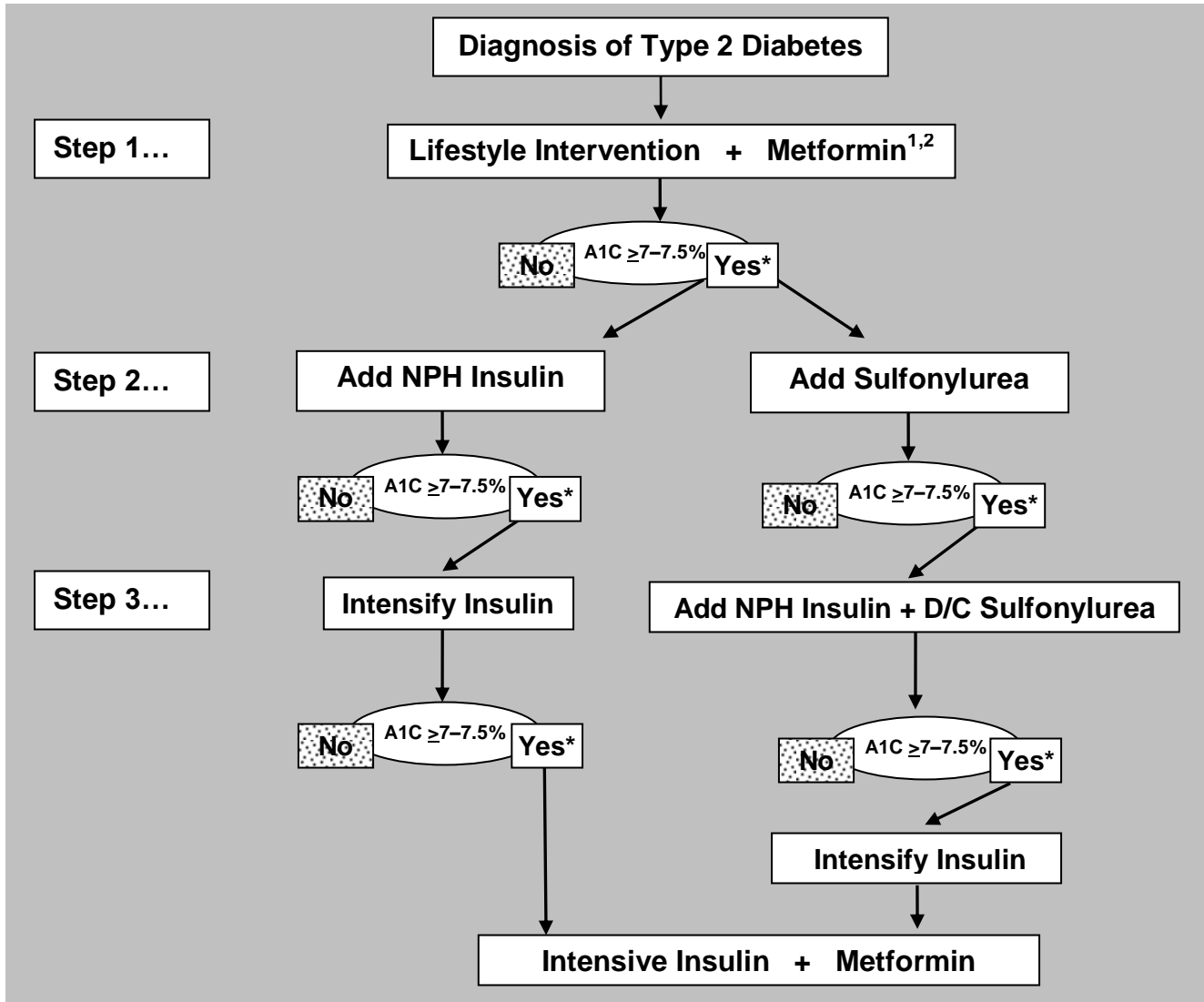
Recommendations for Diabetic Chronic Care Clinic Monitoring				
<b>Patient Evaluation / Routine Exam – SOAP Format</b>				
<p><b>S:</b> -Observations and patient complaints -Compliance with lifestyle changes and medications -Side effects of medications -Symptoms of diabetic complications</p> <p><b>O:</b> -Vital signs: blood pressure, pulse, respiration rate, temperature, weight, height -HEENT (include fundoscopic exam and neck evaluation) -Lungs/heart -Abdomen -Extremities / peripheral pulses / neuropathy / visual foot examination -Labs, x-rays, other studies</p> <p><b>A:</b> Assessment, analysis of data, diagnosis, degree to which glycemic goals are met</p> <p><b>P:</b> -Therapeutic regimen -Diagnostic studies -Education – adherence to all self-care aspects, exercise evaluation, follow-up of referrals, smoking cessation</p>				
Procedure, Test, Examination	Baseline Visit	Quarterly Visit	Semi-Annual Visit	Annual Visit
Routine physical exam	X	(X) as needed	(X) as needed	X
Fasting blood sugar (record results of self-monitoring where applicable) <sup>1</sup>	X	X		
Fasting complete metabolic panel (electrolytes, creatinine, total cholesterol)	X			X
Calculate glomerular filtration rate <a href="http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm">http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm</a>	X			X
Fasting lipid profile (obtain more often if managing a lipid disorder, less often if low risk)	X			X
HbA1C	X	(X) if treatment changes, or if clinically indicated	X	X
Screen for microalbuminuria (albumin to creatinine ratio in a random spot collection) <sup>2</sup>	X			X
Comprehensive, dilated-eye and vision exam, by an ophthalmologist or optometrist	X			X
Fundoscopic exam (by primary care doctor)	X			
Foot Exam: Visual Monofilament	X X	(X) if not reaching target goals	(X) if reaching target goals	X X
EKG	X			
<p><sup>1</sup> <i>Fasting or random glucose (finger stick) monitoring:</i> Methods and times must be determined on a case-by-case basis, depending on the medical needs of the inmate and the severity of the condition.</p> <p><sup>2</sup> <i>Screen for microalbuminuria:</i> Abnormal results should be repeated at least 2–3 times over a 3–6 month period to appropriately diagnose, because of the potential for false positives.</p>				



