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Self-Monitoring of Blood Glucose (SMBG): Considerations for Intensive Diabetes Management

A CME/CPE/CNE/CCM-Certified Supplement

Robyn Graham, PharmD



*Educational Programs
for Managed Markets*

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CME/CPE/CNE/CCM Information

Self-Monitoring of Blood Glucose (SMBG): Considerations for Intensive Diabetes Management

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Activity Description

Approximately 18.2 million people in the U.S., or roughly 6% of the population, have diabetes. Diabetes has been diagnosed in only 13 million people, leaving 5.2 million cases of diabetes undiagnosed and thus untreated. Of the 18.2 million Americans with diabetes, only 14% (about 2.5 million people) practice self-monitoring of blood glucose (SMBG) regularly. The American Diabetes Association states that self-management of diabetes—including SMBG by all patients and caregivers who are able to follow instructions, who are motivated to collect and record accurate results, and who are willing to work with health care providers to adjust therapy based on test results—is an integral part of diabetes therapy.

This supplement reviews diabetes and treatment strategies, including SMBG. Key topics such as epidemiology, pathophysiology, and clinical presentation emphasize the necessity of intensive control of diabetes mellitus. In addition, the economics and quality-of-life effects are included to emphasize the ramifications of mismanagement of the disease.

Following this thorough review are a summary of treatment options incorporating the significance of SMBG, the positive outcomes of intensive glucose management, and a detailed review of blood glucose monitors. The information presented here should enable health care providers to recommend cost-effective monitors for their patients and to incorporate SMBG into diabetes management.

Educational Objectives

1. Identify the role of self-monitoring blood glucose (SMBG) in the treatment and management of diabetes mellitus.
2. Identify key differences in blood glucose monitors.
3. Make recommendations for the most cost-effective blood glucose monitors.
4. Communicate the importance and benefits of SMBG to patients and other health care professionals.
5. Educate patients about when and how to perform SMBG.
6. Recognize the impact of diabetes on health care utilization and cost.

Target Audience

Physicians, pharmacists, nurses, and case managers who treat diabetes or who provide coverage of blood glucose monitors.

Accreditation

CME*

The University of Cincinnati College of Medicine designates this educational activity for a maximum of 1.5 category 1 credits toward the American Medical Association's Physician's Recognition award. Each physician should claim only those credits that he or she actually spent in the activity.

CPE*



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CCMC*

The Commission for Case Manager Certification has approved this activity for 1.5 contact hours.

- **The Post-test and Evaluation must be dated and signed between January 1, 2006, and December 31, 2006, for CCM credit.**

Provider

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** There is no fee for the CE activity.*

Self-Monitoring of Blood Glucose (SMBG): Considerations for Intensive Diabetes Management

INTRODUCTION

Approximately 18.2 million people in the U.S., or roughly 6% of the population, have diabetes. Diabetes has been diagnosed in only 13 million people, leaving 5.2 million cases of diabetes undiagnosed and thus untreated.¹ Of the 18.2 million Americans with diabetes, only 14% (about 2.5 million people) practice self-monitoring of blood glucose (SMBG) regularly.² The American Diabetes Association (ADA) states that self-management of diabetes—including SMBG by all patients and caregivers who are able to follow instructions, who are motivated to collect and record accurate results, and who are willing to work with health care providers to adjust therapy based on test results—is an integral part of diabetes therapy.¹⁻³

SMBG has become a standard of care in the management of diabetes. The benefits of intensive diabetes therapy, including monitoring of blood glucose, have been shown for both type-1 and type-2 diabetes. In 1993, the Diabetes Control and Complications Trial Research Group (DCCT) demonstrated that intensive therapy and control of diabetes effectively delay the onset and progression of diabetes complications in patients with type-1 diabetes mellitus (DM).⁴ Similarly, in 1998, the United Kingdom Prospective Diabetes Study Group (UKPDS) demonstrated that intensive blood glucose control, either with oral therapy or insulin, decrease microvascular complications in type-2 DM patients.⁵

Although SMBG is an integral component of intensive diabetes management, compliance and accuracy of technique are lacking. The accuracy of hand-held blood glucose monitors in controlled environments has been proven. Unfortunately, an ADA consensus panel has reported that up to 50% of patients performing SMBG demonstrate a 20% variance from the true value of blood glucose determinations when performing SMBG at home.² To reduce this variation in SMBG values, the ADA has recommended the following:²

- periodic simultaneous comparisons of patients' monitors with those of a reference laboratory to be conducted

- increased patient education by health care providers and by the manufacturers of monitors
- additional research efforts in determining characteristics of patient–health care provider relationships that influence behavior and improve glycemic control and health outcomes measures

By incorporating SMBG and emphasizing education and key features of self-monitoring into the diabetes-management plan, health care providers can help patients reach their overall glycemic goals.

This supplement will serve as a review of diabetes and treatment strategies, including SMBG. Key topics such as epidemiology, pathophysiology, and clinical presentation emphasize the necessity of intensive control of DM. In addition, the economics and quality-of-life effects are included to emphasize the ramifications of mismanagement of the disease.

Following this thorough review are a summary of treatment options incorporating the significance of SMBG, the positive outcomes of intensive glucose management, and a detailed review of blood glucose monitors. The information presented here should enable health care providers to recommend cost-effective monitors for their patients and to incorporate SMBG into diabetes management.

EPIDEMIOLOGY AND RELEVANT RISK FACTORS

Diabetes directly affects 18.2 million people in the U.S., or 6.3% of the population.¹ It is estimated that 1.3 million new cases of DM will be diagnosed each year in people aged 20 years and older. Diabetes was the sixth leading cause of death in the U.S. in the year 2000. These figures are probably underestimated, because diabetes is listed as the underlying cause of death on death certificates in only 10% to 15% of patients who have diabetes. The risk of death for patients with diabetes is twice that of patients without diabetes.¹

Type-1 DM occurs most commonly in childhood or early adulthood, with some latent development. Approximately 5% to 10% of all diabetic patients

have type-1 DM. According to 2002 U.S. data, approximately 210,000 people under the age of 20 years have diabetes. The prevalence of type-1 diabetes in children and adolescents is one in every 400 to 500.¹

Type-1 DM results from an autoimmune destruction of pancreatic beta cells. Risk factors include genetic makeup, autoimmune disorders, and environmental factors. Some people are genetically susceptible to diabetes, but the disease is not activated until exposure to a specific environmental trigger occurs.^{1,6}

Type-2 DM comprises 90% to 95% of all diabetes diagnoses.⁷ It is associated with the following:⁶

- older age
- obesity (20% or more over one's ideal body weight or a body mass index [BMI] of 27 kg/m² or higher)
- family history (parents or siblings with diabetes)
- chronic physical inactivity
- race and ethnicity (African-Americans, Hispanic/Latino Americans, Native Americans, Asian-Americans, Native Hawaiians, Pacific Islanders)
- hypertension (140/90 mm Hg or higher in adults)
- high-density lipoprotein-cholesterol (HDL-C) at or below 35 mg/dl
- gestational diabetes mellitus (previous delivery of a high-birth-weight baby weighing more than nine pounds)
- polycystic ovary syndrome (PCOS)

Regional studies indicate that type-2 DM is becoming more prevalent in those people younger than 20 years of age.¹

Type-2 DM results from defects in insulin sensitivity or insulin resistance, with a relative defect in insulin secretion. In the U.S., the overall prevalence for type-2 diabetes is approximately 6.6% for patients between 20 and 74 years of age. Experts estimate that for every two cases of type-2 diabetes, one case remains undiagnosed.^{1,6}

Gestational diabetes (GDM) affects an estimated 4% of pregnancies in the U.S. Obese women, women with a family history of diabetes, and women from certain ethnic populations are at higher risk. During pregnancy, women with gestational diabetes require treatment to normalize maternal blood glucose

levels and to prevent or alleviate complications with the infant. Although normoglycemia resumes in most women after the pregnancy, these women have a 20% to 50% chance of developing type-2 DM over the next five to 10 years.^{1,6} Approximately 5% to 10% of women with GDM have type-2 diabetes after the pregnancy.

An additional 1% to 5% of all diagnosed cases of diabetes result from specific genetic abnormalities (e.g., maturity-onset diabetes in youth, a subset of type-2 diabetes) or adverse effects of medications, surgery, malnutrition, infections, or other illnesses.^{1,6}

Combined with an aging population and an increase in the prevalence of obesity, it is projected that the incidence and prevalence of diabetes will continue to rise.

PATHOPHYSIOLOGY

Diabetes comprises a group of metabolic disorders characterized by hyperglycemia resulting from dysfunctions in insulin production, insulin action, or both. Diabetes is associated with abnormalities in carbohydrate, fat, and protein metabolism. Many chronic microvascular, macrovascular, and neuropathic complications occur as a result of diabetes.^{1,3,6}

Type-1 DM is characterized by an absolute deficiency of insulin resulting from immune-mediated pancreatic beta islet-cell destruction. Four main features are evident in type-1 DM:

- a long preclinical period, marked by the presence of immune markers when beta-cell destruction may occur
- hyperglycemia, when 80% to 90% of beta cells are destroyed
- transient remission, or the "honeymoon" phase
- established disease with associated risks for complications and death

It is not known which or how many factors contribute to this autoimmune process.^{1,3,6}

Several antibodies have been identified in patients with type-1 DM; 90% or more newly diagnosed patients have one or another of them. In addition, antibodies are present in 3.5% to 4% of unaffected first-degree relatives. The link between such antibodies and diabetes has not been completely defined.^{6,8}

Type-2 DM involves insulin resistance and insulin secretory defect or beta-cell dysfunction.^{1,3,6}

Type-2 DM commonly begins as insulin resistance, which is the result of an increase in lipolysis (free fatty acid production), increased hepatic glucose production (gluconeogenesis and glycogenolysis), and decreased skeletal muscle uptake of glucose. Most patients with type-2 DM have both insulin resistance and insulin deficiency of varying degrees. Not all patients with insulin resistance develop glucose intolerance.⁶

Genetic factors relating to type-2 DM are not completely understood. There may be multiple genetic components, influencing both pancreatic beta-cell dysfunction and insulin resistance.^{6,8}

Excessive caloric intake, inadequate caloric expenditure, and obesity in patients with a susceptible genotype result in type-2 DM. The amount of weight gain associated with insulin resistance may depend on one's racial and ethnic background. Eighty-five to 90% of patients with type-2 DM are obese.⁸ Insulin resistance, also called "the insulin resistance syndrome," "metabolic syndrome," "dysmetabolic syndrome," or "syndrome X," is associated with a plethora of metabolic and thrombotic abnormalities. When setting goals for glycemic control, it is critical that health care providers ensure that all complications are addressed and monitored.⁶

GDM is the initial onset of glucose intolerance, usually occurring during the second or third trimester of pregnancy.^{6,8}

CLINICAL PRESENTATION

Patients with type-1 DM generally present with acute symptoms—the classic triad of polyuria, polydipsia, and polyphagia as well as significantly elevated blood glucose. Of those patients experiencing polyuria, polydipsia, polyphagia, and weight loss for several days, 20% to 40% present with diabetic ketoacidosis.^{3,6,8}

Patients with type-2 DM sometimes present without symptoms or with advanced complications. An estimated one-third of all cases of diabetes are undiagnosed. Criteria for the diagnosis of diabetes in nonpregnant adults are listed in Table 1.

