Comparison of self-monitoring blood glucose devices for accuracy and ease of use

Kelly Kitabchi Pfrommer

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A Comparison of Self-monitoring Blood Glucose Devices for Accuracy and Ease of Use

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Abstract

Intensive treatment of Diabetes Mellitus (DM) includes frequent blood glucose monitoring and modification of treatment, with the goal of maintaining near-normal glycemic values. This type of therapy is dependent on the DM patient's ability to monitor his/her blood glucose, and is accomplished by the use of a portable blood glucose meter. The purpose of this comparative study was to evaluate several self-monitoring blood glucose (SMBG) devices with regard to accuracy and ease of use. The SMBG devices compared were: MediSense Precision QID, Boehringer Mannheim AccuChek Advantage, Lifescan OneTouch Profile, and Bayer Glucometer DEX. Nola Pender's Health Promotion Model was used as the theoretical framework in this study. Two null hypotheses were tested:

1. There will be no difference in the degree of accuracy of blood glucose values measured by four SMBG devices when compared to a reference standard.
2. There will be no difference in the perceived ease of use of four SMBG devices as determined by patients.

Twenty-eight patients with DM were recruited from a university clinic to measure their own blood glucose on the devices studied. These measurements were compared to a simultaneously obtained laboratory standard. The subjects rated each machine with respect to ease of use using a Visual Analogue Scale. Data analyses were performed by repeated measures ANOVA with post hoc analyses, Dunnett's t Test for accuracy and Tukey's procedure for ease of use. For the variable of accuracy, the percentage of blood
glucose readings in the 10% interval of the reference standard were also calculated. The researcher determined that the One Touch Profile and the AccuChek Advantage were the most accurate of the SMBG devices studied. Precision QID and Glucometer DEX were determined to be less accurate than the others. The Glucometer DEX was found to be more difficult to use than the other machines as rated by patients. Based on these findings, the researcher concluded that the One Touch Profile and the AccuChek Advantage were more accurate and more user-friendly machines than the other two. Further studies with larger samples are necessary before conclusive recommendations can be made for the use of these machines in practice.
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Chapter I

The Research Problem

Self-monitoring of blood glucose (SMBG) has become paramount in the control of diabetes mellitus (DM). Providers of care have had the opportunity and responsibility to educate patients with DM in the importance of SMBG in order to maintain good glycemic control, hence decreasing their risk for complications. The last decade has brought new technology and increasing numbers of SMBG devices to the market. Faced with a variety of machines, patients and providers have had increasing difficulty in choosing the most appropriate SMBG device. According to the 1995 American Diabetes Association (ADA) Consensus Statement on SMBG, the accuracy of SMBG devices on the market ranged from 4% to 33%, although the ADA's recommended performance goal had been placed at a maximum of 10% allowable error. Thus a discrepancy in outcome accuracy has existed.

Comparison studies of SMBG have been implemented; however, few have included samples of actual "users" of the machines, patients with DM, in testing these devices. The purpose of this study was to compare the accuracy and ease of use of four SMBG devices: MediSense QID, Boehringer Mannheim Accuchek Advantage, Lifescan OneTouch Profile, and Bayer Glucometer DEX, using patients with DM. These particular devices were chosen because they had similar features, which are desirable in the optimal management of DM patients, and because of their relative newness on the market. The
similar features of these devices include: storage of at least 100 blood glucose values with downloading capabilities to a patient data management system, housed at the health care provider site; display large enough to read for the elder or sight-impaired client; and use of “wipeless” technology.

Establishment of the Problem

Diabetes mellitus is a heterogeneous disease in which the body cannot properly metabolize carbohydrates, proteins, and fats. There are two major types of DM, type 1 and type 2. Type 1 DM is an autoimmune related disease which frequently occurs at an early age and is characterized by insulinopenia. Type 2 DM is characterized by insulin resistance and is influenced by family history and lifestyle status (Kitabchi, 1999). This chronic illness affects approximately 16 million Americans of which one million are type 1 DM and 15 million are type 2 DM. Of the latter, it is said that about 7.5 million are not diagnosed (ADA, 1996). If left untreated or poorly controlled, DM eventually leads to microvascular and macrovascular complications. Microvascular complications include diabetic retinopathy, nephropathy, and neuropathy. Macrovascular complications include cardiovascular disease and peripheral vascular disease. Patients face the possibility of blindness, end-stage renal failure, amputation, and death as a result of these sequelae. DM has been the leading cause of new cases of blindness each year, with DM patients being 20 times more likely to lose vision than patients without DM (ADA, 1996). DM patients have an increased risk of developing end-stage renal disease as well, at a rate of 25 times more likely than patients without DM. It has been estimated that 40 to 50% of amputations unrelated to traumatic events are due to DM (ADA, 1996). Type II DM and
its related complications has been estimated to reduce life expectancy by approximately 5-10 years (ADA, 1996). DM contributed to the deaths of 118,687 people in 1992 and was the underlying cause of death for 48,259 others (Genuth, et al., 1999). Although there are several classifications of DM, all are characterized and, therefore, diagnosed by fasting hyperglycemia, or elevated blood glucose levels.

In 1993, the Diabetes Control and Complications (DCCT) Research Group concluded that aggressive management of diabetes significantly decreases the incidence of long-term microvascular complications associated with type 1 diabetes. The DCCT Research Group findings led to changes in the ADA recommendations for glycemic control in patients with DM. In addition, several researchers have achieved similar findings in patients with type 2 DM, which support the DCCT Research Group’s results. The researchers of both the Stockholm Diabetes Intervention Study (SDIS) (1993) and the United Kingdom Prospective Diabetes Study (UKPDS) (1998) reported a high correlation between hyperglycemia and the onset and progression of microvascular complications in patients with type 2 DM. Klein, Klein, and Moss (1996) demonstrated a strong relationship between glycemic control and the incidence and progression of microvascular complications in both type 1 and type 2 diabetic patients who participated in the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR). These researchers further underlined the benefits of intensive treatment of DM, namely improvement of the quality and longevity of the DM patient's life by decreasing the risk of complications through the maintenance of euglycemia using frequent SMBG.

Aggressive, or intensive, treatment of DM includes frequent blood glucose
monitoring and modification with the goal of maintaining near-normal glycemic values (DCCT Research Group, 1993). This type of therapy is dependent on the individual with diabetes’ ability to monitor his/her own blood glucose, using a portable device in which blood obtained from a finger stick is used to measure blood glucose. These measurements are recorded by the patient and reviewed by the patient and health care provider, and adjustments in therapy are made accordingly. Ideally the patient makes adjustments in medication and diet therapy immediately, using a patient-specific plan of care developed by the provider and patient.