### Appendix 3. Treatment Goals for Non-Pregnant Inmates with Diabetes

<b>Glycemic Control</b>	
A1C <sup>1</sup>	<7.0–7.5%
Preprandial capillary plasma glucose <sup>2</sup>	90–130 mg/dl
Peak postprandial capillary plasma glucose <sup>2,3</sup>	<180 mg/dl
<b>Blood Pressure</b>	
Blood pressure goal	<130 / <80 mmHg
<b>Lipids<sup>4</sup></b>	
LDL	<100 mg/dl
Triglycerides	<150 mg/dl
HDL <sup>5</sup>	>40 mg/dl
<b>Key concepts in setting glycemic goals:</b>	
<ul style="list-style-type: none"> <li>• A1C is the primary target for glycemic control.</li> <li>• Goals should be individualized.</li> <li>• Certain inmate populations, i.e., pregnant women and the elderly, require special considerations.</li> <li>• Less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia.</li> <li>• Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals.</li> </ul>	
<p><sup>1</sup> The ADA's <i>Standards of Medical Care in Diabetes – 2010</i> sets the A1C diagnostic cut point as 6.5%. Based on the results of multiple randomized trials and correctional considerations, the BOP recommends A1C &lt;7.0–7.5% as a reasonable treatment goal for diabetic inmates.</p> <p><sup>2</sup> Many glucometers automatically convert capillary blood glucose values to plasma glucose values. Check the glucometer. Blood glucose values are 10–15% lower than plasma glucose values.</p> <p><sup>3</sup> Postprandial glucose measurements should be made 1–2 hours after the beginning of the meal.</p> <p><sup>4</sup> Current NCEP/ATP III guidelines suggest that in patients with triglycerides &lt;200 mg/dl, the “non-HDL cholesterol” (total cholesterol minus HDL) be utilized. The goal is ≤130 mg/dl.</p> <p><sup>5</sup> For women, it has been suggested that the HDL goal be increased by 10 mg/dl.</p> <p><b>Adapted from:</b> American Diabetes Association. <i>Standards of medical care in diabetes – 2007. Diabetes Care.</i> 2007;30(Supplement 1):S10.</p>	

## Appendix 4: BOP Treatment Algorithm for Type 2 Diabetes



<sup>1</sup> Exception: Insulin should be utilized if severely uncontrolled DM, i.e., plasma glucose >250 mg/dl, random glucose consistently >300 mg/dl, A1C >10%, ketonuria, or symptomatic diabetes with polyuria, polydipsia, & weight loss.

<sup>2</sup> Use metformin unless contraindicated, i.e., in men with a serum creatinine >1.5 mg/dl, and in women with a serum creatinine >1.4 mg/dl; if age >80 (unless renal sufficiency established); or chronic liver failure. A sulfonylurea can often substitute for metformin if it is contraindicated.

