GLUCOSE MONITORING IN DIABETES CARE: EVIDENCE, CHALLENGES, AND OPPORTUNITIES

Annabelle Rodriguez, MD,* with Mary G. Gabb, MS†

ABSTRACT

Glycemic control influences the 2 most prominent consequences of diabetes: healthcare costs and risk of complications (micro- and macrovascular). Several large clinical studies have shown unequivocally that the risk of microvascular complications accelerates with glycemia, and that the risk is reduced for every 1% decrease in glycosylated hemoglobin (HbA1c) level. However, the risk-versus-reward curve is quite different between microvascular and macrovascular disease. The rate of increase in risk of microvascular complications over the range of HbA1c values appears to be greater than the rate of risk increase for macrovascular complications, and micro- and macrovascular complications can precede the development of overt diabetes. HbA1c is the primary target for glycemic control. However, treatment goals are generalized; in clinical practice, treatment goals should be individualized. Certain populations (ie, children, the elderly, and pregnant women) require special consideration. Unfortunately, most patients do not meet their own treatment goals. Two of the most common barriers to achieving glycemic treatment goals are a lack of awareness of glycemic levels and the risk of hypoglycemia. As with standard diabetes care, much of the control over hypoglycemia prevention is in the hands of the patient, provided they have the tools to address this problem. Patient empowerment involves more than providing the patient with information about diabetes mellitus; it requires practical interventions that facilitate collaborative relationships between healthcare providers and patients and enable patients to become actively involved in and responsible for managing their diabetes. (Adv Stud Med. 2005;5(10F):S1100-S1116)

TRACKING THE DIABETES EPIDEMIC

The diabetes epidemic continues to spread in the United States and worldwide and has profound consequences for patients and the healthcare system. Currently, the American Diabetes Association (ADA) estimates that 18 million Americans have diabetes. The consequences of having diabetes extend far beyond the inconvenience of monitoring blood glucose levels and following a stricter diet than most Americans prefer. The long-term complications of type 1 and type 2 diabetes include permanent pathophysiology of the microvasculature (neuropathy, nephropathy, and retinopathy, and often lead to pain and amputation, kidney failure, and visual impairment/blindness, respectively) and the macrovasculature (ie, cardiovascular disease, leading to heart disease and stroke). In fact, the risk for death among people with diabetes is more than twice that of people without it. The American Heart Association recommends that people with diabetes "belong in the same high-risk category previously reserved for patients with known cardiovascular disease." The ultimate toll that diabetes renders is not only in quality of life and premature mortality, but a financial toll that tops $130 billion annually. With an ever-increasing proportion of adults and children who are overweight and obese

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and a rapidly aging population (both of whom have a high risk of developing type 2 diabetes), the question most often voiced among the entire healthcare community is “What can be done?”

THE IMPORTANCE OF GLYCEMIC CONTROL

The obvious answer to the question of controlling or even reversing the diabetes epidemic is improving glycemic control. Data from several seminal studies show that improved glycemic control influences the 2 most prominent consequences of diabetes—healthcare costs and risk of complications.

REDUCED HEALTHCARE COSTS

Studies are now showing that the level of glycemic control is directly related to healthcare costs in adults with diabetes. For example, in 1997, a study of healthcare costs was conducted in 3017 adults with diabetes (mean age 59.7 years) who were continuously enrolled in a large health maintenance organization (HMO) over a 4-year period. Inpatient and outpatient charges for medical care were assessed based on the patient’s baseline glycated hemoglobin (HbA1c; mean HbA1c 8.3%). For a person with a baseline HbA1c value of 6%, successive 1% increases in HbA1c resulted in cumulative increases in healthcare costs of approximately 5%, 10%, 20%, and 30% for those without cardiovascular complications, as shown in Figure 1A. The increase in charges with increasing HbA1c for patients with diabetes and cardiovascular complications (hypertension and heart disease) maintained the same trend (Figure 1B).

In a second retrospective study of HMO patients with diabetes ($n = 4744$), total healthcare costs were significantly lower for those who had HbA1c reductions of 1% or more over a 1-year period and sustained the improvement for at least 1 additional year (ie, improved; $n = 732$) when compared with patients with diabetes who did not meet these criteria (ie, unimproved; $n = 4012$). As shown in Figure 2, the mean total annual healthcare costs were $685 to $950 lower in the improved versus the unimproved cohort, but the differences were only significant for those patients with the highest baseline HbA1c values. Healthcare utilization (primary care and specialist visits) also was reduced among improved patients, but differences in hospitalization rates were not statistically significant in any year (Figure 3). These data suggest that the cost benefits of good glycemic control appear within 1 to 2 years of improvement, rather than having to wait for differences in long-term complication rates of diabetes.

REDUCED RISK OF MICRO- AND MACROVASCULAR COMPLICATIONS OF DIABETES

Several large clinical studies have shown unequivocally that the risk of microvascular complications accelerates with worsening glycemic control, and that the risk is reduced for every 1% decrease in HbA1c measurement. The results of these studies are summarized in Table 1.

### Figures

#### Figure 1A. Healthcare Costs Increase with Worsening Glycemic Control

<table>
<thead>
<tr>
<th>Baseline HbA1c (1992)</th>
<th>3-year medical costs, 1993–1995 ($)c</th>
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</thead>
<tbody>
<tr>
<td>6%</td>
<td>8000</td>
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<tr>
<td>7%</td>
<td>8500</td>
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<td>9%</td>
<td>9500</td>
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<tr>
<td>10%</td>
<td>10000</td>
</tr>
</tbody>
</table>

Increase in medical costs associated with rising HbA1c levels compared to costs for patients with HbA1c of 6%*.

*In patients with type 2 diabetes alone (no cardiovascular complications).

HbA1c = glycated hemoglobin.

Data from Gilmer et al.*

#### Figure 1B. Healthcare Costs Increase with Worsening Glycemic Control

<table>
<thead>
<tr>
<th>Baseline HbA1c (1992)</th>
<th>3-year medical costs, 1993–1995 ($)c</th>
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<tr>
<td>6%</td>
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<td>7%</td>
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<td>9%</td>
<td>9500</td>
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<tr>
<td>10%</td>
<td>10000</td>
</tr>
</tbody>
</table>

Increase in medical costs associated with rising HbA1c levels compared to costs for patients with HbA1c of 6%*.

*In patients with type 2 diabetes, hypertension, and heart disease.

HbA1c = glycated hemoglobin.

Data from Gilmer et al.*
This was a retrospective study of 4744 adult patients with diabetes who were continuously enrolled in a managed care organization from 1992 to 1997. Patients whose HbA1c decreased at least 1% during the first year and sustained the decline through the second year were considered to be improved (n = 732). All other patients were considered to be not improved (n = 4012), even if their HbA1c had improved by less than 1%. Costs and resource utilization were tracked during the 2-year HbA1c monitoring period and for an additional 3 years. The difference in cost between the 2 groups fell short of significance at the end of the 2-year monitoring period, but it was statistically significant for each of the subsequent 3 years.