Patients who appear at high risk for the disease should be screened for both diabetes and prediabetes. Table 2 presents criteria for screening asymptomatic adults at risk for the development of diabetes.^{3,8}

TABLE 1 Criteria for the Diagnosis of Diabetes in Nonpregnant Adults

- Symptoms of diabetes and a casual plasma glucose \geq 200 mg/dl (11.1 mmol/L). "Casual" is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.
- or
- Fasting plasma glucose \geq 126 mg/dl (7.0 mmol/L). Fasting is defined as no caloric intake for at least eight hours.
- or
- Two-hour plasma glucose \geq 200 mg/dl (11.1 mmol/L) during an oral glucose tolerance test. The test should be performed as described by the World Health Organization using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

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If unequivocal symptoms of hyperglycemia are absent, each aforementioned test for diagnosis must be confirmed on a subsequent day. Most people who meet the diagnostic criteria by the oral glucose tolerance test (OGTT), but not by the fasting plasma glucose (FPG) test, have a glycosylated hemoglobin (HbA_{1c}) level below 7. At this time, the HbA_{1c} value is not recommended for the diagnosis of diabetes.^{3,8}

Two tests are available for screening patients for diabetes: FPG and the two-hour OGTT. These tests do not necessarily identify the same patients. The two-hour OGTT identifies people with impaired glucose tolerance (IGT), who are at increased risk for developing diabetes and cardiovascular disease (CVD). The initial screening test recommended for nonpregnant adults is the FPG, which is more convenient for patients, easy to administer, more reproducible, and less costly.^{3,8}

As previously noted, the incidence of type-2 DM in children and adolescents is increasing rapidly. Screening should be performed for children and youth at risk of having or developing diabetes. Table 3 provides screening criteria for type-2 DM in children.

After the diagnosis of diabetes is confirmed, SMBG becomes a critical component of overall diabetes management and should be used as an adjunct to pharmacological and nutritional therapies.

ECONOMIC ASPECTS

Direct Costs and the Use of Health Care Services

Although only 4.2% of people in the U.S. have a confirmed diagnosis of diabetes, 19% of total health care costs are a result of direct expenditures for diabetes care. The total economic burden of diabetes in 2002 was approximately \$132 billion.⁹⁻¹² This correlates with one out of every 10 health care dollars spent in the U.S. being attributable to diabetes. Patients with diabetes spend 2.4 to 2.6 times more in medical costs than people without diabetes when demographic variations are taken into consideration.

The annual per capita cost for patients with diabetes rose 30% from \$10,071 in 1997 to \$13,243 in 2002. By contrast, the per capita cost for patients without diabetes was \$2,560. It is predicted that the total cost of diabetes might reach \$156 billion by 2010 and \$192 billion by 2020. Increases in cost are attributable to the increased number of diseases and conditions being associated with diabetes.^{9,10,12}

In 2002, direct and indirect costs of diabetes were \$92 billion and \$40.8 billion, respectively. Direct expenditures included \$23.3 billion for diabetes care, \$24.6 billion for chronic diabetes-related complications, and \$44.1 billion for an excess prevalence of general medical conditions. The most costly complication of diabetes is CVD, with annual expenditures of \$17.6 billion, or 19% of direct medical costs.

Diabetes-related office visits to physicians totaled 62.6 million visits in 2002. Diabetes-related hospitalizations totaled 16.9 million days, costing approximately \$40.3 billion. A total of \$13.8 billion was spent on nursing-home care for patients with diabetes in 2002. Total direct medical costs may reach \$138 billion by 2020.⁹⁻¹²

A study of one managed care organization reports the annual average cost of each patient with diabetes to be an estimated \$11,000. Antihyperglycemic prescriptions accounted for only \$561, or 5% of the total. The cost of prescription medications for diabetes-related comorbidities was \$1,267.¹²

TABLE 2 Criteria for Testing for Diabetes in Asymptomatic Adults

1. Testing for diabetes should be considered in all individuals at age 45 years and above, particularly in those with a body mass index (BMI) ≥ 25 kg/m².^{*} If normal, testing should be repeated at three-year intervals.
2. Testing should be considered for those at a younger age or should be carried out more frequently in individuals who are overweight (BMI ≥ 25 kg/m²*) and who have additional risk factors, as follows:
 - are habitually physically inactive
 - have a first-degree relative with diabetes
 - are members of a high-risk ethnic population (e.g., African-American, Latino, Native American, Asian-American, Pacific Islander)
 - have delivered a baby weighing more than nine pounds or have had gestational diabetes mellitus
 - are hypertensive (blood pressure above 140/90 mm Hg)
 - have a high-density lipoprotein-cholesterol (HDL-C) level below 35 mg/dl (0.90 mmol/L) and/or a triglyceride level above 250 mg/dl (2.82 mmol/L)
 - have polycystic ovary syndrome (PCOS)
 - had impaired glucose tolerance or impaired fasting glucose on previous testing
 - have other clinical conditions associated with insulin resistance (acanthosis nigricans)
 - have a history of vascular disease

* May not be correct for all ethnic groups or with PCOS.

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Indirect Costs: Employer Burden

Indirect costs, consisting of lost workdays, restricted activity days, permanent disability as a result of diabetes, and mortality, totaled \$40.8 billion in 2002. In the same year, diabetes accounted for 88 million disability days; 176,000 cases of permanent disability were reported as a result of diabetes. Costs associated with permanent disability totaled \$7.5 billion.¹⁰

QUALITY OF LIFE

Complications associated with diabetes are vast in number, cost, and their impact on daily life. There are three primary areas of diabetes complications: microvascular, macrovascular, and neuropathic.^{1,3,6} Patients with diabetes are considered to be at greater risk for temporary incapacity, measured by lost workdays and bed days, permanent disability, and premature mortality. Diabetic men lose 3.1 and diabetic women lose 0.6 more workdays than peo-

TABLE 3 Criteria for Testing for Type-2 Diabetes in Children

- Overweight (body mass index > 85th percentile for age and sex, weight for height > 85th percentile, or weight > 120% of ideal for height)
plus
- Any two of the following risk factors:
 1. a family history of type-2 diabetes in a first- or second-degree relative
 2. race/ethnicity (Native American, African-American, Latino, Asian-American, Pacific Islander)
 3. signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, or polycystic ovary syndrome)
 4. age of initiation: age 10 years or at onset of puberty if puberty occurs at a younger age
- Frequency: every two years
- Test: fasting glucose tolerance preferred

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ple without diabetes. Men also have 7.9 more bed days per year, on average, than men without diabetes. Women have 8.1 more bed days, on average, than women without diabetes.⁹

Diabetes increases a person's risk for disability because of amputations, vision loss, and other physical problems. In January 2002, approximately 122,000 men and women 18 to 64 years of age received Social Security Disability Insurance (SSDI) benefits as a result of diabetes. An additional 109,000 people of the same age group received SSDI benefits for diabetes-related disabilities. In 2002 alone, 176,000 cases of permanent disability were attributable to diabetes.⁹

Cardiovascular disease (CVD) is the leading cause of diabetes-related deaths in the U.S. The death rates for CVD are two to four times higher in adults with diabetes than those without; similarly, the incidence of stroke is two to four times higher in people with diabetes. Death rates for diabetes result primarily from CVD and stroke, approximately 65%. Seventy-three percent of patients with diabetes have high blood pressure or may be taking one or more blood pressure medications.^{1,3}

Another complication of DM is diabetic retinopathy, a highly specific vascular condition. Its prevalence is strongly related to the duration of diabetes. Diabetic retinopathy is considered the leading cause of blindness among adults 20 to 74

years of age, with 12,000 to 24,000 new cases of blindness reported each year.^{1,3}

Of all patients with diabetes, 20% to 40% have diabetic nephropathy, the primary cause of end-stage renal disease (ESRD). In the year 2000, 43% of new cases of ESRD were a direct result of diabetic nephropathy. In the U.S. in the year 2000, 41,046 people with diabetes began treatment for ESRD, and 129,183 diabetic patients underwent dialysis or renal transplantation.^{1,3}

Mild-to-severe nerve damage occurs in approximately 60% to 70% of all people with diabetes. Consequences of neuropathies include impaired sensation or pain in the feet or hands, slowed digestion, carpal tunnel syndrome, and other nerve problems. Diabetic neuropathy is responsible for 60% of nontraumatic lower-limb amputations in the U.S. Approximately 82,000 nontraumatic lower-limb

amputations were performed among diabetic patients each year in 2000 and 2001.