SMBG has become the cornerstone of aggressive management of DM. SMBG has been called the "single most important advance in the management of diabetes since the discovery of insulin," (Skyler & Cohen, 1997, p. 1042). The technology for SMBG was introduced as early as 1961, but only in the last decade has it become widely accepted as the preferred method for patients' monitoring of their glycemic status over urine testing (Goldstein, Little, Lorenz, Malone, Nathan, and Peterson, 1995).

There have been a number of different types of SMBG machines on the market, incorporating different technology and strips. Providers of care have had to stay abreast of the evaluations of the clinical performance of new and changing machines. Several studies have been conducted comparing various SMBG machines with respect to accuracy and reliability, as well as testing of specific technological aspects (Johnson, Luther, Hipp, Stegeman, and Green, 1995; Poirer, Prieur, Campion, Guilhem, Allannic, and Maugendre, 1998; Strowig & Raskin, 1998). However, little research has been conducted evaluating patients’ experiences using these machines. According to Voss, Bina, McNeil, and
Cembrowski (1996, vol. 27(8), p. 535), “if a meter is to be used for self-monitoring, patients with diabetes must test it.” The purpose of this study was to compare four SMBG devices with regard to accuracy as compared to a laboratory standard and with regard to ease of use as rated by patients.

Theoretical Framework

The theoretical framework for the study was Nola Pender's Health Promotion Model. Pender has studied individuals' beliefs about health, health promoting behaviors, and factors influencing these behaviors throughout the life span. Pender's Health Promotion Model, originally developed in 1987, identified factors that influence individuals' decisions to participate in health-promoting behaviors based on a cue to action. These factors may be divided into cognitive-perceptual factors and modifying factors. According to Pender (1987), an individual has the following cognitive-perceptual factors, or primary motivational mechanisms: importance of health, perceived control of health, perceived self-efficacy, definition of health, perceived health status, perceived benefits of health-promoting behaviors, and perceived barriers to health-promoting behaviors. Modifying factors have an indirect influence on behavior and include demographic characteristics, biological characteristics, interpersonal influences, situational factors, and behavioral factors. In Pender's 1996 edition of The Health Promotion Model, several new concepts or influences on health-promoting behaviors were included: prior related behavior, activity-related affect, commitment to a plan of action, and immediate competing demands and preferences. Patients' past experience with similar events, their attitudes and commitment toward improving their situation, and any distractions from
remaining on task all have an impact on whether and how an individual participates in health-promoting behavior.

One aspect of Pender's Health Promotion Model of particular interest is the concept of promotion of competent self-care in individuals through education (Pender, 1987). “Self-care is a universal requirement for sustaining and enhancing life and health. The competence with which this task is accomplished determines the quality of life experienced and has significant impact on longevity,” (Pender, 1987, p. 185). Pender refers to self-care as an “ongoing activity and a competence to be developed . . . care of self also includes actions directed toward minimizing threats to personal health . . . ,” (Pender, 1987, p. 185).

Pender’s model can be used to help patients with DM identify and understand their beliefs about behaviors, and factors affecting these behaviors. Once these beliefs are identified, the nurse practitioner may use this knowledge to encourage the patient to commit to a plan of action which is individualized to meet the patient's needs (Tillett, 1998).

In the context of this study, the health-promoting behavior of SMBG would be driven by the commitment to a plan of action with the goal being tight glycemic control. This plan of action would include frequent SMBG and subsequent modification of treatment by the patient. Levels of blood glucose below or above the range of acceptable values, as previously determined by the patient and provider, would serve as cues to action to either administer medication or have a snack, as appropriate.

Pender (1987) discussed perceived barriers to health-promoting behaviors as
activities viewed by the patient as being difficult to the point of influencing the patient not to engage in the activities (Tillett, 1998). Using SMBG devices may be perceived by some patients in this way. Conversely, perception of SMBG devices as easy to use could provide a positive influence on patients' adherence to this health-promoting behavior. The current researcher asked subjects to use the SMBG machines under study to obtain their own blood glucose measurements and to rate each machine with regard to their perceived ease of use.

**Significance to Nursing**

Family nurse practitioners (FNP), as providers of primary care, have an important role in helping patients with DM control their disease, thus improving their quality of life by decreasing their risk of complications. In order to successfully manage diabetes, the FNP and the patient must develop goals of treatment specific for the patient's needs. One essential vehicle for achieving these goals is the patient's participation in self-care through frequent SMBG.

Therapeutic and educative treatment decisions made by FNPs are based on research findings, which drive practice theory. The current researcher strived to complete research in the area of DM, which would assist FNPs in making sound, educated treatment decisions for their patients with diabetes, with regard to which SMBG devices to prescribe for these patients.

**Assumptions**

The assumptions of this study include the following:

1. Subjects will attempt to use the SMBG devices to the best of their ability.
2. Subjects will be honest with regard to their rating of the SMBG devices for
the variable ease of use.

3. The HemoCue B-Glucose Analyzer (HemoCue) reference standard glucose
measurement is an accurate measure of blood glucose, with the HemoCue
not malfunctioning or being defective. Note: The HemoCue reference
standard measurement device and technique are described in detail in both
the Definition of Terms section of this chapter and in Chapter III, under the
Instrumentation section.

4. The SMBG devices and test strips used for the study are free from
manufacturer defects.

5. If an SMBG device is perceived by a patient to be easy to use, this will lead
to the patient's increased adherence to the health-promoting behavior of
frequent self-monitoring of blood glucose.

Statement of the Problem

SMBG has become an integral component of diabetes management with the
primary goal of maintaining blood glucose near the physiologic level in order to decrease
the risk of complications leading to increased morbidity and mortality. As the technology
of SMBG devices has continued to evolve, diabetics and providers of care have had an
increasingly difficult selection process. As facilitators of diabetes management plans of
care, nurse practitioners need to be cognizant of the performance of the most common
SMBG devices, as well as those that have incorporated the latest technological advances.
The purpose of this study was to compare four SMBG devices with respect to accuracy
and perceived ease of use.

Research Hypotheses

There were two null hypotheses tested:

\( H_0_1. \) There will be no difference in the degree of accuracy of blood glucose values measured by four SMBG devices when compared to a reference standard.

\( H_0_2. \) The average blood glucose values measured by four SMBG devices are identical to the average blood glucose value measured by a laboratory reference standard.

\( H_A_1. \) There will be no difference in the perceived ease of use of four SMBG devices as determined by patients.

\( H_A_2. \) The averages of the perceived ease of use of four SMBG devices, as determined by patients are equivalent.

Definition of Terms

Several terms were defined theoretically and operationally: patient, SMBG devices, accuracy, reference standard, and ease of use.

Patient

Theoretical: Thomas (1993, p. 1446) defined a patient to be “one who is sick with, or being treated for, an illness or injury.”