The differences in mean annual cost were only significant for those patients with the highest baseline HbA1c level (>10%). HbA1c = glycosylated hemoglobin.

Data from Wagner et al.

Importantly, there also appears to be a long-term memory effect of glycemic control, with an extended benefit in delaying progression of diabetic nephropathy. An 8-year follow-up of the Diabetes Control and Complications Trial (DCCT; now termed the Epidemiology of Diabetes Interventions and Complications study) showed the sustained effect of intensive treatment of type 1 diabetes (ie, external insulin pump or 3 or more daily insulin injections) on the development and progression of diabetic nephropathy. The DCCT cohort was examined annually for 8 years. During this time, glycemic levels no longer differed substantially between the 2 original treatment groups (conventional vs intensive). This was because of the conventional group being treated similarly to the intensive group and the intensive group

Table 1. Diabetic Vascular Complication Risk Reduction per 1% Decrease in HbA1c

<table>
<thead>
<tr>
<th>Study</th>
<th>Eye</th>
<th>Kidney</th>
<th>Nerve</th>
<th>Heart</th>
</tr>
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<tbody>
<tr>
<td>DCCT</td>
<td>27%–38%</td>
<td>22%–28%</td>
<td>29%–35%</td>
<td>40%*</td>
</tr>
<tr>
<td>Kumamoto</td>
<td>28%</td>
<td>50%</td>
<td>1% NCV</td>
<td>25%*</td>
</tr>
<tr>
<td>UKPDSa</td>
<td>19%</td>
<td>26%</td>
<td>18%</td>
<td>14%*</td>
</tr>
</tbody>
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The DCCT Research Group in the United States studied 1441 patients with type 1 diabetes, randomly assigned to intensive therapy (external insulin pump or ≥3 daily insulin injections) guided by frequent blood glucose monitoring. Complication rates were compared to those patients treated conventionally with 1 or 2 insulin injections daily.1 In a Japanese population of 110 patients with type 2 diabetes, patients were treated with multiple insulin injections or conventional insulin treatment. Those patients receiving multiple injections were treated to maintain HbA1c of less than 7%. The goal in the other group was to show no symptoms of hyperglycemia or hypoglycemia and maintain fasting blood glucose concentrations of lower than 140 mg/dL. The UKPDS Group studied 3867 newly diagnosed patients with type 2 diabetes treated with a sulfonylurea or insulin to achieve a fasting blood glucose level less than 6 mmol/L (108 mg/dL). They were compared to patients treated with diet to achieve the best blood glucose levels possible.1 UKPDS showed that the incidence rates for any endpoint related to diabetes (adjusted for age, sex, ethnic group, and duration of diabetes) increased with each 1% increase in mean HbA1c, with no evidence of a ceiling effect. In each study, intensive therapy effectively delayed the onset and slowed progression of diabetes complications. The DCCT reported reduced development of hypercholesterolemia and a nonsignificant reduction in all major cardiovascular events with intensive therapy;7 whereas an epidemiologic analysis of UKPDS patients showed that microvascular and macrovascular outcomes improved with every point drop in glycated hemoglobin.10

*Not statistically significant because of a small number of events; all other values were statistically significant.

DCCT = Diabetes Control and Complications Trial; HbA1c = glycosylated hemoglobin; NCV = nerve conduction velocity; UKPDS = United Kingdom Prospective Diabetes Study.

Data from The Diabetes Control and Complications Trial Research Group; Ohkubo et al; United Kingdom Prospective Diabetes Study Group; and Stratton et al.

*P = .03; †P < .005; ††P = .02.

Same study as described in Figure 2. The data suggest that the economic benefit of improved glycemic control is realized within the first few years of improvement, without having to wait for differences in long-term complication rates. HbA1c = glycosylated hemoglobin.

Data from Wagner et al.
remaining on multiple insulin injections per day or on pump therapy. However, despite comparable HbA1c levels, there were significant differences between the 2 groups throughout the 8-year follow-up in the prevalence and the cumulative incidence of microalbuminuria (Figure 4). There also were significant differences in the number of new cases of clinical or gross albuminuria (defined as more than 300 mg/24 hour), new cases of hypertension, and serum creatinine levels of 2 mg/dL or higher between the 2 original treatment groups at the end of the 8-year follow-up; the results are summarized in Table 2.

The decrease in new cases of clinical albuminuria represents an 84% reduction in odds (95% CI, 67%–92%) compared to a 57% reduction at the end of DCCT (95% CI, 1%–81%).

Of crucial concern to the healthcare professional, and of which the patient is most likely unaware, is that...
micro- and macrovascular complications can precede the development of overt diabetes. Specifically, studies have shown this for peripheral neuropathy and retinopathy. Several studies have identified impaired glucose tolerance (IGT) in approximately 33% of patients with idiopathic peripheral neuropathy. Sumner et al even suggest that the "OGTT (oral glucose tolerance test) is appropriate in patients with idiopathic neuropathy." Just recently, results from the Diabetes Prevention Program (a large national study of patients with IGT) show that diabetic retinopathy was found in nearly 8% of prediabetic participants, and almost 13% of those patients with very early diabetes (diagnosis within 6–12 months). Patients with IGT (ie, prediabetic) also are at increased risk for cardiovascular disease. Balkau et al studied the 20-year mortality rate of nondiabetic working men aged 44 to 54 years in 3 European cohorts totaling 17 285 participants. The results from 2-hour glucose levels and fasting glucose levels were divided into 5 percentile categories—minimum to 80, 80 to 90, 90 to 95, 95 to 97.5, and 97.5 to maximum. The age-adjusted hazard ratios for all-cause mortality were increased 60% for those patients in the top 20% of 2-hour glucose levels and doubled for those in the upper 2.5% (ie, the highest percentile) of fasting glucose levels. For death from cardiovascular disease and coronary heart disease, the corresponding age-adjusted hazard ratios were increased 80% and 170%, respectively. In another large analysis of several European cohorts, 2-hour blood glucose levels appeared to be a better predictor of deaths from all causes and from cardiovascular disease than fasting blood glucose. Importantly, the largest number of excess deaths was observed in subjects who had IGT but normal fasting blood glucose levels. As shown in Figure 6, the hazard ratios in diabetic subjects were significantly increased for mortality from all causes, cardiovascular disease, coronary heart disease, and stroke compared with the
normal 2-hour blood glucose group. The American Heart Association notes that the prevalence, incidence, and mortality from all forms of cardiovascular disease are 2- to 8-fold higher in persons with diabetes than in those patients without diabetes, and that the proportion of new-onset cardiovascular disease attributable to diabetes or IGT ranges from approximately 14% in whites to 50% to 80% in American Indians. As we will discuss later in this article, patient characteristics, including ethnic risk factors, in addition to values and priorities, have a profound effect on the success or failure of any treatment plan.