Neuropathies are a major contributing factor for lower-extremity amputations. People who have had diabetes for more than 10 years; are male; have poor glucose control; or have cardiovascular, retinal, or renal complications have an increased risk of ulcers or amputation.^{1,3}

Other complications associated with diabetes include periodontal disease, problems during pregnancy, biochemical imbalances such as ketoacidosis, and immunosuppression.¹ The DCCT and UKPDS trials demonstrated that all complications could be reduced with tight control of blood glucose,^{4,5} best achieved through proper treatment strategies and SMBG.^{3,4,5,8}

As patients with diabetes begin to take control of their disease and manage it with SMBG, it is important to acknowledge the impact that SMBG has on quality of life. To attain significant levels of glycemic control, patients must perform SMBG at home and in public. For this reason, to ensure patient compliance, patients need monitors that offer convenience, discretion, and comfort. Health care providers should keep this in mind when recommending a blood glucose monitor.

APPROACHES TO TREATMENT THAT INCORPORATE SELF-MONITORING

Diabetes therapy is complex and specific to the disease type and to each patient. Treatment of type-1 DM includes insulin therapy integrated with diet, exercise, and glucose monitoring. Type-2 DM treatment involves diet and/or weight loss, oral anti-glycemic agents, insulin, and glucose monitoring.^{1,8}

Pharmaceutical treatments available for diabetes include insulin, metformin, sulfonylureas, thiazolidinediones, alpha-glucosidase inhibitors, incretins (exenatide), and other agents currently under development. Various pharmaceutical therapies differ in their mechanism of action and are used to manage glycemia in different ways. Because of these significant variations, it may be important to monitor postprandial glucose (PPG) levels to ensure that medical therapy is adjusted accordingly for the best outcome. SMBG plays a significant role in monitoring PPG and in reaching glycemic goals.

Monitoring glucose levels is a critical component of overall diabetes management. It is essential to optimize both fasting (FPG) and PPG levels. FPG is monitored through periodic laboratory testing. PPG can be monitored via SMBG. The key to monitoring PPG is recognizing that PPG levels often rise before FPG levels increase above 126 mg/dl.¹³

Data suggest that patients with type-2 DM have difficulty achieving the recommended HbA_{1C} goal despite having near-normal to normal FPG levels. These data imply that health care providers should adjust pharmacological treatment to decrease PPG levels for better overall blood glucose management.¹³ With recommendations to monitor PPG more closely, SMBG becomes an even more significant part of diabetes care.

SMBG, as a critical component of overall diabetes management, should be used as adjunct therapy with pharmacological treatments. Knowing the results of SMBG is useful for patients in evaluating their response to therapy; the findings can help prevent hypoglycemia and aid in adjusting medications, medical nutrition therapy, and physical activity. Daily self-monitoring is especially important to check for asymptomatic hyperglycemia and hypoglycemia in patients being treated with insulin.

It is recommended that most patients with type-1 diabetes and pregnant women who are using insulin perform SMBG three or more

times daily. The intensity of SMBG directly correlates with the intensity of insulin therapy (i.e., SMBG three or more times each day when multiple doses of insulin are administered each day).^{3,6,8}

The exact role of SMBG in improving glycemic control in patients with type-2 DM who are using oral agents has not been specifically defined. For these patients, SMBG should be performed at a sufficient frequency to reach glucose goals.

Patients with type-2 DM who are not using insulin typically do not need to monitor blood glucose as often as those who do use insulin.^{3,6,8} Patients with low levels of HbA_{1C} (below 6.5%) with either diet therapy or with oral medications that are not known to induce hypoglycemia may not require SMBG.

Table 4 provides a summary of recommendations for SMBG.

It is crucial that health care providers take an active role in educating patients about the importance of SMBG when indicated. They should evaluate patients' abilities to perform SMBG at regular intervals to ensure that patient techniques are accurate. They should also show patients how to use the data from SMBG to adjust food intake, exercise, or pharmacological therapy to achieve specific glycemic goals.³

Plasma blood glucose levels, obtained at medical laboratory facilities, should be performed on a

TABLE 4 Summary of Requirements for Performing Self-Monitoring of Blood Glucose (SMBG) by Diabetes Type

Type-1 diabetes

- Perform SMBG three or more times per day.
- Adjust intensity of monitoring to intensity of insulin therapy.
- Perform SMBG three or more times every day when multiple doses of insulin are administered every day.

Type-2 diabetes

- The exact frequency is undetermined.
- Perform SMBG at a sufficient rate to reach glucose goals.
- If taking insulin therapy, perform SMBG three or more times each day.

Gestational diabetes mellitus

- Perform SMBG three or more times each day.

Data from the American Diabetes Association,³ DiPiro JT, et al., 2002;⁶ and Mooradian AD, et al., 1998.⁸

regular basis to ensure the accuracy of SMBG. Glucose levels in plasma are generally 10% to 15% higher than whole blood glucose measurements.^{11,14} Although most monitors on the market today can convert whole blood glucose readings to the plasma equivalent, older monitors do not possess this capability. The Ascensia®, Accu-Chek™, BD Latitude™, FreeStyle™, OneTouch™ Ultra, and Precision QID® monitors report plasma/serum equivalent glucose results, allowing easy, accurate comparisons.¹¹

Significant opportunities exist to improve quality of care for health plan members by converting to newer, more precise blood glucose monitors. Converting to monitors with more advanced technology (whole blood to plasma equivalent conversion capabilities) allows patients and their health care providers to work together to adjust therapy and achieve glycemic control.

The HbA_{1C} level is another measurement of glycemic control. The DCCT demonstrated a strong correlation between HbA_{1C} levels and long-term complications.⁴ Glycemic control is best evaluated by a combination of SMBG and HbA_{1C} testing. The HbA_{1C} level shows average glycemia levels for the preceding two to three months; SMBG indicates present glucose levels, which is critical for making therapy adjustments.

HbA_{1C} is not recommended as a diagnostic test but should be obtained at the initial assessment to document glycemic control and to determine whether glycemic control has been achieved or maintained within the recommended range. HbA_{1C} may also be used to assess the accuracy of patient-reported blood glucose results and to verify that the SMBG testing schedule is appropriate.³

The frequency of HbA_{1C} monitoring should be patient-specific, depending on the patient's treatment regimen and clinical state. The HbA_{1C} level should be obtained at a minimum of two times per year in patients meeting treatment goals and quarterly for patients not meeting glycemic goals or who have had changes in therapy.³ If glycemic goals are not being met (if HbA_{1C} is 7 or higher), an increase in the frequency of SMBG is recommended to adjust the pharmacological regimen, nutrition therapy, and exercise in order to achieve glycemic control.^{3,4}

Table 5 shows the correlation between HbA_{1C} and plasma glucose levels based on data from the DCCT. Frequent self-monitoring is a critical component of achieving and maintaining glycemic goals.^{3,4}

KEY FEATURES OF BLOOD GLUCOSE MONITORS (Tables 6, 7, and 8)

Accuracy and safety of SMBG are critical on a test-by-test basis as well as when averages are being calculated for the health care provider's review. Factors influencing the overall accuracy of SMBG are meter accuracy and patient technique.

Alto et al. conducted an observational study to determine the technical skill and accuracy of SMBG in an outpatient population.² Medical and laboratory assistants evaluated 111 patients for appropriate technical skills using a checklist developed by diabetes educators.² The following checklist may serve as a reference for health care providers when educating patients in SMBG and in appropriate technique for using monitors. However, not all checklist items apply to all blood glucose monitors.

Checklist for Observing Technical Skills

1. Patients report that they have checked the monitor with the electronic function strip daily.
2. The code on monitor matches the code on the glucose test strip vial.
3. Glucose test strips are stored in their original containers.
4. Test strips are used before the expiration date (they are good for only 90 days after opening;¹¹ containers should be marked).
5. Patients prick the lateral side of their finger with the puncture device.
6. Patients wipe off first drop of blood, then test the hanging drop.
7. Patients correctly apply blood to cover all of the test strip.
8. Patients insert the strip at the appropriate time.
9. Patients clean the monitor weekly or as needed.
10. Patients record blood glucose values properly.
11. Patients use the control solution.
12. The control solution has not passed its expiration date.
13. The control solution and control values are within 10% of the expected range.

In the Alto study, 108 patients provided a blood glucose value for accuracy testing. Patients conducted SMBG with their personal blood glucose meter while simultaneously using the same blood

sample to measure blood glucose on a OneTouch™ II hospital blood glucose monitoring system. The system was calibrated twice daily.²

Approximately 53% of study participants achieved the ADA's goal of less than 10% variance in blood glucose, compared with control monitor values. An additional 31.5% of SMBG values varied by 10% to 20% from control monitor values. SMBG values that varied by more than 20% were observed in 16% of participants.

Similarly, the DCCT established a goal of less than 180 mg/dl for random blood glucose testing. Only 46% of random blood glucose values in this study were below the DCCT goal. In addition, 82.4% of the participants' monitors reported blood glucose results that were below the values found with the control monitor.²

Error Grid Analysis

Associations between accuracy of SMBG and age, sex, diagnosis, frequency of testing, insulin use, and previous checks of glucose meter accuracy were not statistically significant.² Within this population, approximately 83.5% of SMBG values fell within zone A on the error grid analysis. Zone B, representing inaccuracies that can lead to inappropriate treatment changes, contained 14.7% of glucose values. No SMBG values fell into zone C. Fewer than 1.8% of the values fell into zone D, and these were considerably less than control values, resulting in unrecognized hyperglycemia. No values were found in zone E.²

Zone	Definition
A	Less than 20% difference between patient's and reference blood glucose determinations; no effect on clinical action.
B	SMBG values vary 20% or more from the reference blood glucose reading; may lead to change in clinical action with little or no effect on outcome.
C	Potential change in therapy opposite to what is necessary for blood glucose level (i.e., insulin dose was increased when it should have been decreased).
D	Failure to detect and treat.
E	False glucose readings; changes in therapy lead to hypoglycemia or hyperglycemia.