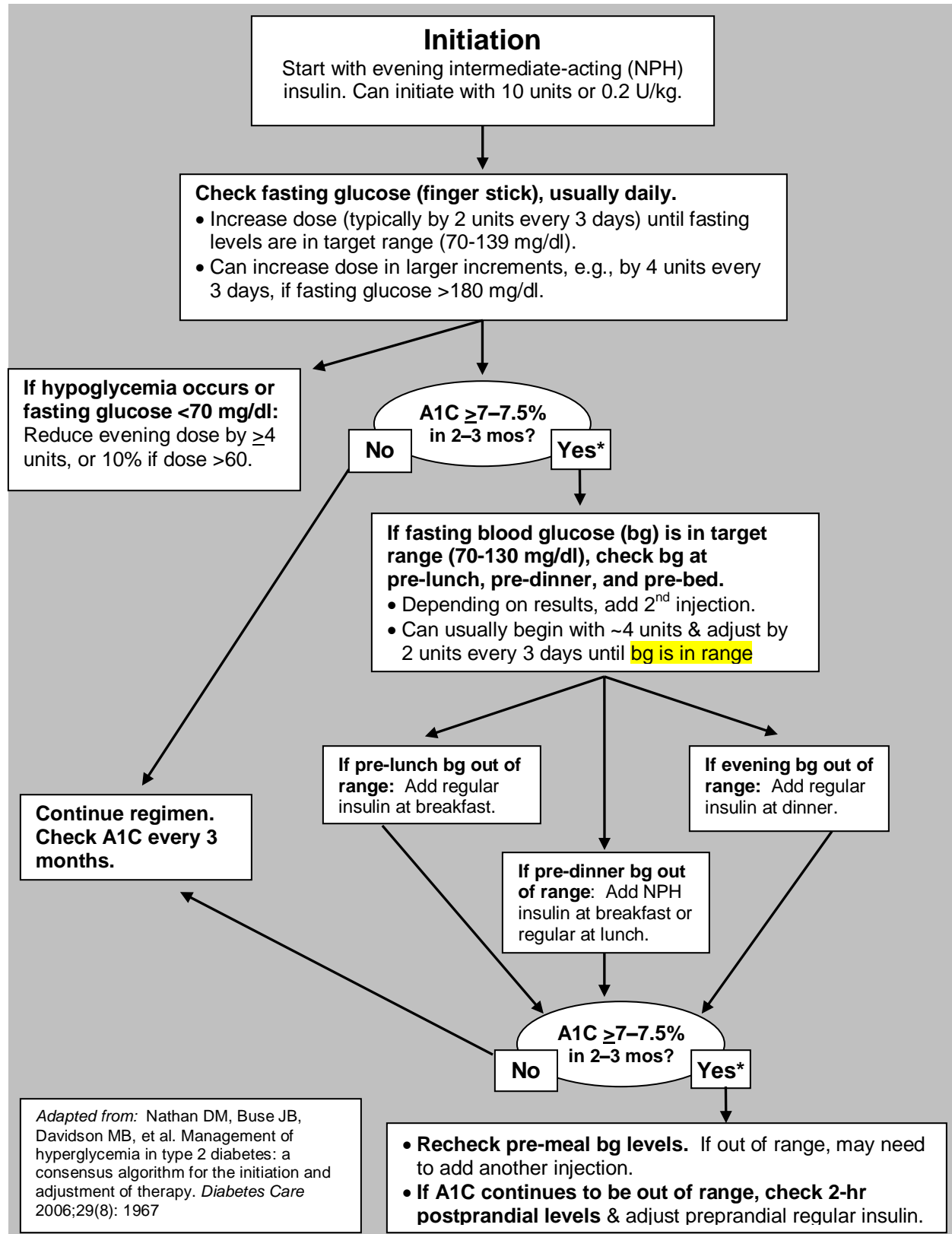
\* Check A1C every 3 months until <7.0–7.5%; then, every 6 months.

### Notes:

- Refer to the BOP National Formulary for the formulary status and non-formulary use criteria for specific medications.
- In order to achieve glycemic goals, medications should be adjusted as frequently as titration allows (i.e., as often as every 3 to 4 days for insulin and every one to two weeks for metformin).

**Adapted from:** American Diabetes Association. *Standards of Medical Care in Diabetes – 2007. Diabetes Care 2007;30 (Suppl 1):S11.*

## Appendix 5: Initiation/Adjustment of Insulin Regimens in Type 2 Diabetes



**Appendix 6: Oral Agents for Treatment of Type 2 Diabetes (Dosing/Side Effects)**

Oral Agents for Treatment of Type 2 Diabetes (Dosing and Side Effects)					
Agent	Initial Dose & Treatment	Maximum Dose	Initial Elderly Dose	Side Effects	Drug Interaction
<b>Biguanides</b>					
<b>Note:</b> Contraindications to metformin therapy: elevated creatinine (>1.4mg/dL in women or >1.5mg/dL in men), or a creatinine clearance <60mL/min in the elderly; history of renal insufficiency, hepatic dysfunction, or serious cardiovascular or pulmonary compromise.					
<b>Metformin</b> (Glucophage)	500 mg with a meal; on the basis of patient's tolerance to metformin and glycemic response, increase dosage by 500 mg/day at weekly intervals, adding a dose to another meal; tid dosing not required for efficacy, but may decrease GI complaints; doses >1000 mg/day with meals will likely be needed for therapeutic effect as monotherapy; doses >2000 mg/day have little added benefit.	2550 mg/day (850 mg tid) OR 2500 mg/day	500 mg	Nausea and diarrhea, which usually subside over 1 week; may limit rate of dose increase. Hypoglycemia only if metformin is given with sulfonylurea or insulin.	* Withhold 48 hours prior to and following surgery or IV contrast x-ray studies.  Alcohol; cimetidine; amiloride; digoxin; morphine; procainamide; quinidine; ranitidine; triamterene; trimethoprim; vancomycin; furosemide; calcium channel blocking agents, especially nifedipine
<b>Sulfonylureas (second generation)</b>					
<b>Glyburide</b> (DiaBeta, Micronase)	2.5 - 5 mg/day; increase dose by 2.5 - 5 mg no more often than every 7 days. <i>Note:</i> Use glyburide only if creatinine clearance is $\geq$ 50 ml/min.	20 mg/day	1.25 - 2.5 mg	Hypoglycemia & weight gain	Alcohol; coumadin; azole antifungals; asparaginase; corticosteroids; thiazide diuretics; lithium; beta blockers; cimetidine; ranitidine; cyclosporine; quinolones; MAO inhibitors; chloramphenicol; octreotide; pentamidine
<b>Glyburide, micro-crystalline</b> (Glynase)	1.5 - 3 mg/day; increase by $\leq$ 1.5 mg weekly if needed. <i>Note:</i> Use glyburide only if creatinine clearance is $\geq$ 50 ml/min.	12 mg/day	1.25 mg	Hypoglycemia & weight gain	Same as above
<b>Glipizide, short-acting</b> (Glucotrol)	5 mg/day, 30 min before breakfast; increase dose by 2.5 - 5 mg a week as needed. <i>Note:</i> Use glipizide only if creatinine clearance is $\geq$ 10 ml/min.	40 mg/day  Give bid when dose reaches 15 mg	2.5 - 5 mg	Hypoglycemia & weight gain	Same as above
<b>Glipizide, extended release</b> (Glucotrol XL)	5 mg/day at breakfast; increase dose by 2.5 - 5 mg at 3-month intervals based on A1C. <i>Note:</i> Use glipizide only if creatinine clearance is $\geq$ 10 ml/min.	20 mg/day	2.5 mg	Hypoglycemia & weight gain	Same as above