DEFINING GLYCEMIC TREATMENT GOALS

Glycemic control can be defined in any of several different ways—HbA1c, pre- or postprandial capillary blood glucose, fasting plasma glucose, or bedtime glucose levels. In the United States, the ADA and the American Association of Clinical Endocrinologists (AACE) have published their clinical practice guidelines on treatment goals for patients with diabetes, summarized in Table 3. HbA1c is the primary target for glycemic control. (In this monograph, Dr Bode reviews the history and rationale for using HbA1c as a measure of blood glucose.) Note that the ADA and AACE have different treatment goals based on HbA1c levels. To set their respective target HbA1c levels, the ADA uses data from the DCCT, whereas the AACE focuses on DCCT and UKPDS. Some would argue that given the higher prevalence of type 2 diabetes versus type 1 diabetes and the higher rates of cardiovascular disease in patients with type 2 diabetes, that the target HbA1c should be lower than 7%

These treatment goals are generalized; in clinical practice, treatment goals should be individualized. Certain populations (ie, children, the elderly, and pregnant women) require special consideration. Although more stringent glycemic goals (ie, normal HbA1c <6%) may further reduce complications, less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia, particularly in those patients with type 1 diabetes. Also, postprandial glucose may be targeted if HbA1c goals are not met, despite reaching preprandial glucose goals. Elevations in the postprandial glucose levels (generally obtained 2 hours after a meal) can be a starting point for diet modification (reduction in portion control and/or reduction in the quantity of simple carbohydrates ingested in the meal) or evidence of the need for starting or altering pharmacologic treatment.

Unfortunately, despite the established clinical practice guidelines and defined treatment goals, most patients do not meet these goals. In a review of data from the Third National Health and Nutrition Examination Survey (NHANES III) and NHANES 1999-2000, 63% of patients with diabetes had HbA1c higher than 7%, and 37.2% were above the recommended “take action” HbA1c level of higher than 8%. In total, only 7.3% of patients met recommended levels for HbA1c, total cholesterol (<200 mg/dL), and blood pressure (<130/80 mm Hg). Therefore, achieving treatment goals has not been realized among most patients with diabetes.

BARRIERS TO ACHIEVING GLYCEMIC TREATMENT GOALS

Two of the most common barriers to achieving glycemic treatment goals are a lack of awareness of glycemic levels and the risk of hypoglycemia. Glycemic unawareness occurs because glycemia is often not adequately or properly assessed. As Dr Bode reviews, to control glycemia one has to assess glycemia. Hypoglycemia is, in fact, the critical limiting factor in the glycemic management of type 1 and type 2 diabetes mellitus, although it is much more common in patients using insulin therapy. The potentially devastating effects of hypoglycemia on brain function make careful glucose control imperative; otherwise, glycemic

Table 3. Targets for Glycemic Control

<table>
<thead>
<tr>
<th></th>
<th>ADA</th>
<th>AACE</th>
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</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>&lt;7%</td>
<td>&lt;6.5%</td>
</tr>
<tr>
<td></td>
<td>“Action suggested”</td>
<td>≥8%</td>
</tr>
<tr>
<td>FPG, mg/dL</td>
<td>80–120</td>
<td>&lt;110</td>
</tr>
<tr>
<td>Preprandial glucose, mg/dL</td>
<td>90–130</td>
<td></td>
</tr>
<tr>
<td>Postprandial glucose, mg/dL</td>
<td>100–180</td>
<td>&lt;140</td>
</tr>
<tr>
<td>Bedtime glucose, mg/dL</td>
<td>100–140</td>
<td>100–140</td>
</tr>
</tbody>
</table>

AACE = American Association of Clinical Endocrinologists; ADA = American Diabetes Association; FPG = fasting plasma glucose; HbA1c = glycosylated hemoglobin.

Data from Workgroup on Hypoglycemia, American Diabetes Association and American College of Endocrinology Consensus Statement on Guidelines for Glycemic Control.
management of diabetes would be a relatively simple process.21 Hypoglycemia occurs much more frequently than patients realize and brings with it substantial morbidity and increased mortality risk, and creates a vicious cycle that perpetuates the risk of hypoglycemia with each episode.

HYPOGLYCEMIA

Because the brain requires glucose for normal metabolism and can store only enough glycogen for a few minutes of normal function, hypoglycemia has an almost immediate impact on neurologic function, and may cause cognitive dysfunction, behavioral changes, seizures, and coma. (Hypoglycemia can cause permanent brain damage, but this is rare.) Other types of physical morbidity include palpitations, trembling, hunger, and paresthesias (burning or tingling in the absence of a stimulus). Not surprisingly, the psychosocial consequences of hypoglycemic episodes can include embarrassment, social ostracism, fear, anxiety, and unhappiness. At the very least, hypoglycemia is a nuisance. In reality, hypoglycemia is feared by patients more than the long-term complications of diabetes.21 Hypoglycemia can be fatal. In patients with diabetes, the proportion of deaths caused by hypoglycemia is estimated at 2% to 4%.21-23

Hypoglycemia is accepted as a fact of life by many patients with type 1 diabetes. These patients have on average 2 hypoglycemic episodes per week that are symptomatic.6,24,25 Approximately 10% of the time, plasma glucose levels fall to less than 50 to 60 mg/dL, and the number of undetected episodes is difficult to accurately count.22,26,27 Studies have shown that severe, disabling hypoglycemia occurs at least once per year in patients with type 1 diabetes.6,24,25 By contrast, the rates of hypoglycemic events in those patients with type 2 diabetes are only approximately 10% of those rates in patients with type 1 diabetes. However, hypoglycemia emerges as a more frequent and important challenge as those patients with type 2 diabetes approach the stage of insulin deficiency and begin to require insulin.21

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In patients with diabetes mellitus, hypoglycemia may be asymptomatic or symptomatic (moderate or severe). Asymptomatic hypoglycemia is very common but of less significance than symptomatic hypoglycemia, unless it predicts more severe hypoglycemia or indicates hypoglycemia unawareness. Moderate symptomatic hypoglycemia is usually self-treated by the patient. Hyperadrenergic symptoms may include palpitations, tremor, hunger, and sweating (usually the symptoms that make the person aware of hypoglycemia). Neuroglycopenic symptoms may include behavioral changes or confusion, but they may progress to seizure, coma, and death. The symptoms of hypoglycemia are often unique to each individual, and each patient often has to learn his or her own symptoms, based on their experience. Hypoglycemia is most convincingly diagnosed in the presence of Whipple’s triad: symptoms that are consistent with hypoglycemia, low measured plasma glucose concentration, and relief of symptoms with raised concentration of plasma glucose. Because moderate hypoglycemia can be self-treated, it is beneficial for the patient to self-treat if hypoglycemia is suspected because the benefits outweigh the risks of hyperglycemia.21