TABLE 5 Correlation between Glycosylated Hemoglobin (HbA_{1c}) and Mean Plasma Glucose Levels in Multiple Testing over Two to Three Months

HbA _{1c} (%)	Mean Plasma Glucose	
	mg/dl	mmol/L
6	135	7.5
7	170	9.5
8	205	11.5
9	240	13.5
10	275	15.5
11	310	17.5
12	345	19.5

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The performance of critical quality control tests was found to be poor. Only 27.9% of glucose meters had been checked for accuracy by patients. Few patients reported checking their monitors with the electronic function strip daily. Several patients had been using expired control solutions. Most patients used improper techniques when collecting blood samples, and 20% of patients neglected to completely cover the test strip with blood. Patients not using proper techniques were educated on the correct use.²

Alto et al. concluded that only about 50% of patients were performing SMBG appropriately and were obtaining reliable blood glucose levels within 10% of the reference values recommended by the ADA. Patients in this study were found to be taking shortcuts to minimize the amount of time necessary for performing SMBG. Opportunities were missed to verify meter accuracy, because test strips are expensive and patients wanted to save money and time.²

A limitation of this study was the small population size, which might not be representative of the larger population of patients with diabetes. There might have been selection bias, because the subjects volunteered to participate and therefore might have been more motivated to perform SMBG. They might have also practiced at home before being evaluated in the office.

Thus, although the findings may have overestimated the accuracy of SMBG, the study did

TABLE 6 Alternative Testing Sites for Monitoring Blood Glucose

Monitor	Base of Thumb/Palm	Forearm	Upper Arm	Abdomen	Thigh	Calf
Ascensia® BREEZE®	•	•	•	•	•	
Ascensia® CONTOUR®	•	•	•	•	•	
Ascensia® DEX® 2	•	•	•	•	•	
Ascensia ELITE®	•	•	•	•	•	
Ascensia ELITE® XL	•	•	•	•	•	
Accu-Chek® Active	•	•	•		•	•
Accu-Chek® Aviva	•	•	•		•	•
Accu-Chek® Compact	•	•	•		•	•
FreeStyle Flash™	•	•	•		•	•
OneTouch™ InDuo		•				
OneTouch™ Ultra		•				
TrueTrack Smart System™		•				

Data from references 16–19, 21, and 25–27.

demonstrate the clinical importance of accuracy in performing SMBG and does encourage other medical practitioners to evaluate their patients’ techniques and performance.

Accuracy of Monitors

The features of blood glucose monitors influence the accuracy and safety of SMBG. The features described next may influence compliance with SMBG.

Automatic Coding

As suggested by the Alto study, coding is an important component of SMBG accuracy.² Coding involves calibrating a blood glucose monitor to the same calibration code on the bottle of test strips being used to test blood glucose. Each monitor and each vial of test strips has a unique code. Several methods of coding exist, including buttons on monitors, chips provided with each box of test strips, bar codes on test drums, and coding strips within boxes of test strips.¹¹ To save time and cost associated with test strips, patients often forgo the coding process.² If the codes on the monitor do not correspond to those on the bottle, inaccurate blood glucose levels may be reported.

Coding errors result in a rate of inaccuracy approaching 43%.¹⁵ Inaccurate blood glucose meas-

urements, when too high or too low, may result in therapy adjustments that, in turn, may cause hypoglycemia or other complications.

Eliminating coding affords less risk of error and saves time.¹¹ Saving time for patients in all likelihood will increase compliance with SMBG. Better compliance will ensure proper management of diabetes and, again, will prevent further costly complications. Preventing short-term and long-term complications of diabetes through better disease management saves health care costs and patient dollars.^{9,10}

As of this writing, the Ascensia® BREEZE®, the Ascensia® CONTOUR®, the Ascensia® DEX®, and the Accu-Chek® Compact are the only monitors that do not require coding.^{16–19}

Underfill Detection

The Alto study reported that 20% of patients did not properly cover test strips with blood.² Not having enough blood on a test strip can result in false-low readings.²⁰ Blood glucose monitors that have underfill detection features alert patients before testing that more blood is needed for an accurate measurement. This feature not only enhances accuracy but also decreases waste, thus reducing expense to patients. Both the Accu-Chek® and the

Ascensia® product lines offer underfill detection features.^{16–19,21}

Temperature Control

Even minor variations in temperature can skew blood glucose test results. Both the Ascensia® CONTOUR® and Accu-Chek® Aviva have automatic temperature controls to ensure accurate test results.^{16,22}

Dialysis

Blood glucose monitors use various methods to measure blood glucose. Patients using certain peritoneal dialysis solutions may obtain false-high blood glucose levels if the glucose dehydrogenase pyrroloquinoline quinone method is used. The Ascensia ELITE® and the Ascensia® BREEZE® monitors use the glucose oxidase method and may be appropriate for these patients.^{17,21,23}

Averages

When blood glucose monitors calculate the averages of blood glucose results, control tests may or may not be included in the average reported. It is important to verify the ability of a monitor to mark a control test as such. With most monitors, patients must manually mark “control test” by pushing a button before or after the blood test. The One-Touch™ Basic monitor has an automatic marking feature.¹¹

The Ascensia® CONTOUR® monitor has an automatic marking feature that excludes control tests from testing averages.¹⁶ Ascensia ELITE® XL monitors use an electrochemical marking feature to identify control tests; this eliminates the manual step of marking control tests.¹¹

Ease-of-Use Features

The ease of using blood glucose monitors is also important. The following features may affect patient compliance.

Disc Systems

A number of errors in technique are associated with patients' use of test strips,²⁰ such as:

- using expired test strips.
- inserting the strip incorrectly.
- storing and handling the strip inappropriately.
- incorrectly calibrating the meters to the test strip lot code.

Disc systems eliminate the need to handle individual, small strips. If patients do have difficulty handling small strips, they may be inserting the strips into the meters improperly, thus causing false-low readings.²⁰ The Ascensia® BREEZE® offers an AUTODISK® system, and the Accu-Chek® Compact offers a 17-test drum system.^{17,19}

Time to Test (Table 7)^{11,16–19,21,22,24–29}

In comparisons of blood glucose monitors, the time to test is always noted. Although it appears that the shortest time to test is best, it is important to consider that the time to test is generally measured from the time the blood is placed on a strip and the glucose measurement is reported. Some monitors seem to provide a much smaller time to test than others, but additional steps in the SMBG process have probably not been included in this time calculation. For example, not having to calibrate a meter or not having to load test strips for each test significantly decreases the overall time to test.

Alternative Site Testing (Table 6)^{16–19,21,25–27}

Many blood glucose monitors allow patients to accurately test blood from alternative sites, such as the base of the thumb, the upper arm, the forearm, the abdomen, and the thigh. Sampling blood from alternative sites is especially beneficial for patients with neuropathy, those with high sensitivity to finger testing, and patients whose occupations require the frequent use of fingertips. However, changes in blood glucose levels are more readily observed in blood from the fingertips than from other parts of the body.

Thus, blood glucose test results from other sites may vary from findings reported from fingertip testing. This inaccuracy is not a product of the blood glucose meter but, rather, the result of different levels of blood glucose at different body sites.^{11,14} This delay in determining glucose levels in arm samples, when compared with finger samples, is known as the *lag time phenomenon*.¹¹

Alternative sites should be used with caution in patients whose glucose levels are not at a steady state.^{11,14}

Table 6 presents a comparison of blood glucose monitors offering alternative site testing.

Sample Size (Table 7)^{11,16–19,21,22,24–29}

Small sample size is advantageous for patients who have difficulty obtaining blood samples. Not

having to struggle to obtain a large sample size decreases the time to test. Most commercially available monitors allow small sample sizes.^{11,24}

Ergonomic Design

Ergonomic design is a feature of some blood glucose monitors. An optimal design aids in alleviating pain for patients with arthritis or other musculoskeletal concerns. The Accu-Chek® Aviva, the Accu-Chek® Advantage, the Ascensia® DEX®, the Ascensia® CONTOUR®, the Ascensia ELITE®, and the OneTouch™ Ultra monitors are small and easy to grip, and they fit into the palm of the hand or rest on a tabletop.

Several of these monitors have large, easy-to-read displays, which are beneficial for visually impaired patients.^{11,16,18,19,21,22,25}

Memory and Data-Management Software (Tables 7 and 8)^{11,16–19,21,22,24–29,32–38}

Some monitors, such as the OneTouch™ UltraSmart, have large memory capabilities and can hold up to 3,000 readings. The readings are stored in an electronic log book.^{30,36} Other monitors have smaller memories in terms of the quantity of readings that can be stored on the monitor, but data-management systems that store all recorded data are available. These systems provide a means of helping health care providers stay abreast of their patients' blood glucose levels so that they can intervene in a timely manner as necessary.^{11,24} Data-management software programs should be included in a blood glucose monitor review to provide full evaluations of the ease of use, memory, and clinical applications for overall disease-management accuracy.

Comparisons of memory capability are shown in Table 7. Table 8 includes a comparison of data-management software programs and their associated costs.

In August 2005, *Consumer Reports* magazine conducted a Quick Ratings evaluation of 13 blood glucose monitors.³⁰ The final recommendations were the OneTouch™ UltraSmart and the OneTouch™ Ultra because of their fast results, small sample size, and the Ultra's compact design. However, shortly after the article was published, *Consumer Reports* reported a product recall because of problems with these two top-rated monitors.³¹ The problem involved changes in the unit of measure. After 40 reports of inaccurate readings, some resulting in the need for medical attention, it was

found that patients could inadvertently change the unit of measure when they were setting the date and time. The unit of measure and the test strip code number may also change if the patient drops the blood glucose meter.

In addition, the UltraSmart meter instructions provided inaccurate information about the appearance of a low-blood-glucose warning message by stating that the message appears at a higher threshold than it actually does. The instructions were also faulty in discussing the use of the upper arm as a potential alternative testing site.

LifeScan, the manufacturer of the OneTouch™ monitors, has stopped making all of the meters identified with such flaws. New OneTouch™ Ultra monitors are being provided to patients who previously used any of the OneTouch™ meters.³¹

It is worth mentioning that the *Consumer Reports* article did not specify many of the parameters evaluated when determining the ratings for accuracy, consistency, and ease of use; these features seem to be self-explanatory. However, many features of blood glucose monitors affect the outcomes of SMBG. For example, user errors are the primary cause of inaccurate blood glucose results.¹¹

Coding, plasma equivalent calculations, alternative testing sites, the time to test, sample size, and memory are all features that influence overall blood glucose monitor evaluations. All of these features have been discussed earlier.