Operational: For the purpose of this study, patient referred to one of a group of diabetic males and females being monitored and treated by a university endocrinology group for diabetes and who met the inclusion criteria for the study. These criteria
included those who: had been diagnosed with diabetes, were free from medications which have been found to interfere with SMBG devices (acetaminophen and vitamin C), had hematocrit (HCT) readings between 35% and 55% during the time they were included in the study, had normal renal function during the time they were included in the study, were not taking anticoagulation therapy medications (aspirin, coumadin, warfarin, or plavix), and were able to read and follow written instructions.

**SMBG devices**

**Theoretical:** According to Schteingart (1997), SMBG devices, also called glucose meters, are small, portable machines used to measure the glucose content in capillary blood obtained from a finger stick. One drop of blood is applied to a small plastic strip and inserted into the glucose meter for measurement using reflectance photometry or more recently, biosensor technology. Both types of systems depend on test strips impregnated with glucose oxidase, an enzyme that catalyzes glucose oxidation (Skyler & Cohen, 1997).

**Operational:** For the purpose of this study, SMBG devices were small, portable machines used to measure the glucose content in capillary blood obtained from a finger stick and included one of four possible devices: MediSense Precision QID, Boehringer Mannheim AccuChek Advantage, Lifescan OneTouch Profile, and Bayer Glucometer DEX.

**Accuracy**

**Theoretical:** Thomas (1993, p. 18) defines accuracy as "the ratio of the error of measurement to the true value, and the state of being free of error." The American Diabetes Association Consensus Conference in 1995 recommended that the goal for
manufacturers of future SMBG devices should be \( \leq 5\% \) analytical error (total error of analytical plus user within \( \pm 10\% \) of the reference standard).

**Operational:** For the purpose this study, accuracy was a comparative, rather than absolute value. That is, the blood glucose measured by the four SMBG devices was compared with the blood glucose measured by a reference standard. Accuracy was defined as the average difference between the capillary blood glucose measured by each SMBG device and the blood glucose measured by the reference standard, HemoCue, which also used capillary blood.

**Reference Standard**

**Theoretical:** Reference refers to "a source of information taken as authoritative," (Cayne, 1993, p. 837). Standard, according to Thomas (1993, p. 1863), is "that which is established by custom or authority as a model, criterion, or rule for comparison of measurement."

**Operational:** Within the confines of this study, reference standard was the blood glucose value as measured by the HemoCue B-Glucose Analyzer (HemoCue). The HemoCue method of determining blood glucose is described in more detail in the Instrumentation section of Chapter III.

**Ease of Use**

**Theoretical:** Ease of use is a phrase describing the degree to which something is found to be easy to use, uncomplicated, not cumbersome or confusing.

**Operational:** In the context of this study, the term ease of use was defined as the degree to which the device was deemed easy to use by the subjects of the study, as rated
on a Visual Analogue Scale (VAS). The VAS is described in detail in the instrumentation section of the methodology chapter.
Chapter II

Review of Literature

Upon review of the literature, the researcher identified several studies that have been done attempting to analyze SMBG devices for accuracy and reliability or to test new features. One study was found in which user-acceptability of SMBG machines was evaluated by certified diabetes educators. In this chapter, pertinent findings of several previous studies and discussion of the need for further study regarding SMBG devices have been presented.

Long-term macrovascular and microvascular complications cause morbidity and mortality in patients with type 1 DM. Although animal experimentation had implicated chronic hyperglycemia as the ultimate cause of these complications, previous clinical trials had not consistently shown that invasive management of type 1 DM could decrease their incidence, improving the quality and longevity of these patients' lives.

The Diabetes Control and Complications Trial (DCCT) Research Group (1993) sought to determine whether intensive treatment of type 1 DM with the goal of maintaining blood glucose values close to the normal range could decrease the likelihood and severity of long-term complications associated with type 1 DM. The researchers questioned whether intensive therapy would prevent diabetic retinopathy in patients with no retinopathy (primary prevention) and slow the progression of early retinopathy.
(secondary intervention) in patients with mild retinopathy. Diabetic retinopathy was the principal outcome studied; however, renal, cardiovascular, and neuropsychosocial outcomes also were examined. Adverse effects of the two treatment regimens were studied as well.

The independent variable in this study was the type of therapy, conventional or intensive. Conventional therapy was comprised of one or two insulin injections per day, daily self-monitoring of urine or blood glucose, and diet and exercise education. Target blood glucose concentrations were not specific, but aimed at absence of symptoms of hyperglycemia or frequent hypoglycemia. Patients were examined once every three months. Intensive therapy was defined as the administration of insulin three or more times daily by injection or insulin pump. Dosages were adjusted according to the results of self-monitoring blood glucose values done at least four times daily, dietary intake of the subjects, and anticipated exercise. Parameters consisted of a) target fasting blood glucose values between 70 and 120 mg per deciliter, and b) monthly hemoglobin A1C (HbA1C) values close to the normal range (upper limit of normal 6.05%). Other lab values, such as postprandial blood glucose concentrations and weekly 3:00 a.m. blood glucose values were carefully monitored and insulin adjusted accordingly.

The dependent variables were the complications associated with type 1 DM, defined as diabetic retinopathy, nephropathy, neuropathy, and macrovascular disease. Retinopathy was defined as a change of three steps or more on fundus photography that was sustained over a 6-month period. Nephropathy was defined by the presence of microalbuminuria (urinary albumin excretion of ≥ 40 mg per 24 hours) or albuminuria
(urinary albumin excretion of $\geq 300$ mg per 24 hours). Neuropathy was defined by the existence of peripheral sensorimotor neuropathy plus either abnormal nerve conduction in at least two peripheral nerves or unequivocally abnormal autonomic nerve testing.

The DCCT was a multicenter, randomized, controlled clinical trial involving 29 centers in the United States and Canada. A total of 1441 volunteers with type 1 DM, ranging in age from 13-39 years and with type 1 DM of 1 to 5 years' duration and no retinopathy at baseline (primary prevention cohort) or with 1 to 15 years' duration and minimal to moderate nonproliferative retinopathy (secondary intervention cohort), were randomly assigned to either conventional or intensive diabetes therapy. Patients were followed for an average of 6.5 years, with a minimum of 5 years and a maximum of 9 years.

The secondary intervention cohort included patients with mild retinopathy, considered to be the presence of at least one microaneurysm in either eye, but less than that which would characterize either eye as P2 or worse according to Early Treatment of Diabetic Retinopathy Standards (ETDRS). The principle outcome in the primary prevention cohort was the initial appearance of background retinopathy, or a change of three steps from baseline on a 25-step scale defined by the ETDRS, and sustained for at least six months. The principle outcome in the secondary intervention cohort was the progression of preexisting minimal retinopathy, defined by a similarly sustained 3-step change from preexisting retinopathy.

Patients were evaluated for outcome analysis based on a schedule. Baseline values were obtained in each area, and many of the data were collected locally but analyzed at a
central location in order to mask these measurements from investigators and subjects.