Severe hypoglycemia requires the assistance of another person because the patient is too confused to recognize the hypoglycemia. This is the most dangerous form of hypoglycemia, especially if it occurs nocturnally.21

Hypoglycemia often begets hypoglycemia. In healthy individuals, the normal physiologic defense against falling glucose concentrations includes decreasing levels of insulin, increasing levels of glucagon, and an increase in epinephrine levels (Sidebar 1).21 These defense mechanisms are compromised in patients with type 1 diabetes and late-stage type 2 diabetes. Other factors that can be associated with hypoglycemia include delayed food intake or mistiming of insulin injections with meals, exercise (particularly in patients who inject insulin into an extremity before exercising), drug interactions (ie, alcohol can reduce hepatic glucose production), and alterations in insulin clearance and sensitivity, such as what may occur in renal insufficiency or failure or if the patient injects insulin before taking a hot shower because warmth will increase insulin absorption.21

HYPOGLYCEMIA UNAWARENESS

Hypoglycemia unawareness is the loss of warning symptoms that allow patients to recognize hypoglycemia and take action. It occurs because episodes of iatrogenic hypoglycemia (ie, hypoglycemia occurring as a result of treatment of diabetes) result, over time, in a reduced sympathoadrenal response to low blood glucose. Without the sympathoadrenal or hyperadrenergic response, there are no obvious symptoms of hypoglycemia, thus most of the hypoglycemic episodes are not recognized.

The concept of hypoglycemia-associated autonomic
failure in type 1 diabetes and advanced type 2 diabetes is illustrated in Figure 7. Iatrogenic hypoglycemia causes defective glucose counter-regulation (by reducing epinephrine response to subsequent hypoglycemia in the setting of an absent glucagon response) and hypo-

SIDEBAR 1

DEFENSE AGAINST HYPOGLYCEMIA

In nondiabetic individuals, the body responds to decreasing glucose levels through 3 counter-regulatory processes—decreased insulin and increased production of glucagon and epinephrine. Decreased insulin secretion favors increased hepatic and renal glucose production and decreased glucose utilization by insulin-sensitive tissues (eg, muscle). Next, glucagon secretion increases, which stimulates hepatic glycogenolysis (the breakdown of glycogen to glucose by hydrolysis) and gluconeogenesis (the formation of glucose from amino acids, lactate, and the glycerol portion of fats). Increased epinephrine secretion stimulates hepatic glycogenolysis and gluconeogenesis (and renal gluconeogenesis) and limits glucose utilization by insulin-sensitive tissues. This becomes critical when glucagon secretion is deficient. Glucagon and epinephrine act within minutes to raise plasma glucose levels. The glucose levels that trigger this sequence of counter-regulatory mechanisms are as follows:

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Plasma Glucose Level</th>
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<tbody>
<tr>
<td>Decreased insulin</td>
<td>~72–108 mg/dL</td>
</tr>
<tr>
<td>Increased glucagon/epinephrine secretion</td>
<td>~65–70 mg/dL</td>
</tr>
<tr>
<td>Neurogenic and neuroglycopenic symptoms and cognitive impairment</td>
<td>~50–55 mg/dL</td>
</tr>
</tbody>
</table>

The magnitude of response to hypoglycemia is determined by how low the glucose concentration falls (the nadir) rather than how fast it falls. The glucose levels that trigger counter-regulatory responses shift to higher plasma glucose concentrations (ie, hypoglycemia is triggered more easily) in those patients with poorly controlled type 1 and type 2 diabetes and to lower plasma glucose concentrations (ie, hypoglycemia is less easily triggered) in those patients with tightly controlled type 1 diabetes.

REFERENCE


Figure 7. Hypoglycemia-Associated Autonomic Failure

aware of these episodes? When do the episodes occur, and how are they related to meals, exercise, and medication administration? What do family members notice? What are the blood glucose values?

When screening for hypoglycemia, consider the conventional risk factors and the risk of impaired glucose counter-regulation. Conventional risk factors include patterns of food ingestion and exercise, alcohol intake, and age (older people tend to have more inconsistent eating patterns, renal insufficiency, and greater potential for drug interactions). Also, mild hypoglycemia often precedes severe episodes; more than 50% of severe hypoglycemic episodes could be predicted through analysis of self-monitoring of blood glucose (SMBG) levels, underscoring the importance of glycemic self-monitoring. Encourage frequent SMBG, especially in patients with hypoglycemia unawareness. Impaired glucose counter-regulation is more likely to occur in patients with a history of hypoglycemia and/or hypoglycemia unawareness.21

The prevention of hypoglycemia should be aggressive, including patient education and empowerment, frequent SMBG, flexible medication regimens, and individualized glycemic goals. However, when comparing type 1 versus type 2 diabetes, prevention of hypoglycemia has specific challenges. Type 2 diabetes mellitus is relatively stable compared with type 1 diabetes mellitus in terms of 24-hour glucose levels. Type 1 diabetes mellitus is relatively unstable (also referred to as “brittle”) and is characterized by insulin sensitivity, which requires fine-tuned insulin therapy. Figure 8 illustrates the difference in 24-hour blood glucose levels between type 1 and type 2 diabetes.

Type 2 diabetes mellitus is traditionally managed by lifestyle modification and pharmacologic therapy, in which most patients will require combination therapy to control the dual defect of insulin deficiency and insulin resistance. Pharmacologic therapy is usually started with a single, followed by multiple, oral hypoglycemic agents. At some point, most patients will require insulin to reach and sustain glycemic targets (Sidebar 2).

**Glycemic Control in Special Populations**

As mentioned earlier in this article, treatment goals must be modified for some diabetic populations, namely pediatric patients, pregnant women, and the elderly.