Although the *Consumer Reports* evaluators found the OneTouch™ products to be superior to other blood glucose monitors, their cost may be prohibitive. HMOs are trying to manage overall spending for drugs while providing quality health care to their members. Patients who do not have health insurance are paying out of pocket for monitors and test strips. Before making a coverage or purchase decision based on the information contained in the magazine article, readers should obtain additional information to determine the significance of the *Consumer Reports* recommendations and should also consider the aforementioned additional features.

COST CONSIDERATIONS (Table 9)^{11,29,32–41}

The expense associated with home testing of blood glucose has been shown to decrease compliance with self-monitoring.² A study conducted by Nyomba and colleagues compared the frequency of SMBG by patients who were given test strips and

SELF-MONITORING OF BLOOD GLUCOSE

TABLE 7 Comparison of Blood Glucose Monitors

Monitor	Brand/ Manufacturer	Calibration Method	Test Strips	Control Solution	Sample Size (µL)	Time to Test (Seconds)
Ascensia® BREEZE®	Bayer HealthCare, Diabetes Care Division	Automatic	Ascensia® AUTODISC®: 10 strips in one disc	Low-high Normal	3.0	30
Ascensia® CONTOUR®	Bayer HealthCare, Diabetes Care Division	Automatic	Ascensia® MICROFILL® strips	Low-high Normal	0.6	15
Ascensia® DEX® 2	Bayer HealthCare, Diabetes Care Division	Automatic	Ascensia® AUTODISC®	Low-high Normal	3.0	30
Ascensia ELITE®	Bayer HealthCare, Diabetes Care Division	Strip calibration	Ascensia ELITE® strips	Low-high Normal	2.0	30
Ascensia ELITE® XL	Bayer HealthCare, Diabetes Care Division	Strip calibration	Ascensia ELITE® strips	Low-high Normal	2.0	30
Accu-Chek® Active	Roche Diagnostics	Snap-in code key	Accu-Chek® Active Strip	Yes	1.0	5
Accu-Chek® Advantage	Roche Diagnostics	Snap-in code key	Accu-Chek® Comfort Curve or Accu-Chek® Advantage	Yes	4.0 9.0	26
Accu-Chek® Aviva	Roche Diagnostics	Snap-in code chip	Accu-Chek® Aviva	Yes	0.6	5
Accu-Chek® Compact	Roche Diagnostics	Automatic	Accu-Chek® Compact	Yes	1.5	8
Accu-Chek® Complete	Roche Diagnostics	Snap-in code key	Accu-Chek® Comfort Curve or Accu-Chek® Advantage	Yes	4.0 9.0	26
Accu-Chek® Voicemate	Roche Diagnostics	Snap-in code key	Accu-Chek® Comfort Curve	Yes	4.0	26
Advance Intuition	Hypoguard	Code chip	Advance Intuition	Yes	3.0	10
Advance Micro-draw	Hypoguard	Code chip	Advance Micro-draw	Yes	1.5	15
Assure	Hypoguard	Code chip	Assure	Yes	10.0	35
Assure II	Hypoguard	Code chip	Assure II	Yes	3.0	30
Assure 3	Hypoguard	Code chip	Assure 3	Yes	3.0	10
BD Logic Blood Glucose Monitor*	BD	Built-in button	BD	Yes	0.3	5
FreeStyle®	Abbott Diabetes Care	Built-in button	FreeStyle™	Yes	0.3	7
FreeStyle Flash™	Abbott Diabetes Care	Built-in button	FreeStyle™	Yes	0.3	7
OneTouch™ Basic	LifeScan	Built-in single button	OneTouch™	Yes	10	45
OneTouch™ InDuo	LifeScan	Built-in single button	OneTouch™ Ultra	Yes	1.0	5
OneTouch™ SureStep	LifeScan	Built-in single button	SureStep	Yes	5.0	15–30
OneTouch™ Ultra	LifeScan	Built-in single button	OneTouch™ Ultra	Yes	1.0	5
OneTouch™ UltraSmart†	LifeScan	Built-in single button	OneTouch™ Ultra	Yes	1.0	5
Prestige IQ™	Home Diagnostics, Inc.	Standard strip	Prestige Smart System	Yes	7–10	10–50
Precision QID®	Abbott/Medisense	Calibrator in each box of test strips	Precision QID®	Low/normal/ high	3.5	20
Precision Xtra™	Abbott/Medisense	Calibrator in each box of test strips	Precision Xtra™	Low/normal/ high	1.5	10
QuickTek	Hypoguard	Built-in button	QuickTek	Yes	3.5	10–30
ReliOn® NewTek	Hypoguard/Wal-Mart Pharmacies	Built-in button	Built in	Yes	3.0	15
ReliOn® Ultima	Wal-Mart Pharmacies	Calibrator on each box of strips	ReliOn Ultima	No (available via toll-free number)	2.5	20
TrackEase™ Smart System	Home Diagnostics, Inc.	Code chip	Touchable Test Strip	Low/normal/ high	1.0	10
TrueTrack Smart System™	Home Diagnostics, Inc.	Code chip	TrueTrack Smart System™	Yes	1.0	10

Data from references 11, 16–19, 21, 22, and 24–29. * Stores up to 2,500 tests in electronic log book. † Stores up to 3,000 tests in electronic log book.

TABLE 7 Comparison of Blood Glucose Monitors (continued)

Monitor	Alternate Site Testing (AST) (Y/N)	Range of Measurement (mg/dl)	Memory (Test Count)	Size of Meter (Inches)	Warranty (Years)	Battery Type
Ascensia® BREEZE®	Y	10–600	100	2.5 x 4.1 x 1.0	5 years	1 x 3-volt lithium
Ascensia® CONTOUR®	Y	10–600	240	2.9 x 2.09 x 0.68	5 years	2 x 3-volt lithium
Ascensia® DEX® 2	Y	10–600	100	2.5 x 3.2 x 0.75	5 years	2 x 3-volt lithium
Ascensia ELITE®	Y	20–600	20	3.2 x 2.0 x 0.6	5 years	2 x 3-volt lithium
Ascensia ELITE® XL	Y	20–600	120	3.9 x 2.2 x 0.6	5 years	2 x 3-volt lithium
Accu-Chek® Active	Y	10–600	200	4.6 x 1.07 x 0.9	3 years	2 x CR2023 or lithium equivalent
Accu-Chek® Advantage	N	10–600	100	3.3 x 2.8 x 0.8	3 years	1 x 3-volt coin cell #2032
Accu-Chek® Aviva	Y	10–600	500	3.7 x 2.0 x 0.9	3 years	1 x 3-volt lithium (CR2032)
Accu-Chek® Compact	Y	10–600	100	4.0 x 2.0 x 1.2	3 years	2 x AAA
Accu-Chek® Complete	N	10–600	1000	4.8 x 2.8 x 1.1	3 years	2 x AAA
Accu-Chek® Voicemate	N	10–600	100	6.5 x 3.0 x 2.4	3 years	9-volt (voice synthesizer); 3-volt coin cell #2450
Advance Intuition	N	30–550	10	3.9 x 2.3 x 0.8	5 years	3 volt (CR2032)
Advance Micro-draw	N	20–600	250	3.0 x 2.5 x 0.5	5 years	3 volt (CR2032)
Assure	N	30–550	180	4.4 x 2.4 x 0.4	5 years	1 x J-cell (home change)
Assure II	N	30–550	10	3.9 x 2.3 x 0.8	5 years	1 x 3-volt (CR2032)
Assure 3	N	30–550	10	3.9 x 2.3 x 0.8	5 years	1 x 3-volt (CR2032)
BD Logic Blood Glucose Monitor*	N	20–600	250	3.6 x 2.3 x 0.9	3 years	1 x 3-volt coin cell # 2450
FreeStyle®	N	20–500	250	3.8 x 1.6 x 0.8	5 years	2 x 2032, 3-volt lithium coin cell
FreeStyleFlash™	Y	20–500	250	3.0 x 1.6 x 0.8	5 years	2 x 2032, 3-volt lithium coin cell
OneTouch™ Basic	N	0–600	75	4.3 x 2.6 x 1.2	3 years	2 x AAA alkaline (home change)
OneTouch™ InDuo	Y	20–600	150	4.8 x 2.1 x 1.4	3 years	1 x 3-volt lithium
OneTouch™ SureStep	N	0–500	150	3.5 x 2.4 x 0.8	3 years	2 x AAA (home change)
OneTouch™ Ultra	Y	20–600	150	3.1 x 2.2 x 0.8	3 years	1 x 3-volt lithium (#2032)
OneTouch™ UltraSmart†	N	20–600	3,000†	3.8 x 2.3 x 0.9	3 years	2 x AAA (home change)
Prestige IQ™	N	25–600	365	4.0 x 2.75 x 0.75	5 years	AAA
Precision QID®	N	20–600	10/125 downloadable	3.82 x 1.89	Lifetime	3-volt non-replaceable
Precision Xtra™	N	20–500	450	2.94 x 2.1 x 0.64	Lifetime	2 x AAA home change 1 x CR 2032 lithium
QuickTek	N	20–600	250	3.9 x 2.0 x 0.75	5 years	3-volt (CR3032)
ReliOn® NewTek	N	20–600	100	4.7 x 2.4 x 1.0	Through expiration date	Built in
ReliOn® Ultima	N	20–500	450	4.25 x 2.5 x 0.94	1 year	
TrackEase™ Smart System	N	20–600	200	3.52 x 2.15 x 0.67	5 years	CR 2032
TrueTrack Smart System™	Y	20–600	365	3.5 x 2.1 x 0.77	5 years	CR 2032 or 3-volt lithium

Data from references 11, 16–19, 21, 22, and 24–29. * Stores up to 2,500 tests in electronic log book. † Stores up to 3,000 tests in electronic log book.