(Appendix 6 – page 1 of 3)

<b>Oral Agents for Treatment of Type 2 Diabetes (Dosing and Side Effects)</b>					
<b>Agent</b>	<b>Initial Dose &amp; Treatment</b>	<b>Maximum Dose</b>	<b>Initial Elderly Dose</b>	<b>Side Effects</b>	<b>Drug Interaction</b>
<b>Glimepiride</b> (Amaryl)	1-2 mg daily with breakfast or first main meal; increase at 1-2 mg increments every 1-2 weeks as needed. <i>Note:</i> Use glimepiride only if creatinine clearance is $\geq 30$ ml/min.	8 mg once daily	0.5 - 1 mg	Hypoglycemia & weight gain	Same as above
<b>Glitazones (Thiazolidinediones or TZDs)</b>					
<b>Rosiglitazone</b> (Avandia)	4 mg qd or 2 mg bid; increase to 8 mg qd or 4 mg bid in 12 weeks as needed. <b>FDA Restriction:</b> Should be restricted as the final option for achieving glycemic control. For most patients, risks outweigh the benefits.	8 mg/day	2 mg	Edema; fluid retention may cause or exacerbate CHF; weight gain; increased risk MI.	Erythromycin; calcium channel blocker; corticosteroids; cyclosporine; HMB-CoA reductase inhibitors; triazolam; trimetrexate; ketoconazole; itraconazole
<b>Pioglitazone</b> (Actos)	15 or 30 mg qd; increase to 45 mg qd monotherapy or 30 mg qd as combo therapy.	45 mg/day monotherapy; 30 mg/day combo therapy	15 mg	Edema, weight gain *Decreases oral contraceptive efficacy.	Same as above
<b>Alpha-Glucosidase Inhibitors</b>					
<b>Acarbose</b> (Precose)	25 mg tid with first bite of meals; lower dose may be needed if gastrointestinal distress is noted; increase dose to 50 mg tid with meals after 4–8 weeks.	100 mg tid with meals OR 50 mg tid with meals (in patients $\leq 60$ kg)	25 mg	Diarrhea (33%), abdominal pain (12%), flatulence (77%). *Serum transaminase elevations may occur at doses $>50$ mg tid.	Absorbents; intestinal agents such as activated charcoal; digestive enzyme preparations containing carbohydrate-splitting enzymes such as amylase or pancreatin
<b>Miglitol</b> (Glyset)	25 mg tid at the start of each meal.	100 mg tid		Flatulence, diarrhea, abdominal pain	Digoxin, propranolol, ranitidine, GI enzymes
<b>Glinides</b>					
<b>Repaglinide</b> (Prandin)	0.5 mg with each meal if A1C $<8\%$ ; 1–2 mg with each meal if HbA1C $\geq 8\%$ ; increase by 1 mg weekly as needed.	4 mg with meals (max 16 mg total per day)	0.5 mg	Hypoglycemia & weight gain	* Contraindicated in moderate-to-severe hepatic dysfunction. Beta-adrenergic blocking agents; drugs metabolized by the cytochrome p450 system; erythromycin; ketoconazole; miconazole; sulfonamides; MAO inhibitors; NSAIDs; anticoagulants (warfarin derivatives)
<b>Nateglinide</b> (Starlix)	120 mg tid, 1 to 30 minutes before meals; patients close to HbA1C goal may be started at 60mg tid.	120 mg tid	60 mg	Hypoglycemia & weight gain	Same as above

(Appendix 6 – page 2 of 3)

<b>Oral Agents for Treatment of Type 2 Diabetes (Dosing and Side Effects)</b>					
<b>Agent</b>	<b>Initial Dose &amp; Treatment</b>	<b>Maximum Dose</b>	<b>Initial Elderly Dose</b>	<b>Side Effects</b>	<b>Drug Interaction</b>
<b>Dipeptidyl peptidase 4 (DPP-4) inhibitors</b>					
<b>Sitagliptin (Januvia)</b>	100 mg once daily. If CrCl is 30-49 mL, min., dose is 50 mg daily. If CrCl <30 mL, min. dose is 25 mg daily.			Nasopharyngitis, headache, upper respiratory infection	None known
<i>(Appendix 6 – page 3 of 3)</i>					

## Appendix 7: Alternative Medications for Treatment of Type 2 Diabetes

### Glitazones (thiazolidinediones--TZDs)

Agents in this drug category, **pioglitazone** and **rosiglitazone**, reduce insulin resistance in target tissues and enhance insulin action, without directly stimulating insulin secretion from the pancreas. Glitazones can be prescribed as monotherapy, or in combination therapy with insulin (pioglitazone only), sulfonylureas, or metformin.