**Pediatric Patients**

Pediatric patients are not simply “small adults,” thus the guidelines for diabetes management should not be applied to them. Because research in children is restricted, the ADA published their own recommendations and guidelines pertaining to the care of children and adolescents with diabetes.32,33 As noted by the ADA, the differences between children and adults with respect to diabetes management include differences in insulin sensitivity related to sexual maturity, physical growth, ability to provide self-care, and unique neurologic vulnerability to hypoglycemia. Most children younger than age 7 years have hypoglycemia unawareness; their counter-regulatory mechanisms are immature, and children often lack the cognitive capacity to recognize and respond to hypoglycemic symptoms. In addition, there is evidence to indicate that near-normalization of blood glucose levels is seldom attainable in children and adolescents. For example, in the DCCT, the adolescent group who received intensive treatment (ie, insulin regimen designed to maintain near-normal glycemic levels) achieved HbA1c levels...
that were greater than 1% higher than those levels achieved for older patients and current ADA recommendations for patients in general.12

SIDEBAR 2
MOST PATIENTS WITH TYPE 2 DIABETES MELLITUS WILL EVENTUALLY REQUIRE INSULIN THERAPY

This study assessed the efficacy of adding insulin therapy over 6 years in patients whose type 2 diabetes mellitus was inadequately controlled with maximal sulfonylurea therapy. Patients were randomly assigned to a conventional glucose control policy, primarily with diet (n = 242), or an intensive policy with insulin alone (n = 252) or sulfonylurea (n = 339). In patients receiving sulfonylurea therapy, insulin was added if the fasting plasma glucose remained greater than 6 mmol/L (108 mg/dL), despite maximum sulfonylurea doses.

Over 6 years, approximately 50% of patients allocated to sulfonylurea therapy required additional insulin therapy (Figure A), and significantly more patients in the sulfonylurea ± insulin group had a HbA1c less than 7% than in the group receiving insulin alone (47% vs 35%, respectively; P = .011; Figure B).1 Thus, early addition of insulin when maximal sulfonylurea therapy is inadequate can significantly improve glycemic control.

(Continued on page S1110)

Figure. Most Patients with Type 2 Diabetes Mellitus Will Eventually Require Insulin Therapy

![Figure](https://example.com/figure.png)

Insulin added when FPG >6 mmol/L (>108 mg/dL).
FPG = fasting plasma glucose; HbA1c = glycosylated hemoglobin; SU = sulfonylurea.

There are several possible reasons to explain the challenges of achieving normoglycemia in adolescents. First, subjective parental perceptions of glycemic control do not always correspond to reality. In one study, parents’ perceptions regarding the adequacy of their child’s (n = 159) glycemic control was assessed through questionnaires. Parents whose children had lower HbA1c values (≤7.5%) correctly perceived the status of glycemic control in their children, whereas parents of children with poor glycemic control (HbA1c ≥9.5%) had inaccurate perceptions. Five factors were found to correlate significantly with good glycemic control (HbA1c ≤8.5%): younger age, shorter duration of diabetes, higher socioeconomic status, fewer diabetes-associated hospitalizations, and parents who reported that they were “always worried” about nocturnal blood glucose variations.31

During adolescence, poor glycemic control may also be the result of puberty-related physiologic changes and psychological factors that may result in poor treatment adherence and failure to keep scheduled appointments.32 Psychiatric disorders are more common in teenagers with type 1 diabetes than in teenagers without it, but the long-term effects on outcomes have not been established. A small longitudinal study of 76 adolescents ages 11 to 18 years with type 1 diabetes suggests a relationship between behavioral problems at baseline and higher mean HbA1c levels during the 8 years of study follow-up and between hospitalization for diabetic ketoacidosis and current psychological state. The educational levels of the study participants were similar to those of the general population and there was no unemployment in the study cohort. Thus, adolescents require targeted intervention to overcome these many obstacles to normoglycemia.33

There is an epidemic of type 2 diabetes mellitus in children, and glycemic control often deteriorates in adolescence at the same time that the risk of developing long-term complications accelerates.32 Therefore, the ADA recommends that glycemic treatment goals in children must be individualized, and lower goals may be reasonable based on the assessment of relative risks and benefits. The ADA-recommended plasma blood glucose levels and HbA1c goals for children and adolescents with type 1 diabetes are listed in Table 4.32

Blood glucose goals should be higher than those listed in Table 4 in children with frequent hypoglycemia or hypoglycemia unawareness. Postprandial blood glucose values should be measured when there is dispari-
ty between preprandial blood glucose values and HbA1c levels. For children aged 13 to 19 years, a lower HbA1c goal level (<7%) is reasonable if it can be achieved without excessive hypoglycemia.

PREGNANCY

Congenital malformations are the leading cause of morbidity and mortality in infants of mothers with type 1 and type 2 diabetes. For example, a prospective, Danish registry study of 1218 pregnancies in 980 women with type 1 diabetes revealed that the perinatal mortality rate was 3.1% (compared to 0.75% in the general population), and the congenital malformation rate was 5% (compared to 2.7% in the general population). Other significant complications are shown in Table 5.36 According to the ADA, observational data indicate that the risk of malformations increases continuously with increasing maternal glycemia during the first 6 to 8 weeks of gestation, and several studies have now shown that aggressive preconception care to normalize blood glucose will decrease the rate of malformations in infants of diabetic mothers. Sixty-six percent of pregnancies in diabetic mothers are not planned, thus those critical first 6 to 8 weeks to avoid hyperglycemia are often unknown.

Table 4. Plasma Blood Glucose and HbA1c Goals for Type 1 Diabetes Mellitus by Age Group

<table>
<thead>
<tr>
<th>Age, yrs</th>
<th>Preprandial BG, mg/dL</th>
<th>Overnight BG, mg/dL</th>
<th>HbA1c, %</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6</td>
<td>100–180</td>
<td>110–200</td>
<td>≤8.5 but ≥7.5</td>
<td>High risk of and vulnerability to hypoglycemia</td>
</tr>
<tr>
<td>6–12</td>
<td>90–180</td>
<td>100–180</td>
<td>&lt;8</td>
<td>Risk of hypoglycemia; relatively low risk of complications before puberty</td>
</tr>
<tr>
<td>13–19</td>
<td>90–130</td>
<td>90–150</td>
<td>&lt;7.5</td>
<td>Risk of hypoglycemia; developmental and psychological issues</td>
</tr>
</tbody>
</table>

Glycemic treatment goals in children must be individualized, and lower goals may be reasonable based on the assessment of relative risks and benefits. Blood glucose goals should be higher than those listed above in children with frequent hypoglycemia or hypoglycemia unawareness. Postprandial blood glucose values should be measured when there is disparity between preprandial blood glucose values and HbA1c levels. For children ages 13 to 19 years, a lower HbA1c goal level (<7%) is reasonable if it can be achieved without excessive hypoglycemia. BG = blood glucose; HbA1c = glycosylated hemoglobin.

Adapted with permission from American Diabetes Association, Diabetes Care. 2005;28(suppl 1):S4-S36.32 Copyright © 2005.
Therefore, the ADA recognizes the importance of educating all diabetic women of childbearing age about achieving and maintaining optimal control before and during pregnancy and counseling contraception and family planning. Preconception care should consist of the appropriate diet, SMBG, and intensified insulin treatment (although postprandial SMBG may be more effective than preprandial monitoring). The Danish registry study also showed that women whose pregnancies resulted in serious complications were less likely to perform SMBG at conception, less likely to have preconceptional care, and more likely to have higher HbA1C values throughout the pregnancy (Table 6). Manderson et al found that postprandial SMBG in pregnant patients with type 1 diabetes mellitus significantly reduced the incidence of maternal pre-eclampsia and resulted in a smaller neonatal triceps skinfold thickness compared to preprandial monitoring. In a population of Hispanic women with gestational diabetes treated with insulin therapy, De Veciana et al showed that insulin therapy adjustments based on postprandial rather than preprandial blood glucose values improved glycemic control and decreased the risk of neonatal hypoglycemia, macrosomia (excess fetal growth), and cesarean delivery (Table 7).