TABLE 8 Comparison of Data Management Software for Blood Glucose Monitors

Monitor	Data Management Software	PC Download	Cost*	Comment
Bayer HealthCare, Diabetes Care Div. Ascensia® Products BREEZE® CONTOUR® DEX® 2 ELITE® XL	WinGlucofacts®	PC-based. Download data into software on PC.	Free; \$29.95 charge for connecting cable	Produce average calculations; data reported in easy-to-read tables and graphs. E-mail or faxes data directly to health care provider.
Abbott Laboratories FreeStyle® FreeStyle Flash™	FreeStyle™ CoPilot	PC-based. Download data into software on PC.	Free software download; \$19.99 charge for connecting cable	Print reports or e-mail reports to health care provider. Patient and health care provider can view on-line data, automatic statistical analysis, results in customized tables and graphs.
Precision Xtra	Precision Link Direct	PC-based.	\$7.99 for software; \$24.95 charge for connecting cable	E-mail, fax, or print reports for the health care provider's review.
BD BD Logic Blood Glucose Monitor	InterActiv	PC-based. Download data into software on PC.	\$9.99 for software; \$29.99 charge for connecting cable; \$39.99 special offer for both	Create customized charts and graphs, color-coded target reports. Print to share with health care provider.
Home Diagnostics Prestige TrueTrack	MediCompass	Download via cable or manual entry. Internet tracking tool.	\$4.95 per month; free connecting cable	Print reports to take to health care provider visit. Graphs and reports highlight important trends and patterns.
Hypoguard, Inc. Advance Micro-draw QuickTek Assure	Glucobalance	PC-based. Download data into software on PC.	\$44.95 for software and cable	Print reports to take to health care provider visit. Easy-to-use charts, graphs, and trend reports.
LifeScan InDuo OneTouch™ Basic, Ultra, UltraSmart, SureStep	OneTouch™ Diabetes Management Software	PC-based. Download data into software on PC.	Free; \$29.99 charge for connecting cable	E-mail, fax, or print reports for health care provider's review. Easy-to-use charts, graphs, and trend reports.
Roche Diagnostics Accu-Chek® Active, Compact, Complete, Advantage, Aviva	Accu-Chek® Compass Software Accu-Chek® Pocket Com- pass Software	PC-based. Download data into software on PC. PDA-based; not for use with PC.	\$30.00 for software; \$30.00 charge for connecting cable. \$30.00 for software; connects to PDA data synchronizer.	E-mail, fax, or print reports for health care provider's review. If health care provider has a \$50 connecting cord for all Accu-Chek® monitors, he or she can download data in the office directly to the PC.

* 2005 costs. Costs do not include shipping and handling.
PC = personal computer; PDA = personal digital assistant.
Data from references 11, 29, and 32-38.

by those who had to pay for test strips themselves. The sample size of this study was small, but it was noted that supplying free test strips increased compliance with SMBG. Better compliance enhanced diabetes self-management and improved HbA_{1C} and average blood glucose levels.⁴⁰

Soumerai and associates also assessed whether providing free blood glucose monitors increased SMBG and whether initiating SMBG was associated with increased medication compliance and improved glucose control.⁴¹ They measured rates of SMBG in a cohort of 3,219 adults with diabetes who were continuously enrolled in the Harvard Pilgrim Health Care plan. Measurements were taken at 19 months before a change in coverage policy occurred, during the change in policy, and after the policy change. Using computerized pharmacy records, the investigators compared changes in compliance in the use of oral sulfonylureas for patients who initiated SMBG and patients who did not initiate SMBG. They also compared changes in trends of glucose control in patients who did and did not initiate SMBG.⁴¹

Approximately 70% of insulin-treated patients had received test strips before the new coverage policy was initiated. The results revealed minimal changes in test strip dispensing after the change in coverage policy. SMBG increased dramatically, however, in patients receiving oral sulfonylurea treatment. In the 20 months prior to the change in insurance coverage, test strips had been dispensed to 27% of the patients. The availability of free monitors resulted in a 10% increase in patients receiving test strips. This figure increased to 60% by the end of the follow-up period. Six months after the policy change and after controlling for an increasing baseline trend, the predicted absolute increase in the number of oral sulfonylurea-treated patients who initiated SMBG was 14 per 1,000 per month, a relative increase of 98.7%.⁴¹

The overall quantity of test strips used was measured to determine the intensity of SMBG. An increase of 3.5 strips per person per month was noted in the insulin-treated group immediately after the policy change. Only a small additional increase was reported during the post-policy period. In the oral sulfonyl-urea-treated patients, a clinically and statistically significant effect on the intensity of test strip use was reported. During the baseline period, and prior to the policy change, the number of test strips used increased from 2.0 per patient per month

to 3.9. After the change in coverage, test strip use increased markedly, from four strips per patient per month to more than 10 by the end of follow-up.

At six months after the policy change, test strip use increased over the pre-policy expected levels by 17.9 strips per cohort member, a relative increase of 75.3% in oral sulfonylurea-treated patients. The change in the number of test strips used was specific only to the oral sulfonylurea patients who were newly initiating monitoring. No clinically or statistically significant changes in test strip use were noted among patients who were already performing SMBG before the free glucose monitors were provided.⁴¹

Initiators of SMBG had immediate reductions in mean gaps between refills compared with non-initiators. This effect, however, abated during the 12-month follow-up period.⁴¹

After controlling for baseline and comparison group trends, initiators who had poor glycemic control were able to lower their mean HbA_{1C} levels by 0.63%. Patients initiating SMBG who had adequate or good glycemic control did not show improved HbA_{1C} levels.⁴¹

Soumerai et al. concluded that a program providing free blood glucose monitors along with patient education had significant effects on self-care behavior in oral sulfonylurea-treated patients. In new trials of SMBG and frequency of test strip use per patient, significant improvements in regularity of diabetes medication use and glucose control were noted compared to patients who did not initiate SMBG. In previous studies, similar decreases in HbA_{1C} levels were associated with a reduced risk of diabetic complications in type-2 DM.⁵ Previous studies concur with the relationship between SMBG and compliance with medication use.⁴¹

This study indicates that patients may be able to achieve improved rates of SMBG, improved regularity of medication use, and better glucose control through the provision of free home glucose monitors. Cost, in addition to accuracy, safety, and ease of use, can be added to the list of key features of home blood glucose monitors.

Table 9 provides a comparison of the costs associated with various blood glucose monitors.

CONCLUSION

Diabetes affects the lives of millions of people, directly and indirectly each year. It is a disease that results in exorbitant expenditures and leaves

SELF-MONITORING OF BLOOD GLUCOSE

TABLE 9 Cost Comparisons of Blood Glucose Monitors

Monitor/Kit	AWP	Strip/Disc Package Size	AWP	Control Solution	AWP
Ascensia® BREEZE	\$58.75	Ascensia® AUTODISC® 50/100	\$47.00/\$85.00	Low-high 2.5 ml/NL 2.5 ml	\$6.30/\$11.90
Ascensia® CONTOUR®	\$75.00	50/100	\$47.50/\$87.50	Low-high 2.5 ml/NL 2.5 ml	\$6.30/\$11.90
Ascensia® DEX® 2	\$71.90	Ascensia® AUTODISC® 50 (5 x 10)/100 (10 x 10)	\$47.00/\$85.00	Low-high 2.5 ml/NL 2.5 ml	\$6.30/\$11.90
Ascensia ELITE®	\$43.75	25/50/100	\$25.00/\$46.20/\$83.20	Low-high 2.5 ml/NL 2.5 ml	\$6.30/\$11.90
Ascensia ELITE® XL	\$56.25	25/50/100	\$25.00/\$48.20/\$83.20	Low-high 2.5 ml/NL 2.5 ml	\$6.30/\$11.90
Accu-Chek® Active	\$18.75	50	\$29.69	Low-high	\$8.44
Accu-Chek® Advantage	\$68.75	50/100	\$47.19/\$89.69	Level 1 and 2	\$8.44
Accu-Chek® Aviva		50		Level 1 and 2	
Accu-Chek® Compact	\$75.00	Strip drums; 51 (one drum); 102 (two drums)	\$48.44/\$92.19	Low-high	\$8.44
Accu-Chek® Complete	\$118.75	50/100	\$47.19/\$89.69	Low-high/low-high-mid	\$8.44/\$9.38
Accu-Chek® Voicemate	\$493.75	50/100	\$47.19/\$89.69	Low-high/low-high-mid	\$8.44/\$9.38
Advance Intuition	\$68.00	50	\$38.50	Normal	\$10.00
Advance Micro-draw	\$68.00	50/100	\$38.50/\$69.30	Level 1 and 2	\$10.00
Assure	\$30.00*	50/100	\$39.30/\$56.00	Level 1 and 2	\$11.00
Assure II	\$85.00	50/100	\$29.25/\$53.00	Level 1/level 1 and 2	\$6.30/\$10.00
Assure 3	\$68.00	50/100	\$38.50/\$69.30	Level 1 and 2	\$10.00
BD Logic Blood Glucose Monitor	\$73.75	Strips 50/100	\$45.50/\$87.86	Patient must contact BD for delivery.	Free
FreeStyle®	\$75.00 \$83.10	50	\$46.56	High-low/normal	\$7.82/\$6.69
FreeStyle Flash™	\$73.75	50	\$46.56	High-low/normal	\$7.82/\$6.69
OneTouch™ Basic	\$50.00	25/50/100	\$25.31/\$48.12/\$89.38	High-low/normal	\$7.38/\$7.38
OneTouch™ InDuo	\$98.75	25/50/100	\$26.25/\$49.38 / \$92.50	Normal	\$7.38
OneTouch™ SureStep	\$62.50	50/100	\$48.12/\$89.38	High-low/normal	\$9.38/\$9.38
OneTouch™ Ultra	\$68.75	25/50/100	\$26.25/\$49.38/\$92.50	Normal	\$7.38
OneTouch™ UltraSmart	\$92.81	25/50/100	\$26.25/\$49.38/\$92.50	Normal	\$7.38
Prestige IQ™	\$70.68	50/100	\$28.60/\$45.99	High control/low control	\$4.75/\$4.75
Precision QID®	\$47.94	50/100	\$45.13/\$83.08	Normal/mid low/high/normal	\$8.28/\$10.50
Precision Xtra	\$71.94	50/100	\$44.47/\$83.21	Normal/mid low/high/normal	\$8.28/\$10.50
QuickTek	\$19.95	50/100	\$38.50/\$69.30	Normal	\$10.00
ReliOn® NewTek	\$55.90	50/100	\$26.12/\$52.24	Patient must contact for delivery.	Free
ReliOn® Ultima	\$26.40	50/100	\$31.20/\$62.40	NA	NA
TrackEase™ Smart System	\$21.40	50/100	\$26.75/\$52.00	High/low	\$6.90/\$6.90
TrueTrack Smart System™	\$23.70	50/100	\$30.50/\$53.50	High/low	\$6.90/\$6.90

AWP = average wholesale price.
 * Standard list price. This monitor will not be manufactured after January 2006.
 Data from *Red Book*®, 109th ed. Montvale, NJ: Thomson; 2005.³⁹

patients and health care providers challenged with complications that are difficult to manage. Such complications result in a decrease in quality of life for diabetic patients and their families, loss of work-days, and more than twice the number of bed days compared with patients without diabetes. Overall, DM is difficult to manage without intensive therapy and management strategies.