Only in cases where the values were of potential danger for the patient were the results unmasked. Ophthalmologic measurements were obtained every 6 months, with an additional measurement of fundus photography at 3 months. Ophthalmologic measurements included visual acuity, intraocular pressure, slit-lamp exam, and seven-field stereoscopic fundus photography. Blood glucose control was measured during clinic visits every 3 months in the form of capillary blood glucose profiles and HbA1C values. Renal function was monitored every 6 months by testing of microalbuminuria, creatinine clearance, and serum creatinine and albumin. Neurologic function was monitored every 6 months by assessing: 1) symptom history and physical exam using a standardized tool; 2) autonomic nervous system function using 12-lead EKG and looking for an RR variation; and 3) noninvasive nerve conduction. Cardiovascular function was monitored every 6 months by history and physical, blood pressure and pulse (done every 3 months), resting EKG, serum triglycerides, serum total cholesterol, HDL, and calculated LDL. Psychosocial measurements included neurobehavioral assessments done biannually, assessment of psychological symptoms at 3 months, at 6 months, and every 6 months thereafter, using the SCL-90-R tool, and a quality of life questionnaire administered to the patients at 3 months, at 6 months, and every 6 months thereafter. Compliance or adherence to the prescribed treatment regimen was assessed every 3 months, and a diet history was obtained every 6 months.

Ninety-nine percent of the patients enrolled completed the study, and greater than 95 percent of all scheduled clinic visits were completed. The mean blood glucose value
for the intensive therapy group across both cohorts after therapy had been consistent for more than one year was $155 \pm 30 \text{ mg/dl}$, while the conventional therapy groups' mean value after one year of therapy was $231 \pm 55 \text{ mg/dl} (P < 0.001)$. These two means were compared with the baseline glucose values of both intensive and conventional therapy groups which were essentially equal at approximately $232 \pm 80 \text{ mg/dl}$. The average HbA1C value at baseline for both groups in the primary prevention cohort was similar at $8.8 \pm 1.65\%$, with a slightly higher baseline value for the secondary intervention cohort at $8.95 \pm 1.5\%$. Upon completion of the study, both cohorts of the intensive therapy group achieved an average HbA1C of $7.5\%$, while the cohorts of the conventional therapy group obtained an average HbA1C of $9.11\% (P < 0.001)$.

The researchers concluded that when compared with conventional therapy, intensive diabetes therapy was shown to reduce the development of retinopathy by 76 percent. Progression of retinopathy was shown to be retarded by 54 percent in the intensive treatment group, and proliferative or severe nonproliferative retinopathy incidence was reduced by 47 percent in the same group. Intensive therapy was associated with a 39 percent reduction rate in the development of microalbuminuria and a decrease of incidence of albuminuria by 54 percent across both cohorts. The risk of neuropathy was shown be 60 percent less in the intensive therapy group in the two cohorts combined. Combining all major cardiovascular and peripheral vascular events, intensive therapy was shown to reduce the risk of macrovascular disease by 41 percent. Severe hypoglycemia and weight gain were risks found to be associated with intensive therapy, with a two-to-threefold increase in severe hypoglycemia for these patients.
The DCCT Research Group concluded that aggressive management of patients with type 1 diabetes reduced microvascular complications associated with their disease by a value of between 35 and 70 percent. To that end, the researchers recommended that most patients with 13 years old or older be treated with closely monitored intensive regimens, with the goal of maintaining blood glucose values close to the physiologic normal range. The researchers further recommended that intensive treatment be used with caution in all patients, due to the risk of hypoglycemic episodes, and desired glycemic goals adjusted for the safety of the patient. Caution with aggressive management of DM is particularly important in the elderly, those with advanced complications such as end-stage renal disease, cardiovascular or cerebrovascular disease, and those with repeated episodes hypoglycemia or poor prediction of hypoglycemic episodes. The DCCT was a landmark study which helped end the debate on correlation of blood glucose levels to the complications of diabetes. It thus implicated the importance of close monitoring of blood glucose values by patients as well as their providers in decreasing long-term complications associated with type 1 DM. Similar results regarding control of glycemia and risk reduction of diabetic complications have subsequently been reported in patients with type 2 DM.

The UK Prospective Diabetes Study (UKPDS) Group (1998) had a similar goal and reported similar findings to the DCCT study, but with 3867 patients with type 2 DM as the participants. The intensive therapy group was divided into those treated with sulfonylureas (chlorpropamide or glibenclamide) or insulin. An 11% reduction in HbA1C was realized in the intensive therapy group as compared to the conventional therapy
group, with no difference among the three intensive agents (insulin, chlorpropamide, or glibenclamide). Intensive treatment yielded a 12% risk reduction for any diabetes-related endpoint ($P = 0.029$). The researchers determined that most of the risk reduction in the any diabetes-related aggregate endpoint was due to a 25% risk reduction in microvascular endpoints ($P = 0.0099$), e.g. the need for retinal photocoagulation. The DCCT as well as the UKPDS are germaine to the current study as results from the DCCT study clearly established not only the need to monitor blood glucose values, but also provided the basis for needing an accurate monitoring device.

During the past decade, SMBG has become commonplace in both hospitals and in patients' homes as part of diabetes management programs. According to Johnson, Luther, Hipp, Stegeman, and Green (1995), the accuracy of SMBG devices has been questioned, in part due to older technology. To address this concern and to allow for storage of more data, manufacturers developed SMBG devices which have two new features: “wipeless” technology and sophisticated software with capabilities for increased storage, display, and analysis of data.

Johnson, et al. (1995), evaluated the precision and accuracy of three SMBG devices which use new technology as compared to a commonly used SMBG devices utilizes the older technology. The new SMBG devices evaluated were: One Touch II Hospital Meter, LifeScan, Milpitas California and Satellite G, MediSense, Cambridge, Massachusetts. These monitoring devices were compared to the popular Accu-Check III, Boehringer Mannheim Diagnostics, Indianapolis, Indiana. A fourth machine designed with the new features, Accu-Check Easy, Boehringer Mannheim Diagnostics, Indianapolis,
Indiana, was evaluated during a separate study, as it became available on the market after the initial study was completed. Blood glucose values obtained using these machines was compared with a reference standard to determine their accuracy.

The independent, categorical variable in this study included the four SMBG devices described above. The dependent variable was the blood glucose measurement obtained from the various machines. Accuracy was defined as the difference between the reference standard and the value obtained from the machine. Precision was defined as the calculated mean, or standard deviation, of the repeated measurements and the coefficient of variation (Johnson, et al., 1995). “In general, a precision standard of a coefficient of variation less than 5% and accuracy to within 10% of a reference standard have been considered acceptable” (Johnson, et al., 1995, p. 424). Accuracy of the SMBG devices was measured across four blood glucose ranges defined as follows: low = < 60 mg/dL, normal = 60-140 mg/dL, high = 141-300 mg/dL, and very high = > 300mg/dL.