Finally, the ADA also recommends that women contemplating pregnancy should be seen by a multidisciplinary team with experience in managing diabetes, which should include a diabetologist, internist or family physician, obstetrician, diabetes educator, dietitian, social worker, and other specialists as necessary. The goals of preconception care are listed in Table 8.

### Table 5. Obstetric Complications and Fetal Characteristics for Pregnancies in Women with Type 1 Diabetes and the Background Population

<table>
<thead>
<tr>
<th>Type 1 Diabetic Pregnancy</th>
<th>Background Population</th>
<th>RR (95% CI) or P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>1215</td>
<td>70 089</td>
</tr>
<tr>
<td>Pre-eclampsia</td>
<td>220 (18.1%)</td>
<td></td>
</tr>
<tr>
<td>Caesarean section</td>
<td>680 (55.9%)</td>
<td>8831 (12.6%)</td>
</tr>
<tr>
<td>Preterm delivery</td>
<td>507 (41.7%)</td>
<td>4205 (60%)</td>
</tr>
<tr>
<td>Gestational age at delivery, days</td>
<td>256 ± 16</td>
<td>280</td>
</tr>
<tr>
<td>Birth weight, g</td>
<td>3487 ± 817</td>
<td>3478</td>
</tr>
<tr>
<td>Birth weight ≥4500 g</td>
<td>97 (8.0%)</td>
<td>2383 (3.4%)</td>
</tr>
<tr>
<td>Large for gestational age infant</td>
<td>761 (62.5%)</td>
<td>—</td>
</tr>
<tr>
<td>Stillbirth</td>
<td>26 (2.1%)</td>
<td>318 (45%)</td>
</tr>
<tr>
<td>Perinatal mortality</td>
<td>38 (3.1%)</td>
<td>525 (7.5%)</td>
</tr>
<tr>
<td>Congenital malformations</td>
<td>61 (5.0%)</td>
<td>1987 (2.8%)</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>202 (17.1%)</td>
<td>ND</td>
</tr>
<tr>
<td>Jaundice</td>
<td>215 (18.1%)</td>
<td>ND</td>
</tr>
</tbody>
</table>

Data are means ± SD or n (%). *Blood pressure ≥140/90 mm Hg and proteinuria. The frequency in the background population is 2.6% (other data source); **Before 37 completed weeks of gestation; †Birth weight ≥90th percentile. The expected frequency in the background population is 10%, but exact numbers are not available; ‡Use of continuous positive airway pressure for >1 h postpartum; §Use of phototherapy.

CI = confidence interval; ND = no data; SD = standard deviation.


### Table 6. Maternal Characteristics in Pregnancies with Serious Adverse Outcomes* versus Other Pregnancies

<table>
<thead>
<tr>
<th>Serious Adverse Outcome</th>
<th>Others</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>93</td>
<td>1125</td>
</tr>
<tr>
<td>SMBG at conception</td>
<td>18 (22.5%)</td>
<td>363 (34.6%)</td>
</tr>
<tr>
<td>HbA1C 0–3 months before conception (%)</td>
<td>8.0 (7.3–9.1)</td>
<td>7.6 (6.8–8.5)</td>
</tr>
<tr>
<td>HbA1C during first trimester (%)</td>
<td>7.6 (6.6–8.6)</td>
<td>7.3 (6.6–8.1)</td>
</tr>
<tr>
<td>HbA1C during second trimester (%)</td>
<td>6.9 (6.2–8.0)</td>
<td>6.6 (6.0–7.3)</td>
</tr>
<tr>
<td>HbA1C during third trimester (%)</td>
<td>7.1 (6.5–7.0)</td>
<td>6.7 (6.2–7.4)</td>
</tr>
</tbody>
</table>

*Perinatal death and/or congenital malformation. Data are median (interquartile range) or n (%).

HbA1C = glycosylated hemoglobin; SMBG = self-monitoring of blood glucose.


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**Older Adults**

Older adults are complex patients in general and the number of diabetic patients who are elderly is increasing rapidly. At least 20% of per-
sons older than age 65 years have diabetes mellitus. Successful treatment of diabetes in older adults means overcoming several important challenges. Older adults very often have complex comorbid medical conditions and are taking multiple medications. Cardiovascular risk factors are of particular concern in the elderly because older adults with diabetes have higher rates of premature death, functional disability, and coexisting illnesses (ie, hypertension, coronary heart disease, and stroke) than those persons without diabetes. In these patients, it is necessary to control all cardiovascular risk factors, not just hyperglycemia. In fact, greater reductions in morbidity and mortality may be achieved with controlling cardiovascular risk factors other than glycemic control. Another challenge lies with insulin administration and SMBG, which require intact visual, motor, and cognitive skills. Older adults also face circumstances that can confound diabetes treatment, namely polypharmacy, depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain. When creating a treatment plan for an older adult with diabetes, the clinician must consider the overall life expectancy of the patient. Is the patient expected to live long enough to reap the benefits of long-term intensive diabetes management (eg, 10 years)? Unfortunately, there are no long-term studies in adults older than the age of 65 years that show the benefits of tight glycemic control, blood pressure, and lipid control on the long-term complications of diabetes. Older adults with diabetes are a clinically heterogeneous population. Older adults could have had diabetes for a long time (since middle age), thus many comorbidities, or they may be newly diagnosed (with or without unrecognized comorbidities). Older adults also have differences in life expectancy and cognition. All of these factors must be taken into consideration when developing a treatment plan. However, those persons with good cognition and an active, willing, and responsible approach to self-care should be encouraged to receive treatment using the same goals as for younger adults with diabetes.

Regarding medication considerations in older adults, the American Geriatrics Society has published their own guidelines. Metformin is contraindicated in patients with renal insufficiency or heart failure. Sulfonylureas, other insulin secretagogues, and insulin can cause hypoglycemia. Thiazolidinediones should not be used in patients with congestive heart failure. Regarding drugs commonly used in patients with diabetes, statins are pregnancy category X, angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers are category C in early pregnancy but category D after the first trimester; metformin and acarbose are category B, and all other hypoglycemic agents are category C. HbA1c = glycosylated hemoglobin. Data from American Diabetes Association.