The ultimate goal in managing patients with diabetes is to achieve glycemic control. To accomplish this, it is essential that diabetes therapy and management become better understood and more efficient.

Diabetes is a chronic illness that requires intensive, ongoing medical care. The treatment and management of diabetes result in glycemic control and attaining glycemic goals. When glycemic goals are met, the risks of short-term and long-term complications are reduced, and overall quality of life is improved.^{4,5}

Improved management of diabetes can be accomplished through an active partnership between health care providers and patients. The key to achieving glycemic control is monitoring.

Health care providers should take an assertive approach to enforcing patient self-management education with special attention to the importance of SMBG. They should make sure that their patients have appropriate, safe, accurate, and the most cost-effective tools to perform SMBG. They should also take an active role in teaching patients with diabetes the proper technique to ensure accurate results of SMBG.

Patients with diabetes also must take responsibility for actively managing the disease. With new technologies and the advent of smaller, more accurate blood glucose monitors requiring smaller blood samples and providing results in seconds, patients have no excuse for noncompliance with SMBG.

Health plans should facilitate patient compliance by ensuring the availability of blood glucose monitors with the best safety and accuracy profiles. All disease-management programs for diabetes should include SMBG as a significant component of diabetes self-management. Providing insurance coverage for safe, accurate, and cost-effective blood glucose monitors, in addition to encouraging SMBG, decreases overall health care expenses, improves patient care, and helps guarantee member satisfaction with their health plans.

REFERENCES

1. American Diabetes Association. National Diabetes Fact Sheet, 2002. Available at: www.diabetes.org/diabetes-statistics/national-diabetes-fact-sheet.jsp.
2. Alto WA, Meyer D, Schneid J, et al. Assuring the accuracy of home glucose monitoring. *J Am Board Fam Pract* 2002;15:1-6.
3. American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care* 2005;28:S4-S36.
4. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993;329:977-986.
5. United Kingdom Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. (UKPDS33). *Lancet* 1998;352:837-853.
6. Oki JC, Isley WL. Diabetes mellitus. In: DiPiro JT, Talbert RL, Yee GC, et al., eds. *Pharmacotherapy: A Pathophysiological Approach*, 5th ed. New York: McGraw-Hill, 2002:1335-1358.
7. National Center for Chronic Disease Prevention and Health Promotion. Diabetes Public Health Resource Data and Trends, 2003. Available at: www.cdc.gov/diabetes/statistics/prev/national/index.html.
8. Arshag D, Mooradian AD, eds. *Internist's Handbook of Endocrinology, Diabetes, and Metabolism*. St. Louis, MO: St. Louis University; 1998:1-22.
9. American Diabetes Association. Economic costs of diabetes in the U.S. in 2002. *Diabetes Care* 2003;26:917-932.
10. Zhang P, Engelgau MM, Norris SL, et al. Application of economic analysis to diabetes and diabetes care. *Ann Intern Med* 2004;140:S972-S977.
11. Briggs AL, Cornell S. Self-monitoring blood glucose (SMBG): Now and the future. *J Pharmacy Practice* 2004;17:1:29-38.
12. Roseman HM, Blonde L, Brixner D, Cannon HE. Emerging perspectives on type 2 diabetes. *J Manag Care Pharm* 2005;11:S3-S28.
13. Abrahamson MJ. Optimal glycemic control in type 2 diabetes mellitus. *Arch Intern Med* 2004;164:486-491.
14. U.S. Food and Drug Administration (FDA). Diabetes information: Glucose meters and diabetes management, 2005. Available at: www.fda.gov/diabetes/glucose.html.
15. Diabetes directory. Why bother to calibrate? Available at: www.mendosa.com/coding.htm. Accessed June 19, 2005.
16. Ascensia® CONTOUR® Blood Glucose Monitoring System, fact sheet. Tarrytown, NY: Bayer HealthCare, Diabetes Care; 2004.
17. Ascensia® BREEZE® Blood Glucose Monitoring System, fact sheet. Tarrytown, NY: Bayer HealthCare, Diabetes Care; 2004.
18. Ascensia® DEX® 2 Blood Glucose Monitoring System, fact sheet. Tarrytown, NY: Bayer HealthCare, Diabetes Care; 2004.
19. Roche Diagnostics. Accu-Chek® product information. Available at: www.accu-chek.com/us/rewrite/content/en_US/2.1:10/article/ACCM_general_article_2353.htm. Accessed June 2005.
20. FDA. Office of In Vitro Device Evaluation and Safety, 2005. Available at: www.fda.gov/cdrh/oivd/homeuse-glucose.html.

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21. Ascensia ELITE® and ELITE® XL Blood Glucose Monitoring Systems, fact sheet. Tarrytown, NY: Bayer HealthCare Diabetes Care; 2004.
22. Accu-Chek® Aviva, product information. Roche Diagnostics. Available at: www.accu-chek.com/us/rewrite/content/en_US/2.1.6:5/article/ACCM_general_article_2838.htm. Accessed September 2005.
23. OneTouch™ product information on methods utilized by manufacturers in current blood glucose monitors. Customer correspondence Web specialist via e-mail. Milpitas, CA: LifeScan; October 6, 2005.
24. Diabetes forecast. Blood glucose meters and data management systems. *Diabetes Forecast* January 2005: RG36–RG54.
25. OneTouch™ product information. LifeScan. Available at: www.lifescan.com/products/meters. Accessed June 2005.
26. Prestige IQ™, TrackEase™, and TrueTrack Smart System™, product information. Home Diagnostics, Inc. Available at: www.homediagnosticsinc.com/products-1.asp. Accessed June 2005.
27. FreeStyle® and FreeStyle Flash™. Abbott Laboratories. Accessed June 2005. Available at: www.diabeteshealthconnection.com/products/monitors/freestyle/ and Precision QID® and Precision Xtra™ Available at: www.diabeteshealthconnection.com/products/monitors/precision/index.aspx. Accessed June 2005.
28. Assure, Advance, and ReliOn®, product information. Hypoguard. Available at: www.hypoguard.com/blood_glucose_monitoring_systems_pat.html. Accessed June 2005.
29. New meter comparison chart. Available at: www.diabetesstore.com/meterchart.asp. Accessed June 20, 2005.
30. Quick Ratings: Blood glucose monitors. *Consumer Reports*, August 2005.
31. LifeScan Blood Glucose Monitors. Available at: www.consumerreports.org/main/detailv3.jsp?CONTENT%3C%3Ecnt_id=333247&FOLDER%3C%3Efolder_id=31239&bmUID=1129230042974. Accessed August 2005.
32. Prestige™ and TrueTrack™. Home Diagnostics, Inc. Available at: www.homediagnosticsinc.com/upload.asp. Accessed June 20, 2005.
33. FreeStyle CoPilot™. Abbott Laboratories. Available at: www.diabeteshealthconnection.com/products/monitors/freestyle/freestylecopilot/features.aspx. Accessed June 20, 2005.
34. InterActiv™ Diabetes Software. BD. Available at: www.bddiabetes.com/us/bgm/software.asp. Accessed June 20, 2005.
35. GlucoBalance™ Data Management System. Hypoguard. Available at: www.hypoguard.com/glucobalance.html. Accessed June 20, 2005.
36. OneTouch™ Data Management Software. LifeScan. Available at: www.lifescan.com/products/otdms/software. Accessed June 20, 2005.
37. Accu-Chek® Compass Software. Roche Diagnostics. Available at: www.roche-diagnostics.com/products_services/accuchek_datamanagement_compass.html. Accessed June 20, 2005.
38. Ascensia® WinGLUCOFACTS® Diabetes Management Software. Bayer HealthCare Diabetes Care. Available at: www.bayercarediabetes.com/prodserv/products/glucofacts/index.asp. Accessed June 19, 2005.
39. *Red Book*®, 109th ed. Montvale, NJ: Thomson, 2005.
40. Nyomba BL, Berard L, Murphy LJ. The cost of self-monitoring of blood glucose is an important factor limiting glycemic control in diabetic patients. *Diabetes Care* 2002;25:1244–1245.
41. Soumerai SB, Mah C, Zhang F, et al. Effects of health maintenance organization coverage of self-monitoring devices on diabetes self-care and glycemic control. *Arch Intern Med* 2004;164:645–652.