Within the BOP, glitazones should ordinarily be restricted to patients who fail or cannot take metformin and/or sulfonylurea. There is a lack of long-term data on both the adverse effects and the impact on occurrence of microvascular and macrovascular diabetes complications. Recently reported data suggests that rosiglitazone may increase the risk of myocardial infarction and death. The glitazones are associated with added benefits: slight reductions in blood pressure, increases in HDL cholesterol, and decreases in triglycerides. Glitazones may cause weight gain, but they do not increase the risk of hypoglycemia.

#### **Clinical Precautions:**

- 1) **Glitazones may precipitate heart failure and peripheral edema, and therefore are contraindicated in patients with congestive heart failure.**
- 2) **Increased risks of myocardial infarction and death have been associated with rosiglitazone.**
- 3) **Glitazones are contraindicated with moderate-to-severe liver disease.** Liver function studies should be monitored at baseline, every two months for one year, and then periodically thereafter.

### Alpha glucosidase inhibitors (AGIs)

Agents in this category, **acarbose** and **miglitol**, decrease postprandial hyperglycemia by inhibiting carbohydrate digestion and absorption. AGIs, which reduce A1C levels by only 0.5–1%, are somewhat less effective than sulfonylureas and biguanides in controlling hyperglycemia. An AGI is best used in a combination regimen to treat diabetes; they are particularly useful in patients with predominantly postprandial hyperglycemia (mild fasting hyperglycemia with disproportionately elevated A1C). In order for these medications to be effective, they must be taken 15 minutes before or after the start of a meal.

Significant gastrointestinal symptoms may occur with AGIs, including flatulence, diarrhea, and abdominal cramps. Symptoms tend to diminish over time and are minimized if therapy is initiated gradually. AGIs are contraindicated in patients with cirrhosis or inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis), or if creatinine >2.0 mg/dl.

**Clinical Precaution:** *Hypoglycemic reactions to acarbose or miglitol therapy must be treated with glucagon or glucose (IV or oral), since oral treatment with sucrose will be blocked by the acarbose or miglitol.*

### Glinides – non-sulfonylurea secretagogues (non-SUSs) (AKA meglitinides)

Drugs in this category, including **repaglinide** and **nateglinide**, stimulate insulin secretion from the pancreas, but they have shorter half-lives than the similar-acting sulfonylureas. Therapy with repaglinide reduces A1C levels, comparable to monotherapy with sulfonylureas or metformin; nateglinide is somewhat less effective. Non-SUS agents can cause weight gain and hypoglycemia, but these adverse effects may be less pronounced than with sulfonylureas.

**Because their long-term safety profile has not been determined, non-SUS agents ordinarily should not be used as first-line agents.**

### Exenatide

Only one glucagon-like peptide (GLP)-1 agonist agent, exenatide (Byetta), is approved for use in the United States. Exenatide acts as an incretin mimetic, stimulating insulin production in response to high blood glucose levels, inhibiting the release of glucagon after meals, and slowing the rate of gastric emptying. An A1C reduction of 0.5-1% is expected with the use of exenatide. This medication is approved for use in combination with metformin or a sulfonylurea. Exenatide is administered as a subcutaneous injection in the thigh, abdomen, or upper arm, twice daily within one hour prior to the breakfast and evening meals; it should not be administered after meals. It is supplied in pre-filled syringes that provide 60 doses, and must be kept refrigerated. The pen should be discarded 30 days after the first use.

Administration of exenatide can cause significant nausea, vomiting, and diarrhea, which may lead to weight loss. Hypoglycemia may occur when this medication is used with a sulfonylurea; therefore, the dose of the sulfonylurea may need to be decreased when initiating exenatide. Since exenatide slows gastric emptying, the rate and extent of absorption of orally administered medications **may be altered**. Other medications should be given at least one hour before exenatide administration.

**Clinical Precaution:**

***Exenatide should not be used in patients with creatinine clearance less than 30 ml/min or with end stage renal disease. It should not be used in patients with severe gastrointestinal disease, including gastroparesis. Stop medication in the event of severe abdominal pain.***

## Sitagliptin

Sitagliptin (Januvia) is the only dipeptidyl peptidase 4 (DPP-4) inhibitor currently approved; vildagliptin (Galvus) is awaiting FDA approval. DPP-4 inhibitors work as incretin enhancers, stimulating the alpha and beta cells in the pancreas to release insulin in response to a glucose load and signaling the liver to stop glucose production. The expected reduction in A1C is only 0.6–0.8%. Sitagliptin is given by mouth, 100 mg once daily, and is approved for use both as monotherapy and in combination with metformin and/or glitazones. Sitagliptin has not been shown to cause weight gain or weight loss, and does not cause hypoglycemia.