In this exploratory study, Johnson, et al. (1995) measured the glycemic value of 262 whole, venous blood samples from inpatients at Overland Park Regional Medical Center in Overland Park, Kansas. Statistical power for determining accuracy of the machines was obtained by testing adequate numbers of samples in each of the four glycemic ranges defined above against a reference standard. However, the researchers found it difficult to obtain an adequate sample size from their hospitalized patients in the low, or hypoglycemic range; therefore, four healthy, nondiabetic volunteers were used to complete the development of the low range. The volunteers agreed per informed consent to undergo insulin-induced hypoglycemia in a controlled setting. Repeated blood samples
were obtained for the study as the patients' blood glucose levels dropped after the intravenous administration of 0.15 units/kg of human regular insulin. The patients were monitored closely during this period with regard to blood glucose and symptoms of hypoglycemia and were subsequently fed to increase glycemia to a normal value. The hypoglycemic episode was reversed early by feeding if the blood glucose level dropped below 35 mg/dl or if symptoms of neuroglycopenia were present. Very high blood glucose samples were obtained by mixing the blood samples with 50% dextrose. Blood samples were obtained from the subjects by trained phlebotomists and placed in heparinized tubes for transfer to the laboratory. Aliquots were taken from the blood tube for measurement by the DuPont Dimension autoanalyzer - the reference plasma glucose concentration measurement - within 3 hours of phlebotomy. This machine used an automated hexokinase technique. Within 30 minutes, either before or after, of the reference measurement, the same blood sample was used to obtain an aliquot for measurement by each of the SMBG devices being studied. This was the method for determination of accuracy. Precision of each SMBG machine was measured by performing 20 tests using the same blood sample in the normal and high or very high ranges. A separate study involving 111 blood samples (n = 65 for the normal range, n = 23 for the high range, and n = 20 for the very high range) and utilizing the same methods was completed to evaluate the precision and accuracy of the Accu-Check Easy; however, no low blood glucose values were obtained in this study.

Johnson, et al. (1995) determined that One Touch II was significantly correlated to the reference standard in each clinical blood glucose subset, expressed as both Pearson
and Spearman correlation coefficients, ranging from 0.93 (Pearson and Spearman) to 0.99 (Pearson). The Accu-Check III also had a high level of correlation to the reference standard with regard to the four glycemic ranges, from 0.88 (Pearson and Spearman) to 0.97 (Pearson). The Satellite G and Accu-Check Easy were found to have lower correlation coefficients in the independent subsets, reaching as low as 0.64 (Spearman) for Satellite G and 0.59 (Spearman) for Accu-Check Easy. When measured across the entire range of blood glucose values, all devices were highly correlated with a coefficient ranging from 0.94 to 0.99. The Accu-Check II and Accu-Check Easy were found to be the most accurate machines, the One-Touch II following closely behind, with regard to both testing of subsets and the entire range of glycemic values. However, all devices fell below what was considered to be acceptable accuracy in virtually all subsets and the entire range. Notable differences from the reference standard were found in the very high range, especially with the Satellite G device.

Precision was expressed as the coefficient of variation (CV). One Touch II and Satellite G were found to be precise, (CV < 5%) in both normal and high/very high ranges, with One Touch II being the most precise in the normal range. Accu-Check III and Accu-Check Easy both fell below acceptable precision in the normal range, with CV of 6.6% and 6.2%, respectively.

Johnson, et al. (1995) concluded that the machines which were found to be the most accurate were not necessarily the most precise, and that there was a large variance in correlation, precision, and accuracy for machines approved for use in the market. In addition, studying various ranges of glycemia provided meaningful results which may have
been lost if only entire ranges were examined for precision and accuracy. Overall, the One Touch II, a SMBG device which uses the "wipeless" technology and sophisticated software, was shown to have the highest correlation with regard to accuracy and precision.

The current researcher compared four SMBG devices for accuracy and ease of use. Johnson, et al.'s research had a similar design to the current research and explored similar research questions. However, Johnson, et al. did not include patients in the testing of these devices, an important consideration since an integral component of diabetes management is patients' own monitoring of their blood glucose.

Health care providers and patients alike face the challenge of achieving and maintaining patients' blood glucose value to within near-normal range. Patients' self-monitoring of blood glucose several times daily is an integral part of aggressive management of DM. Health care providers have the task of reviewing the blood glucose values provided by patients, which often means relying on patients' manual records. Strowig and Raskin (1998) cited researchers who have shown that: 1) patients' manual logs of blood glucose values are not sufficiently maintained by patients; 2) the data are often not adequately interpreted and utilized for modification of patients' treatment regimens; and 3) manual logs of blood glucose kept by patients are often unreliable sources of actual values.

The purpose of Strowig and Raskin's research was to evaluate the effectiveness of patients' utilization of blood glucose meters with storage capabilities in conjunction with computer-assisted analyses on the improvement of glycemic control in the aggressively-
managed diabetic patient. The authors hypothesized that utilization of these meters together with accurate interpretation and analysis of the data could lead to effective treatment modification for intensively managed patients with diabetes.

The independent variable of this study was the type of glucose meter used, one with memory capabilities or no memory capabilities. The patients under study initially used a reflectance meter without memory capabilities to monitor their blood glucose and subsequently switched to using either a Glucometer M or One-Touch II, both of which had storage and averaging capabilities. Other independent variables of this research were duration of illness, duration of intensive therapy, and frequency of home blood glucose testing. The primary dependent variable was mean glycosylated hemoglobin (HbA₁C) level. Other dependent variables were frequency of patient visits to the dietician, physician, and psychologist; change in mean insulin daily dosage; and number of changes in insulin dose made by the clinician.

A quasi-experimental, time series design was utilized to measure HbA₁C levels of 22 adults (11 men, 11 women) with type 1 DM for 12 months before and 12 months after the subjects were switched from reflectance glucometers to glucometers with memory capabilities. All subjects were followed by the intensive diabetes treatment team at the University of Texas Southwestern Medical Center at Dallas. This team included a nurse practitioner, dietician, physician, and mental health personnel. The team remained constant throughout the entire study period. Other eligibility criteria for the study subjects were completion of intensive diabetes education training, ability to accurately measure blood glucose values and maintain an intensive insulin treatment program, consistency of
method of intensive insulin delivery (insulin pump or four daily insulin injections) for the year previous to the study period, and commitment to maintenance of monthly clinic appointments. Two patients used four insulin injections per day (pre-meal regular insulin and bedtime NPH insulin) as their method of insulin delivery, while twenty patients used an insulin pump. Eighteen patients were assigned to use a Glucometer M memory meter, and four patients used a One Touch II memory meter.