CONTINUING EDUCATION POST-TEST: CME/CPE/CNE/CCM

- 1. The DCCT trial demonstrated that:**
 - a. moderate therapy and control of diabetes delay the onset and progression of complications in type-1 diabetes mellitus.
 - b. moderate therapy and control of diabetes delay the onset and progression of complications in type-2 diabetes mellitus.
 - c. intensive therapy and control of diabetes delay the onset and progression of complications in type-1 diabetes mellitus.
 - d. intensive therapy and control of diabetes delay the onset and progression of complications in type-2 diabetes mellitus.
- 2. Diabetes affects approximately what percentage of people living in the U.S.?**
 - a. 2%
 - b. 10%
 - c. 20%
 - d. 6%
- 3. Diabetes is associated with abnormalities in the metabolism of:**
 - a. fat.
 - b. protein.
 - c. fat and carbohydrate.
 - d. b and c.
- 4. Chronic complications associated with diabetes include:**
 - a. microvascular.
 - b. macrovascular.
 - c. neuropathic.
 - d. all of the above.
- 5. What percentage of patients with diabetes are obese?**
 - a. 100%
 - b. 70% to 80%
 - c. 85% to 90%
 - d. 20% to 30%
- 6. What percentage of patients experiencing the classic triad of symptoms present with diabetic ketoacidosis?**
 - a. 20% to 40%
 - b. 10% to 20%
 - c. more than 50%
 - d. fewer than 5%
- 7. Which test(s) should be used for the diagnosis of diabetes?**
 - a. HbA_{1c}
 - b. fasting plasma glucose
 - c. postprandial glucose
 - d. all of the above
- 8. Which is *not* a risk factor for type-2 diabetes mellitus?**
 - a. gestational diabetes mellitus
 - b. physical activity
 - c. obesity
 - d. HDL-cholesterol above 35 mg/dl
- 9. Which patients should perform SMBG three or more times daily?**
 - a. all patients with diabetes
 - b. all patients with type-1 diabetes
 - c. patients taking oral sulfonyl-ureas
 - d. most patients using insulin
- 10. Patients with type-2 diabetes mellitus using oral agents should perform SMBG:**
 - a. twice daily.
 - b. at a sufficient frequency to reach glycemic goals.
 - c. three times a week.
 - d. once daily.
- 11. The most costly complication resulting from diabetes is:**
 - a. nephropathy.
 - b. neuropathy.
 - c. cardiovascular disease.
 - d. retinopathy.
- 12. Glucose levels in plasma are generally what percentage higher than whole blood measurements?**
 - a. 5% to 10%
 - b. 10% to 15%
 - c. 15% to 20%
 - d. 20% to 25%
- 13. Based on the observational study by Alto et al., one can assume that:**
 - a. 50% of patients perform SMBG appropriately and obtain reliable results.
 - b. 70% of patients perform SMBG appropriately and obtain reliable results.
 - c. 100% of patients perform SMBG appropriately and obtain reliable results.
 - d. 25% of patients perform SMBG appropriately and obtain reliable results.
- 14. Errors in the calibration of blood glucose monitors to strips results in which percentage of inaccuracies?**
 - a. 25%
 - b. 33%
 - c. 43%
 - d. 53%
- 15. Not covering a test strip with enough blood results in:**
 - a. false-high readings.
 - b. false-low readings.
 - c. accurate readings.
 - d. none of the above.
- 16. Which blood glucose monitor product lines offer a monitor with underfill detection, temperature control, and automatic coding?**
 - a. Accu-Chek®
 - b. Ascensia®
 - c. Precision®
 - d. a and b
- 17. Alto et al. reported that what percentage of blood glucose monitors had been checked for accuracy?**
 - a. 84%
 - b. 38%
 - c. 28%
 - d. 15%
- 18. Blood glucose levels are observed in blood from fingertips more readily than from other parts of the body.**
 - a. true
 - b. false
- 19. The number one cause of inaccurate blood glucose results is:**
 - a. size of the meter
 - b. user's error
 - c. lack of education
 - d. manufacturer's error
- 20. Soumerai et al. found that providing blood glucose monitors at no cost:**
 - a. improved rates of SMBG.
 - b. improved medication compliance.
 - c. decreased HbA_{1c} levels.
 - d. all of the above.

(See answer sheets on following pages.)

PHYSICIAN CONTINUING EDUCATION

RECORD OF COMPLETION

To qualify for 1.5 category 1 credits toward the AMA Physician's Recognition Award, this form must be completed and submitted via mail to **The University of Cincinnati Continuing Medical Education • P.O. Box 670567 • Cincinnati, Ohio 45267** or faxed to **(513) 558-1708**. Your CE statement will be mailed directly to you at the address you have noted below for a passing grade of 70% or better. Please allow 4–6 weeks for processing. Only physicians may apply for CE credit using this form. Please submit this form prior to the expiration date of 12-31-06. There is no fee for this activity.

Name: _____
FIRST LAST DEGREE(S)

Address: _____

Street _____

City _____ **State** _____ **Zip** _____

Contact

Information: **Business Phone** _____ **Fax** _____ **E-mail Address** _____



This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Cincinnati College of Medicine and The GMR Group-Health Insights. The University of Cincinnati College of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Cincinnati College of Medicine designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the educational activity.

By signing below, I verify that I have completed and reviewed the program materials and acknowledge that all information given above is accurate based upon my participation in this program.

Signature: _____ **Date:** _____

GENERAL EVALUATION

	Poor	Fair	Satisfactory	Good	Excellent
1. Please rate this programs on the following areas: (1 = Poor; 5 = Excellent)					
Quality of information	1	2	3	4	5
Usefulness to my practice	1	2	3	4	5
Readability and presentation	1	2	3	4	5

2. Additional comments about this program: _____

POST-TEST ANSWER KEY

	A	B	C	D		A	B	C	D		A	B	C	D		A	B	C	D
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PHARMACY CONTINUING EDUCATION

RECORD OF COMPLETION

To receive 0.15 CEUs (1.5 contact hours) of ACPE accredited Continuing Pharmacy Education for this program, this form must be completed and submitted via mail to **The GMR Group–Health Insights • 755 Business Center Drive, Suite 270 • Horsham, PA 19044** or faxed to **(215) 653-7982**. Your CE statement will be mailed directly to you by The GMR Group–Health Insights at the address you have noted below for a passing grade of 70% or better. Please allow 4–6 weeks for processing. This form must be submitted prior to the expiration date of 12-31-06. There is no fee for this program.

Name: _____
FIRST LAST DEGREE(S)

Address: _____

Street _____

City _____ **State** _____ **Zip** _____

Contact

Information: **Business Phone** _____ **Fax** _____ **E-mail Address** _____



"The GMR Group – Health Insights" is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of Continuing Pharmacy Education. This program offers a total of 1.5 contact hours or 0.15 CEUs.

ACPE#: 404-000-05-003-H01



By signing below, I verify that I have completed and reviewed the program materials and acknowledge that all information given above is accurate based upon my participation in this program.

Signature: _____ **Date:** _____

GENERAL EVALUATION

	Poor	Fair	Satisfactory	Good	Excellent
1. Please rate this programs on the following areas: (1 = Poor; 5 = Excellent)					
Quality of information	1	2	3	4	5
Usefulness to my practice	1	2	3	4	5
Readability and presentation	1	2	3	4	5

2. Additional comments about this program: _____

POST-TEST ANSWER KEY

1. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	6. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	11. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	16. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
2. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	7. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	12. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	17. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
3. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	8. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	13. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	18. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
4. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	9. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	14. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	19. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
5. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	10. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	15. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	20. <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

NURSING CONTINUING EDUCATION

RECORD OF COMPLETION

To receive 0.15 CEUs (1.5 contact hours) of ANCC and California Board of Nursing accredited continuing nursing education for this program, this form must be completed and submitted via mail to **The GMR Group–Health Insights • 755 Business Center Drive, Suite 270 • Horsham, PA 19044** or faxed to **(215) 653-7982**. Your CE statement will be mailed directly to you by The GMR Group–Health Insights at the address you have noted below for a passing grade of 70% or better. Please allow 4–6 weeks for processing. This form must be submitted prior to the expiration date of 12-31-06. There is no fee for this program.

Name: _____
FIRST LAST DEGREE(S)

Address: _____

Street _____

City _____ **State** _____ **Zip** _____

Contact

Information: **Business Phone** _____ **Fax** _____ **E-mail Address** _____



*Educational Programs
for Managed Markets*

The GMR Group-Health Insights is an approved provider of Continuing Nursing Education by the Pennsylvania State Nurses Association, is an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation, and is a provider approved by the California Board of Registered Nursing, California Provider # CEP 12643.

By signing below, I verify that I have completed and reviewed the program materials and acknowledge that all information given above is accurate based upon my participation in this program.

Signature: _____ **Date:** _____

GENERAL EVALUATION

	Poor	Fair	Satisfactory	Good	Excellent
1. Please rate this programs on the following areas: (1 = Poor; 5 = Excellent)					
Quality of information	1	2	3	4	5
Usefulness to my practice	1	2	3	4	5
Readability and presentation	1	2	3	4	5

2. Additional comments about this program: _____

POST-TEST ANSWER KEY

	A	B	C	D		A	B	C	D		A	B	C	D		A	B	C	D
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CASE MANAGEMENT CONTINUING EDUCATION

RECORD OF COMPLETION

To receive CCM credits for this program, this form must be completed and submitted via mail to **The GMR Group–Health Insights • 755 Business Center Drive, Suite 270 • Horsham, PA 19044** or faxed to **(215) 653-7982**. A CE Verification Form will be mailed directly to you by The GMR Group–Health Insights at the address you have noted below for a passing grade of 70% or better. Upon receiving the CE Verification Form, you must complete the form and mail it to **CCMC • 1835 Rohlwing Road, Suite D, • Rolling Meadows, IL 60008**. Please allow 4–6 weeks for processing. The CE Verification form must be post marked by the expiration date of 12-31-06. There is no fee for this activity.

Name: _____
FIRST LAST DEGREE(S)

Address: _____

Street _____

City _____ **State** _____ **Zip** _____

Contact

Information: **Business Phone** _____ **Fax** _____ **E-mail Address** _____

By signing below, I verify that I have completed and reviewed the program materials and acknowledge that all information given above is accurate based upon my participation in this program.

Signature: _____ **Date:** _____

GENERAL EVALUATION

	Poor	Fair	Satisfactory	Good	Excellent
1. Please rate this programs on the following areas: (1 = Poor; 5 = Excellent)					
Quality of information	1	2	3	4	5
Usefulness to my practice	1	2	3	4	5
Readability and presentation	1	2	3	4	5

2. Additional comments about this program: _____

POST-TEST ANSWER KEY

	A	B	C	D		A	B	C	D		A	B	C	D		A	B	C	D
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