**Clinical Precaution:**

***The dose of sitagliptin must be modified in patients with renal disease. In patients with a creatinine clearance that is between 30-50 ml per minute, the dose should be decreased to 50 mg once daily. With a creatinine clearance of less than 30 ml per minute or for those who are on dialysis, the dose is 25 mg once daily.***

## Pramlintide

Pramlintide (Symlin) is an injectable amylin agonist that is only approved for use in patients using insulin. Pramlintide acts by slowing gastric emptying, preventing an increase in serum glucagon and increasing the feeling of fullness following a meal. Adding pramlintide to the treatment regimen of a patient who is using insulin is expected to lower the A1C by 0.5–0.7%. Pramlintide is used as adjunctive treatment in type 1 patients who use mealtime insulin, and in type 2 diabetics who use insulin with or without concurrent sulfonylureas and/or metformin. Pramlintide is administered as a subcutaneous injection in the abdomen or thigh, prior to major meals containing at least 250 calories and 30 gm of carbohydrates. Gastrointestinal adverse effects are common with pramlintide. Nausea, vomiting, and diarrhea may occur and can cause weight loss. Pramlintide alone does not cause hypoglycemia, but it can cause hypoglycemia when used with insulin. The mealtime preprandial dose of insulin should be reduced when pramlintide is initiated. Prescribing information for pramlintide suggests lowering the mealtime preprandial dose of insulin by 50%.

**Clinical Precaution:**

***Pramlintide has the following black box warning: Symlin is used with insulin and has been associated with an increased risk of insulin-induced hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia associated with Symlin occurs, it is seen within three hours following a Symlin injection. If severe hypoglycemia occurs while operating a motor vehicle, heavy machinery, or while engaging in other high risk activities, serious injuries may occur. Appropriate patient selection, careful patient instruction, and insulin dose adjustments are critical elements for reducing this risk.***

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## **Appendix 8. Infection Control for Diabetes Care Procedures**

The potential for transmission of bloodborne pathogens exists with diabetes care procedures, including insulin administration and capillary blood glucose monitoring. Outbreaks of hepatitis B have been reported in association with blood glucose monitoring in nursing homes. The following infection control procedures should be followed to prevent transmission of bloodborne pathogens in BOP facilities during diabetes care procedures.

### **Diabetes Care Procedures and Techniques**

- Prepare medications such as insulin in a centralized medication area; multiple-dose insulin vials should be assigned only to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients. Consider selecting single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in an approved sharps container.
- Environmental surfaces such as glucometers should be decontaminated regularly and anytime that contamination with blood or body fluids occurs or is suspected.
- Glucometers generally should be assigned to individual patients. If a glucometer that has been used for one patient must be reused for another patient, the device must be cleaned and disinfected. Local facilities should have procedures for decontamination based on the manufacturer's recommendations.
- Any trays or carts used to deliver medications or supplies to individual patients should remain outside patient rooms. Do not carry supplies and medications in pockets.
- Because of possible inadvertent contamination, unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should not be used for another patient.

### **Hand Hygiene and Gloves**

- Wear gloves during fingerstick glucose monitoring, administration of insulin, and any other procedure that involves potential exposure to blood or body fluids.
- Change gloves between patient contacts. Before touching clean surfaces, change gloves that have touched potentially blood-contaminated objects or fingerstick wounds.
- Remove and discard gloves in appropriate receptacles after every procedure that involves potential exposure to blood or body fluids, including fingerstick blood sampling.
- Perform hand hygiene (i.e., handwashing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other residents.

*(Appendix 8 – page 1 of 2)*

## Medical Management

- Review regularly the individual patients' schedules for fingerstick blood glucose sampling and insulin administration and reduce the number of percutaneous procedures to the minimum necessary for appropriate medical management of diabetes and its complications.
- Assure that adequate staffing levels are maintained to perform all scheduled diabetes care procedures, including fingerstick blood glucose monitoring.
- Consider the diagnosis of acute viral hepatitis infection in diabetic inmates who develop an illness that includes hepatic dysfunction or elevated aminotransaminase levels (AST or ALT).

## Training and Oversight

- Provide a full hepatitis B vaccination series to all previously unvaccinated correctional facility health care workers.
- Establish responsibility for oversight of infection control activities. Investigate and report any suspected case that may represent a newly acquired bloodborne infection.
- In accordance with BOP policy, maintain control of sharps and lancets in the work area.
- Have staff demonstrate knowledge of standard precautions guidelines, as well as proficiency in the application of these guidelines during procedures that involve possible exposure to blood or body fluid.
- For staff members who assume responsibilities involving percutaneous procedures, provide infection control training that includes practical demonstration of aseptic techniques and instruction regarding reporting exposures or breaches. Provide annual retraining to all staff members who perform procedures that involve exposure to blood or body fluids.
- Assess compliance with infection control recommendations for fingerstick glucose monitoring (such as hand hygiene and glove changes between patients) by periodically observing personnel and tracking use of supplies.