### Table 7. Neonatal Outcomes of Mothers with Gestational Diabetes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Preprandial Monitoring Mean ± SD</th>
<th>Postprandial Monitoring Mean ± SD</th>
<th>Relative Risk (95% CI) P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight, g</td>
<td>3848 ± 434 (n = 33)</td>
<td>3469 ± 668 (n = 33)</td>
<td>1.3 (1.0–1.7) 0.01†</td>
</tr>
<tr>
<td>Large for gestational age*</td>
<td>14 (42)</td>
<td>4 (12)</td>
<td>3.5 (1.8–7.2) 0.01†</td>
</tr>
<tr>
<td>Birth weight &gt;4000 g</td>
<td>12 (36)</td>
<td>3 (9)</td>
<td>4.1 (1.3–13.2) 0.01†</td>
</tr>
<tr>
<td>Small for gestational age</td>
<td>0</td>
<td>1 (3)</td>
<td>— 1.00‡</td>
</tr>
<tr>
<td>Shoulder dystocia</td>
<td>6 (18)</td>
<td>1 (3)</td>
<td>6.0 (1.8–20.8) 0.01†</td>
</tr>
<tr>
<td>Neonatal hypoglycemia</td>
<td>7 (21)</td>
<td>1 (3)</td>
<td>7.0 (0.5–53.8) 0.05†</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td>4 (12)</td>
<td>3 (9)</td>
<td>1.3 (0.5–5.5) 0.001‡</td>
</tr>
<tr>
<td>Transient tachypnea</td>
<td>2 (6)</td>
<td>2 (6)</td>
<td>1.0 (0.2–4.7) 1.00‡</td>
</tr>
<tr>
<td>Apgar score at 5 min ≤7</td>
<td>3 (9)</td>
<td>1 (3)</td>
<td>3.0 (0.7–12.0) 0.10‡</td>
</tr>
<tr>
<td>Stillbirth†</td>
<td>1 (3)</td>
<td>0</td>
<td>— 1.00‡</td>
</tr>
</tbody>
</table>

*Infants who were large for gestational age had birth weights above the 90th percentile for gestational age and sex according to population-specific growth curves, and those who were small for gestational age had birth weights below the 5th percentile; †By student’s t-test; ‡By Fisher’s exact test (two-tailed); †One unexplained stillbirth at 21 weeks; the autopsy was normal. CI = confidence interval; SD = standard deviation.


### Table 8. Goals of Preconception Care for Diabetes

- Integrate the patient into the management of her diabetes.
- Achieve the lowest HbA1c level possible without excessive hypoglycemia.
- Assure effective contraception until stable and acceptable glycemia is achieved.
- Identify, evaluate, and treat long-term diabetic complications, such as retinopathy, nephropathy, neuropathy, hypertension, and coronary artery disease.

Regarding drugs commonly used in patients with diabetes, statins are pregnancy category X, angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers are category C in early pregnancy but category D after the first trimester; metformin and acarbose are category B, and all other hypoglycemic agents are category C. HbA1c = glycosylated hemoglobin.
Heart Association functional class III or IV). Insulin use also requires good cognition and good visual and motor skills of the patient or caregiver. Drugs should be administered at the lowest dose and titrated up gradually until targets are reached or side effects develop. The potential benefits must always be considered against the risks.32

THE ROLE OF PATIENT EMPOWERMENT

Patient empowerment involves more than providing the patient with information about diabetes mellitus; it requires practical interventions that facilitate collaborative relationships between healthcare providers and patients and enable patients to become actively involved in and responsible for managing their diabetes. Any member of the diabetes healthcare team can motivate patients by increasing the patient's knowledge of the disease, and each practitioner should take advantage of opportunities to educate patients and ensure adequate patient contact. Because diabetes is a chronic disease with many factors that influence glycemic control, care plans need to be individualized and the patient can and should provide the clinician with the psychosocial information necessary to develop a comprehensive care plan. Patients should be encouraged to join diabetes patient associations from where they can obtain information, resources, advice, and support. Self-management can be facilitated using titration schedules to initiate and titrate insulin. Patients can learn to self-monitor and self-adjust their insulin dose, thereby actively participating in their treatment. Sidebar 3 summarizes 4 studies that describe the optimization of a diabetic patient's care plan from 4 perspectives—the physician, the diabetes educator, the pharmacist, and the patient.

CONCLUSIONS

Glycemic control in diabetes is imperative to reduce the risk of micro- and macrovascular complications, reduce the risk of hypoglycemia (and hypoglycemia unawareness), and reduce healthcare costs and resource utilization. We now have many studies to show that glycemic control can provide all of these benefits. Yet, obstacles remain, as witnessed by the abysmal numbers of patients with diabetes who actually reach their treatment targets. Treatment goals must be individualized, based on the myriad factors

SIDEBAR 3

OPTIMIZING TREATMENT PLANS: PERSPECTIVE OF THE PHYSICIAN, DIABETES EDUCATOR, PHARMACIST, AND PATIENT

CLINICAL INERTIA TOWARD DIABETES CARE AMONG PHYSICIANS

Most patients with diabetes are treated and managed in a primary care setting. However, studies are now showing that many patients are not reaching their glycemic targets and are not receiving the extent of diabetic care recommended by the American Diabetes Association. As a result, many patients are not even aware of what type of care they should be receiving (eg, eye examinations and glycosylated hemoglobin [HbA1c] tests) or what their therapeutic targets should be.

Clinical inertia describes the failure of providers to intensify therapy when appropriate. Clinical inertia is common not only in diabetes but also in the management of hypertension and dyslipidemia. This study sought to determine whether clinical inertia contributes to higher HbA1c levels in a cohort of patients managed in a primary care setting compared to those managed in a diabetes clinic.

The patients were selected from a medical clinic and diabetes clinic in Grady, Georgia, both of which are part of a major academic medical center that serves a common population. Both sites have healthcare team resources such as dietitians, health educators, pharmacists, and social workers. The medical center is staffed by residents, nurse practitioners, physician assistants, and attending physicians. Approximately 30% of the patients have diabetes. In the medical clinic, patients are first seen by a resident who makes the therapeutic recommendations, which are then finalized by a general medicine faculty member. In the diabetes clinic, a nurse or nurse practitioner first sees the patients and makes the therapeutic recommendations, which are then finalized by an endocrinology faculty member. The results showed that the average HbA1c level was higher in the medical clinic (8.6%) than in the diabetes clinic (7.7%); P <.0001. This trend was true for all types of therapy: diet (7.3% vs 6.8%), oral medication (8.4% vs 7.2%), and insulin (9.3% vs 8.2%), all P <.05. The frequency of therapy intensification also was lower in the medical clinic compared to the diabetes clinic: 36% vs 54% (diet), 31% vs 49% (oral medication), and 28% vs 75% (insulin; all P <.02). The frequency of intensification was uniformly lower in the medical clinic when patients were stratified by their glucose levels.