Baseline HbA₁C levels were obtained at the beginning of the study, with a normal reading ≤ 6.05%. Throughout the study period, subjects were assessed monthly by the nurse practitioner. The patients were able to consult with any member of the intensive management team at any time. For the twelve-month period during which the patients were using reflectance meters, the nurse practitioner made changes in the patients’ treatment regimens based on the manual logs brought in by the patients, their HbA₁C levels, and patients’ adherence to the treatment regimens. After the subjects switched to memory meter usage, the data from the subjects’ meters were downloaded to the Glucofacts Data Management System at each monthly visit for analysis of blood glucose patterns. This computer-generated data became the driving force for modifications of the treatment regimens. HbA₁C levels continued to be monitored.

A random coefficients regression model was utilized by the researchers to measure change in HbA₁C levels from baseline, with baseline HbA₁Cs from each period as a covariate. Use of covariates was done to account for the fact that larger decreases in HbA₁C would be found when initial, or baseline, values were higher, and smaller decreases would be found if initial values were lower; or, the change in HbA₁C was relative to the
starting point. Pearson correlation coefficients were used to determine relationships among HbA1C levels, HbA1C slopes, duration of illness, duration of intensive regimen, and average number of daily blood glucose measurements.

Important findings included: 1) significantly lowered HbA1C levels associated with memory meter usage when adjusted for the baseline HbA1C level (P = 0.046) and 2) the negative correlation between monthly change in HbA1C levels and frequency of blood glucose monitoring (r = -0.54, p = 0.01); i.e., those who tested blood glucose values more often tended to show greater decreases in HbA1C levels. The mean monthly HbA1C level across the 12-month period during which a meter without memory was used was 6.9 ± 0.12%, while the mean monthly HbA1C level across the 12-month period when patients used a memory meter was 6.4 ± 0.10% (p = 0.0004). Just prior to the use of the memory meter, the average HbA1C level was 7.0%; however this average significantly declined to 6.3% after twelve months of usage of a meter with memory. Not only did HbA1C levels decline over the twelve-month period following the change of the glucose meters, but rising blood glucose values evident in the twelve-month period prior to the change of meters reversed. In addition, Strowig and Raskin (1998) found that duration of intensive therapy was significantly related to the number of daily glucose tests performed (r = 0.42, P = 0.05). Other relationships studied, such as number of visits to various team members before and after meter change, number of insulin dosage changes made before and after meter change, and total daily insulin dose before and after meter change, were not significant.

Strowig and Raskin (1998) concluded that the use of computer-generated glucose
analyses driven by data from glucometers enhanced with memory capabilities could indeed increase glycemic control, when utilized within aggressive diabetes treatment regimens. HbA₁C levels were lowered by 10% from baseline in this study after patients utilized memory meters for twelve months. The authors recommended the use of memory meters in accordance with computer-generated interpretation of blood glucose patterns as a useful tool in facilitating successful intensive diabetes therapy.

The current researcher compared several blood glucose monitoring devices for accuracy and ease of use. All four glucometers used for comparison in the current research had memory and storage capabilities. Strowig and Raskin's research provided the current researcher with valuable information regarding enhanced memory and storage capabilities as important features of these devices.

Chan, et al. (1997) examined the accuracy, precision, and user-acceptability of six recently developed SMBG devices; Accutrend, Reflolux S (Boehringer Mannheim Diagnostics, Germany), Companion 2 (MediSense USA), Glucometer GX, Glucometer IV (Miles Laboratories Elkhart) and One Touch II (LifeScan, Mountain View, CA). The purpose of the study was to evaluate several of the newer devices on the market, including some which used the "non-wipe" technology. Reflolux S and Glucometer GX were the only two studied which did not utilize this technology.

In this descriptive study, the researchers evaluated 88 venous samples from patients at the Prince of Wales Hospital, Hong Kong, during a five-week period. Extra blood was collected from every 5th patient seen in the clinic, per informed consent, during five consecutive weeks. One hundred patient samples were obtained, at 20 per week, but
only those with a hematocrit between 35 and 55 mg/dl were accepted under study criteria. Random plasma glucose concentrations were measured using the patients' blood samples, which were obtained between 10:00 a.m. and 1:00 p.m. during the patient's clinic visit.

Four SMBG machines of each of the six brands tested were randomly selected from ten new machines supplied by each company. The four machines of each type were labeled A, B, C, and D, respectively for the purpose of the study. The researchers used representatives of the local companies or their agents to test the SMBG machines "to minimize bias caused by unfamiliarity with the machines" (Chan, et al., 1997, p. 92). Each machine was calibrated for whole blood glucose values.

Blood glucose measurements for each of the devices were measured immediately after obtaining the blood samples from the patients. Hematocrit samples were collected and measured simultaneously. A third sample was obtained, centrifuged to separate plasma, and stored in ice for batch evaluation of plasma blood glucose concentration at a later time -- the reference standard measurement. The reference standard machine utilized was the Cobas Bio, which entailed a glucose oxidase method. The company representatives, who were performing the blood glucose measurements on the patient samples, were blinded as to the reference value. Two precision tests were completed every week for the first four weeks of the study on one machine of each brand (A, B, C, or D) for each of the six machines tested. This totaled eight precision tests for each brand of machine. User-acceptability was assessed via a questionnaire administered to 11 diabetes educators from six public hospitals.
Whole blood glucose values obtained from the SMBG devices were multiplied by 1.12 to correct for the difference in whole blood and plasma for comparison to the reference standard. The difference between the adjusted SMBG device value and the Cobas Bio (plasma) blood glucose value was calculated for each sample. The measurements on each of four machines of the same brand were considered repeated measures; therefore, a repeated measures of analysis of variance (ANOVA) was used to determine the variability between different machines of the same type, and to add strength to the testing of accuracy. Accuracy was determined by several factors: 1) the average difference and percentage difference between the corrected SMBG blood glucose value and the reference standard; 2) the frequency of values within ±10% of the reference value; 3) the correlation coefficient; and 4) the error grid analysis, or linear regression line. The questionnaire regarding user-acceptability included ranking each machine in descending order of acceptability for each question, or item.

Error grid analysis is a method which was originally designed to estimate diabetic patients' ability to estimate their blood sugar levels from symptomology, after a period of training and experiencing low, normal, and high blood glucose levels under controlled conditions. Zones A through E were established in a linear format, or grid, to measure the degree of difference between what patients estimated their blood glucose to be and what their actual blood glucose values were. This design has been commonly employed in more recent years to compare SMBG machine measurements of blood glucose to a reference standard to determine their degree of accuracy. Zone A represented blood glucose values within 20% of the standard or which are in the hypoglycemic range as measured by the
SMBG device and the reference standard. Zone B represented "benign errors" which are > 20% in difference from the reference standard, but that would not lead to harmful treatment decisions. Zones C, D, and E represented potentially harmful treatment decisions, indicating a clinically significant error if a SMBG device's measurements fell within this range.