*Adapted from:*

CDC. Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities — Mississippi, North Carolina, and Los Angeles County, California, 2003–2004. *MMWR* 2005;54(09):220-223. Available from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm>

*(Appendix 8 – page 2 of 2)*

## Appendix 9: Resources for Information on Diabetes

**American Diabetes Association**

<http://www.diabetes.org>

800-342-2383

**American Dietetic Association**

<http://www.eatright.org>

800-366-1655

**Centers for Disease Control and Prevention**

<http://www.cdc.gov/diabetes>

877-232-3422

***Diabetes Medication Supplement***

[http://www.ncdiabetes.org/\\_pdf/Drug\\_tables\\_supplement.pdf](http://www.ncdiabetes.org/_pdf/Drug_tables_supplement.pdf)

**National Diabetes Education Program,  
Health Resources & Services Administration  
(HRSA)**

**Lower Extremity Amputation Prevention  
Program (LEAP), Health Resources & Services  
Administration (HRSA)**

<http://www.hrsa.gov/leap/>

**National Diabetes Information Clearinghouse**

<http://www.niddk.nih.gov/health/diabetes/ndic.htm>

800-860-8747

**National Institute of Diabetes and Digestive  
and Kidney Diseases (NIDDK)**

<http://www.niddk.nih.gov>

800-860-8747

**National Kidney Foundation**

<http://www.kidney.org>

800-622-9010

## **Appendices 10–12: Inmate Handouts**

The following Appendices, *revised in June 2012*, are designed as handouts for BOP inmates:

Appendix 10: Fact Sheet on Diabetes

Appendix 11: The Three Keys to Controlling Your Diabetes

Appendix 12: Eating to Manage Your Diabetes in the Bureau of Prisons

## Appendix 10: Fact Sheet on Diabetes

### 1. What is diabetes?

Diabetes is a chronic disease that has no cure, but can be controlled by a combination of diet, exercise, and medical care. People with diabetes have too much sugar (glucose) in their blood—sugar builds up in the blood instead of going into the cells.

### 2. What are the symptoms of diabetes?

Most people with diabetes may not notice any symptoms, at first. However, some symptoms of diabetes are:

- Frequent urination
- Increased thirst and increased hunger
- Unexplained weight loss
- Weakness, fatigue, drowsiness
- Wounds and cuts that heal slowly
- Blurred vision or changes in vision

### 3. What puts you at risk for diabetes?

- You are age 45 and older.
- You are a member of a high-risk ethnic group (African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander).
- You are overweight.
- You have high blood pressure (at or above 140/90).
- You have a family history of diabetes.
- You have a history of diabetes during pregnancy.
- You weighed more than nine pounds at birth.

### 4. What are the possible complications of diabetes?

- Eye damage – poor vision, retina damage, cataracts, glaucoma, blindness
- Kidney damage – progressive failure, which may require hemodialysis or organ transplantation
- Heart problems – damaged blood vessels, which may lead to heart attacks and strokes
- Nerve damage – problems with nerve sensations and with moving muscles; loss of reflexes
- Decreased ability to fight infections
- Sores and ulcers of the legs and feet

### 5. How is diabetes controlled? And why is it important to control it?

Diabetes is controlled by a combination of diet, exercise, and medication. The goals are to **(1)** keep your blood sugar near normal, **(2)** control your blood pressure, **(3)** lower your cholesterol and fat levels, and **(4)** lose weight or maintain a healthy weight. Research shows that keeping blood sugar as near to normal as possible means fewer complications from the disease. Strict control of blood sugar helps to prevent kidney failure, amputations, blindness, heart attacks, and stroke.

### 6. What are the symptoms of blood sugar that is too low (hypoglycemia)?

- Shakiness
- Sweating and clammy feeling
- Extreme fatigue
- Hunger
- Irritation or confusion
- Rapid heart rate
- Blurred vision

## Appendix 11: The Three Keys to Controlling Your Diabetes

Years ago, the diabetic diet was strict and boring. Today, you do not need special foods. In fact, the foods that are good for you are actually good for everyone. Diabetes cannot be cured, but it can be controlled so that you can lead a normal life. Keeping good control of your diabetes helps to delay or even prevent potential complications.

**There are three keys to controlling diabetes: diet, exercise, and medication.**

All three are equally important. Eating the right foods and limiting how much you eat, along with regular exercise, help you achieve and maintain a healthy weight. Keeping good control of your blood glucose also requires that your food intake and your level of activity balance with the medication you are taking.

**Follow these steps to maintain a healthy weight *and* good blood glucose control:**

- **Eat a wide variety of foods every day.** Increase high-fiber foods such as grains, beans, vegetables, and fruits to fill you up.
- **Limit concentrated sweets** such as sugar, honey, jelly, syrup, cakes, cookies, candy, ice cream, pies, pastries, regular soda, and other sugary drinks. Concentrated sugars do not cause diabetes, and you don't need to avoid them totally. However, they are very high in calories—and the more calories you eat, the higher your blood glucose!
- **Limit fats** such as butter, margarine, cheese, fried foods, cream soups, gravy, salad dressings, mayonnaise, and breakfast meats (bacon, sausage, etc.).
- **Control portion sizes.** Too much of even the right foods can also cause high blood glucose. If you want to lose weight, cut down on portion sizes.
- **Never skip meals.** Eat all three meals and include snacks as needed. Eat your meals at about the same time every day.
- **Exercise.** Increase your activity level (as permitted by your doctor). This will decrease your blood glucose level.
- **Monitor your weight.** Weigh yourself only once a week to determine if your diet is effective. If you are overweight, a weight loss of 1–2 pounds per week is a good goal.
- **Take medication as directed.** If you take pills or insulin injections for your diabetes, always take your medication as your doctor has recommended.