The authors acknowledge some of the study limitations, including the possible need to deal with other disorders during medical clinic visits, which can limit time (Continued on page S1114)
and effort for diabetes management. However, they also suggest that clinical inertia in the medical clinic "reflects limited exposure to education that emphasizes treating to target and the need to act each time that intensification of therapy is clinically indicated." Thus, in primary care settings, physicians (and indeed all primary care providers) face their own barriers to diabetes education and management that need to be overcome if patient outcomes are to be optimized.¹

**The Diabetes Educator: Using Empowerment in a Self-Management Education Program**

Funnell et al describe a self-education program they developed to address the needs of community-based African Americans with type 2 diabetes in Detroit, Michigan.² The program consisted of 6 weekly group sessions of 5 to 15 participants, led by a nurse and dietitian, both of whom were certified diabetes educators. The philosophy of the program was to identify the instructors as diabetes experts, but not experts in what was best for each patient. The program was designed such that the content was determined by the patients, based on the questions they posed to the instructors. In this way, their "education" would be more meaningful to their specific circumstances. However, the instructors kept careful notes of what information was covered to ensure that all content of the National Standards for Diabetes Self-Management Education Programs was adequately addressed.

Each session had 4 components: reflecting on self-management, discussing the emotional experience of living with diabetes, engaging in systematic patient-centered goal setting and problem solving, and answering clinical questions. This format allowed patients to identify a goal and a behavioral step, and inform the group of how their plans worked. This underscored the importance of learning, rather than success or failure. It also helped participants to think about behavioral aspects of managing diabetes. Patients were empowered because the program structure and philosophy affirmed that the patient is responsible for and in control of the daily self-management of diabetes, educated patients to act on informed decision making rather than adherence/compliance, taught patients to set behavioral goals so patients could make changes of their own choosing, and affirmed patients as experts on their own learning needs and their innate capacity to identify and learn to solve their own problems.

The investigators noted that the participants paid close attention during the sessions and were highly motivated. Importantly, they were not interested in the subject of diabetes per se but in their own diabetes and how it affected their lives. Despite the less structured format, the questions they posed were thoughtful and often complex, illustrating that the participants were thinking seriously about their illness. The investigators caution that this approach should only be used by experienced educators (especially those experienced with teaching) and those who are flexible with excellent group facilitation skills.

This program was based on trusting the wisdom of the patients in living their own lives and managing their own diabetes. Participants attended an average 5.07 of the 6 sessions, despite transportation problems and other barriers.²

**A Pharmacist-Led Education Program that Addresses Literacy Barriers in Patients with Diabetes**

It is well known that low literacy is common in people with diabetes, and low literacy often includes low health literacy, which compromises clinical outcomes. This study evaluated a diabetes education program that included low-literacy-oriented interventions to determine if there would be an effect on HbA₁c levels.

The study was conducted by pharmacists, some of whom had PharmD degrees and residency training in hospital and outpatient pharmacy programs, at the University of North Carolina General Internal Medicine Practice, which serves a large indigent population.

The program consisted of an initial 1-hour session in the examination room (after the patient had seen the physician), during which information on glucose control, glucose monitoring and management, nutrition and exercise, proper foot and eye care, and medication management was provided. At the end of the session, the pharmacist made care recommendations. After the initial session, the pharmacist then focused on education related to self-management and medication management for glucose control. Contact was made with each patient (by phone or in person at the clinic) every 2 to 4 weeks to assess adherence, self-management behaviors, and titrate medication (if necessary). Patients were followed for 6 months.

The pharmacists used techniques that have been shown to improve comprehension in those with poor literacy, such as simplifying the information provided, avoiding use of jargon, focusing on selected critical behaviors, using concrete examples, limiting the number of topics covered in one session, using easy-to-read picture-based materials, and asking patients to teach back the information they just learned.

Patients were divided into 2 groups: those with reading levels at or below the 6th grade and those with reading levels above the 6th grade. HbA₁c measures were obtained before the program, at enrollment, and 6 months later. Before and at enrollment, both groups of patients had similar HbA₁c levels (before enrollment 10.3% lower literacy group, 9.7% higher literacy group; at enrollment 10.7% and 10.6%, respectively). After 6 months of the program, both groups improved their HbA₁c levels by almost 2%—1.9% lower literacy group and 1.8% higher literacy group.

(Continued from page S1113)

(Continued on page S1115)
(Continued from page S1114)

The results showed that educational programs targeted to lower-literate patients can have significant impact on their clinical outcomes. Pharmacists are clearly in a position to implement these programs. In fact, 2 of the pharmacists ultimately obtained certification as diabetes educators during the study.4

**PATIENT-IDENTIFIED BARRIERS TO DIABETES EDUCATION**

This study of 605 new patients attending an outpatient diabetes clinic of a county hospital system in Atlanta, Georgia, sought to determine patients’ perceptions of barriers to diabetes education. The clinic provides comprehensive diabetes care by diabetes nurse educators, dietitians, podiatrists, endocrinologists, and an optometric technician.

The population had a mean age of 50 years and 56% were female. The vast majority (89%) were African American. Approximately 33% reported some college education, whereas 55% had some or completed high school and 14% had only an elementary school education. Eighty percent of the participants had an annual individual income of less than $20,000. Thirty-one percent were employed, 31% were unemployed, and the remaining were disabled (25%) or retired (13%). Participants completed a questionnaire about perceived barriers to care.

More than 50% perceived that they would have difficulty with diabetes education and 33% anticipated more than 1 problem. The most commonly reported problems were poor vision (74%), cannot read well (presumably indicating illiteracy; 29%), hearing problems (19%), problems with English language (11%), or some other type of problem (7%). Those patients more likely to have a barrier were older, male, disabled, and had an elementary education or less.

The list of possible barriers was not exhaustive (and not meant to be) and it was not determined whether perceived barriers led to poorer clinical outcomes. However, the results provide insight into the fears and concerns about diabetes education among patients, at least in this demographic. The challenge for any “diabetes educator” (whether or not officially certified) is to work with each patient to identify specific barriers to that patient, thus the educational program can be targeted accordingly and the patient’s sense of self-efficacy can be fulfilled.4

**REFERENCES**


That constitute the patient's profile (eg, age, comorbidities, and psychosocial pressures). Patient empowerment is an essential tool to achieving treatment targets. Once patients realize that they control their own health and diabetes management, they can act more effectively in preventing the long-term complications of diabetes. Each member of the diabetes care team has an important role to play in providing diabetes education and patient empowerment. Successful treatment of diabetes can only be achieved when each care team member, in addition to the patient, takes an active role and assumes responsibility for their contribution to the treatment plan.

**REFERENCES**