After Bonferroni adjustment, P < 0.0071 was deemed inaccurate for the difference in SMBG device measurement from the reference standard or between machines of the same brand. The Glucometer IV, Companion 2, and Accutrend exhibited the least variability within a brand, as evidenced by the repeated measures ANOVA "within-brand consistency P values" of 0.255, 0.531, and 0.012 respectively. Other SMBG machines had variability within brand as follows: Glucometer GX (0.004), One Touch II (P < 0.001), and Reflolux, S (P < 0.001). The correlation coefficients between the reference standard and the SMBG device values were r > 0.95 (0.95-0.98) for all six machines. Glucometer IV had the highest frequency of adjusted SMBG machine values within 10% of the reference standard, with 83.0% within ± 10% of the reference. The rest of the machines finished in the following order, with most accurate first: 1) Accutrend (65.9%), 2) Companion 2 (56.8%), 3) Reflolux S (53.4%), 4) Glucometer GX (31.8%), and 5) One Touch II (27.3%). None of the machines studied met 1995 ADA standards for accuracy of SMBG devices, with 83% being the highest frequency of any SMBG device's measurements falling within 10% of the reference standard. The mean of reference values were: 96.0% for Accutrend, 101.6% for Companion 2, 85.8% for Glucometer GX, 98.6% for Glucometer IV, 86.3% for One Touch II, and 92.5% for Reflolux. When
using the error grid analysis, Accutrend, Companion 2, and Glucometer IV all had > 90% of measurements within Zone A. All other SMBG devices studied by Chan, et al. fell within Zone A or Zone B. One Touch II was determined to be the most "user-friendly" SMBG machine as determined by its having the highest mean score on a four-category questionnaire. The categories included features such as calibration, operator procedure, and length of training time.

Chan, et al. concluded that most SMBG devices they tested were clinically acceptable. Companion 2, Glucometer IV, and Accutrend were deemed to have the least amount of variability within brands. Glucometer IV appeared to be the most accurate, with > 80% of the SMBG measurements within ± 10% of the standard. One Touch II was determined to be the most user-friendly as determined by the 16-item questionnaire, which was administered to diabetes educators. The authors recommended that further studies be done to test these machines in the hands of patients (Chan, et al., 1997). This recommendation was the basis for the current study.

Glasmacher, et al. (1998) evaluated five SMBG devices for accuracy in the normoglycemic range. The researchers claimed that relatively few numbers in the data sets of previous studies had included blood glucose values below 100 mg/dl, but contended that in order to safeguard against the risk of hypoglycemia associated with intensive therapy in diabetes, ensuring that SMBG devices are accurate in this range is important. Glasmacher, et al. evaluated Accutrend, Precision QID, Accu-Chek III, Companion 2, and One Touch II for accuracy as compared to a laboratory reference standard on healthy subjects.
The researchers conducted their study in a three-part series, using capillary blood from \( n = 207 \) for Series 1, \( n = 214 \) for Series 2, and \( n = 49 \) for Series 3. Series 1 included testing of Accu-Chek III and Companion 2; Series 2 included testing of Accu-Chek III, Accutrend, and One Touch II; and Series 3 included testing of Precision QID and Companion 2. Capillary blood samples were obtained from subjects in a fasting state or after intensive physical exercise by trained investigators. The first and third drops of blood after lancing the subject's fingertip were used for laboratory reference measurement, while the other drops were used alternately to test the SMBG devices. The reference laboratory value was measured in duplicate using a hexokinase method, the Eppendorf ACP 4050 Analyzer. Statistical analyses included the Wilcoxon matched-pairs signed rank test to calculate the differences between the blood glucose measurement of the SMBG devices and the reference standard, and ANOVA to compare the relative difference of the SMBG devices' blood glucose values from the reference standard. The number within 10% of the laboratory standard was compared with the Chi-square test. P values were two-sided and \( p \) values less than 0.05 were considered significant. No calibration of SMBG machines or adjustment factors were performed prior to comparison of SMBG value to reference standard, presumably since capillary blood was used for both measurements.

Wilcoxon matched-pairs values were referred to as "actual deviations" of SMBG devices from the laboratory standard, and ANOVA values were referred to as "relative deviations." Actual deviation results were as follows: One Touch II 12.5 mg/dl, Companion 2 10.0 mg/dl, Accu-Chek III 4.5 mg/dl, Precision QID 3.0 m/dl, and Accutrend -1.5 mg/dl. Relative deviation results included: OneTouch II 15.2 %,
Companion 2 14.1%, Accu-Chek III 7.5%, Precision QID 7.1%, and Accutrend 5.5%.

The percentage of SMBG measurements within ± 10% of the reference standard were as follows: One Touch II 22%, Companion 2 41%, Accu-Chek III 61%, Precision QID 61%, and Accutrend 73%. Based on the 1995 ADA Consensus Statement guideline for accuracy of SMBG devices to be within 10% of laboratory reference standards, Glasmacher, et al., concluded that Accutrend, Precision QID, and Accu-Chek III could be recommended for most patients performing SMBG who are on intensive insulin therapy. Glasmacher, et al.’s (1998) study was germaine to the current research because both the current researcher and Glasmacher believed that the inclusion of samples in the normoglycemic range is an important aspect of a comparison study of SMBG devices.

Selection of the appropriate statistical tests for evaluation of SMBG devices has been the subject of some controversy. Poirier, et al. (1998) compared statistical and clinical methods of evaluation of five SMBG meters to determine which methods, if any, were best suited to this type of application. The five SMBG devices studied were: Glucometer IV, Accuchek-Easy, One Touch Basic, Exactech Companion, and Supreme.

The participants included 225 patients with DM treated with insulin therapy who had serum creatinine ≤ 110 umol/l, hematocrit between 35% and 55% and who were not being treated with sulfonylureas, biguanides, paracetamol, aspirin, or vitamin C. Patients had two samples of capillary blood taken from two different fingers for measurement on one of five meters randomly assigned for that purpose. The patients were fasting when the samples were collected. A venous sample was then collected and used for measurement of plasma glucose (the reference standard) and hematocrit. The plasma glucose was
measured using a Beckman CX5 analyzer. Accuracy was determined by four different methods of comparison between the two meter readings and the reference standard: 1) Spearman’s correlation, 2) Wilcoxon’s paired test, 3) percentage of values within the 10% interval of the reference standard value, and 4) error grid analysis (x-axis: reference blood glucose; y-axis: SMBG blood glucose). The researchers were blinded to the names of the SMBG machines, with the machines concealed and labeled I-V, to decrease bias. Statistical significance was defined as $p < 0.05$.