## Appendix 12: Eating To Manage Your Diabetes in the Bureau of Prisons

The heart-healthy food options that are offered on the BOP National Menu should be “at the heart” of your diabetes management plan. These foods are (1) lower in calories to help with weight management, (2) lower in sodium to help with blood pressure control, and (3) lower in fat to help manage cholesterol levels.

### **Do you take diabetes medication? Be consistent with your carbohydrates.**

If you take diabetes pills that help your body make more insulin, or if you take set doses of insulin every day, eating consistently makes it easier for you to gain control of your blood glucose. Eating similar amounts of carbohydrates at meals and snacks, from one day to the next, can help you keep your blood glucose in a healthy range.

### **Five Steps for Counting Your Carbohydrates:**

#### **Step 1: Know which foods have carbohydrates.**

Foods with the most carbohydrates include:

- Breads, crackers, and cereals
- Pasta, rice, and grains
- Starchy vegetables such as potatoes, corn, and peas
- Beans, lentils, and other legumes
- Milk and yogurt
- Fruits and fruit juice
- Sweets such as cakes, cookies, and pastries
- Regular sodas and other sugary drinks

#### **Step 2: Know your carbohydrate and blood glucose goals.**

- Your carbohydrate goals depend on the diabetes medications and/or insulin you use, your body weight, and how active you are.
- In diabetes meal planning:  
1 serving/choice of a food with carbohydrate = about 15 grams of carbohydrate
- A general rule of thumb:  
*Men:* 4 to 5 carbohydrate servings/choices (60 to 75 grams) at each meal  
*Women:* 3 to 4 carbohydrate servings/choices (45 to 60 grams) at each meal
- If you eat snacks, choose foods that are 1 to 2 carbohydrate servings/choices (15 to 30 grams).
- *Please Note:* If you take insulin or diabetes medications that may cause low blood sugar, do not skip meals!

### Step 3: Read and understand the “Nutrition Facts” on food labels.

The “Nutrition Facts” on food packages lists how many grams of carbohydrate are in a standard serving of that particular food. However, you will still need to figure out how many carbohydrate servings (15 grams of carbohydrate) are in that standard serving of food.

- Look first at the label’s standard **Serving Size**.
- Then, check the grams of **Total Carbohydrate** in a standard serving size.  
*In this example, there are 10 grams of carbohydrate in a standard serving (1 cup) of this food.*
- Divide the grams of **Total Carbohydrate** by 15. This number equals the number of carbohydrate servings in a standard serving of this food.  
*In this example, divide 10 by 15 = 2/3. So, if you ate one cup of this food, you would have eaten 2/3 of a carbohydrate serving.*
- **Note:** You may ignore the grams of **Sugars** on the “Nutrition Facts” panel because they are already included in the grams of Total Carbohydrate.

Nutrition Facts	
Serving Size 1 cup (4 oz)	
Serving Per Container 3	
Amount Per Serving	
Calories 75 Calories from Fat 27	
	% Daily Value*
Total Fat 3 g	5%
Saturated Fat 0 g	0%
Cholesterol 0 mg	0%
Sodium 300 mg	4%
<b>Total Carbohydrate 10 g</b>	<b>3%</b>
Dietary Fiber 5 g	20%
Sugars 3 g	
Protein 2 g	
Vitamin A 80% - Vitamin C 60% - Calcium 4% - Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
	Calories: 2,000      2,500
Total Fat	Less than 65g      80g
Sat Fat	Less than 20g      25g
Cholesterol	Less than 300mg      300mg
Sodium	Less than 2,400mg      2,400mg
Total Carbohydrate	300g      375g
Dietary Fiber	25g      30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

- The serving size for the food is 1 cup.
- There are 3 servings or 3 cups in this container.
- The total carbohydrate tells how many grams of carbohydrate are in 1 serving.
- Sugar is already included in the total carbohydrate amount. This value shows the amount of natural or added sugar.

### Step 4: Write down your food intake and your blood glucose levels.

Keep a food record that lists (1) each time you ate, (2) your food choices, and (3) the amounts of each food. The more days and meals you can record, the more information you will have about how different amounts of carbohydrates affect your blood glucose, allowing you to make adjustments as needed.

### Step 5: Review your records.

If you are above your blood glucose target: Check the carbohydrates in your last meal or snack to see which foods or amounts may have caused your blood glucose to be too high. If you are below your blood glucose target, you may have not eaten enough carbohydrates.

**Remember:** Any blood glucose below 70 mg/dl must be treated immediately.

#### Sources:

Academy of Nutrition and Dietetics (formerly the American Dietetic Association), Diabetes Care and Education Practice Group. *Carbohydrate Counting: Focus on Consistency for People Who Use Diabetes Pills and Basic Insulin Regimens* [patient handout]. 2008.

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