The Spearman’s correlation and Wilcoxon’s paired tests were similar in value for all five machines, ranging from $r = 0.94$ to 0.98 for the first measurement and $r = 0.92$ to 0.99 for the second measurement. In addition, the Wilcoxon's paired test showed statistical significance for each meter except one (meter III on the second measurement). However, there was a much greater variance among the accuracy of the five devices with both the percentage within the 10% interval method and the error grid analysis. The five meters were divided into all three categories when using the percentage within the 10% interval method: good (meters I and II, both > 60% for both measurements), acceptable (meters III and IV, 60 % and 51 % for the first measurement and 53 % and 51 % for the second measurement), and unacceptable for clinical use (meter V, 35% for the first measurement and 37% for the second measurement). Error grid analysis produced similar results to that of the interval method, with > 97% of the two measurements in Zone A for meters I and II; 82 % of the two measurements in Zone A for meter V; and a majority in Zone A, but some in Zone B and one value in Zone C for meters III and IV (exact values not reported).
Poirer, et al. (1998) concluded that the coefficient of correlation test, which is commonly used to determine the accuracy of SMBG devices, is inappropriate, as is the Wilcoxon’s paired test. Instead, the researcher recommended the percentage of SMBG values within the 10% interval and the error grid analysis for determination of accuracy of these devices. Poirier et al. (1998, p. 1921) stated that “it should be stressed that most investigators and manufacturers assume that a perfect correlation indicates a small amount of error in the SMBG system. In fact, this assumption is not correct, because the r coefficient measures the extent to which two sets of data fit a linear relationship, not the consistency between the data.” Poirer, et al.’s (1998) research provided the current researcher with information regarding the appropriate statistical methods to use for comparison studies of SMBG devices.

In summary, this review of literature revealed several salient points regarding the comparison of SMBG meters. First, The DCCT Research Group (1993) and The UKPDS Group (1998) clearly established the importance of close monitoring of blood glucose in patients with type 1 and type 2 DM, respectively, in order to decrease comorbidity associated with DM. The knowledge that decreasing complications associated with DM is possible with intensive therapy and close monitoring of glycemic values, in essence, means patients and providers need assurance of accurate and user-friendly SMBG machines. In addition, Johnson, et al. (1995), Strowig & Raskin (1998), Chan, et al. (1997), and Glasmacher, et al. (1998) compared blood glucose meters with varying features and using various study designs for accuracy, precision, user-acceptability, and effectiveness when used with diabetes computer management systems. These four research groups provided
the current researcher with knowledge of what previous researchers had found with regard to SMBG devices, a basis for comparison of the current researcher’s results, and suggestions for future research. Finally, Poirer, et al. (1998) provided a comparison of statistical and clinical evaluation methods for comparing accuracy of SMBG devices. Poirer, et al. suggested that the percentage of SMBG meter readings within the 10% interval and the error grid analysis method were the two most appropriate methods for comparing SMBG meters.

The researcher concluded after a review of the literature, that patients, the primary users of SMBG machines, had been left out of the testing process in previous SMBG device comparison studies. Chan, et al. (1997) recommended the use of patients in testing SMBG machines in future studies. The current researcher sought to determine if there was a difference among four SMBG devices with respect to their degree of accuracy as compared to a reference standard and their ease of use as rated by patients.
Chapter III

The Method

This study was conducted to determine if there was a difference in the clinical performance of four SMBG devices with respect to two variables: accuracy and ease of use. Prior researchers who studied SMBG performance have lacked patient involvement in evaluating these machines. As patients are the primary users of these machines, the researcher believed it was essential that patients be included in the testing process. This chapter provides information regarding the design, the variables, the setting, population, and sample of the study, as well as methods of data collection and analysis, and limitations of the study.

Design of the Study

A descriptive design was selected for this study. A prospective, non-randomized format was employed because the study was a comparative analysis of the clinical performance of medical equipment. No intervention was conducted; therefore, no randomization of the sample subjects was necessary. However, by randomizing the SMBG devices and the reference standard reading for each patient, the negative bias associated with order within the testing process was decreased.

Variables

There are many potential variables associated with the performance of SMBG
machines. The current researcher chose to evaluate two variables of interest, relative accuracy and ease of use, on four brands of SMBG machines. The independent variable for this study was the SMBG device, and the dependent variables examined were the comparative accuracy and ease of use of the devices.

Setting, Population and Sample

Setting. The setting was an outpatient endocrinology clinic associated with the University of Tennessee, (UT). The clinic was established in 1973 and has expanded to include six faculty physicians and one nurse practitioner who practice at the clinic. The physicians and nurse practitioner see approximately 20-30 patients per day, who range in age from 18 to 95 years, with median age of 60 years, and who represent all socioeconomic groups, as well as all races. The study was conducted in the conference room of the clinic.

Population. Persons between the ages of 20 and 70 and who met the population inclusion criteria as described in the operational definition of patient were included in the targeted population. Approximately 50-60 charts were reviewed in order to obtain the sample, with approximately 15 failing to meet inclusion criteria and 2 refusing to participate.

Sample. The target sample was to include the first 30 patients who met the inclusion criteria and were willing to participate. The actual sample consisted of N = 28 participants.

The sample type was non-probability, convenience. The researcher obtained a list of patients scheduled for clinic visits with the assistance of clinic personnel. Charts were
reviewed to exclude ineligible patients. The researcher approached eligible patients during a clinic visit, verified eligibility through questioning, and requested that they participate in the study on the basis of informed consent. The informed consent form provided information regarding the study, procedures to be followed, potential risks and benefits, and lack of cost or payment for participation (see Appendix A). The researcher made clear that participation was completely voluntary, and subjects were free to withdraw from the study at any time, without change in their usual care, medications, or relationship with the clinic. The consent form included the issue of confidentiality, as did the letter to the physicians at the clinic. All subjects who initiated participation in the study completed the study; there were no subjects who withdrew from the study. All charts remained secure and all patient information was kept confidential, with initials rather than names being used in the data collection and analysis process.

Methods of Data Collection

Instrumentation. Instruments utilized in the study were the four SMBG devices, the HemoCue B-Glucose Analyzer (HemoCue) as the reference standard for blood glucose measurement, and a Visual Analogue Scale (VAS) (see Appendix B) used for participant determination of ease of use of the SMBG devices.

Blood glucose measurement. Blood samples obtained by the participants using the finger stick method were measured for blood glucose using each of the four SMBG devices. The manufacturer’s guidelines for glucose measurement were followed, with participants reading the user instructions for each machine prior to testing their blood glucose. The HemoCue and all SMBG machines were calibrated as per manufacturer
guidelines, and each device’s calibration values fell within the recommended range for the
time period. All blood glucose values from SMBG devices as well as the HemoCue were
expressed as mg/dl. For each subject, a blood sample from the finger stick used for the
SMBG machine reading just prior to the HemoCue’s random assignment was taken, using
a cuvette, by the current researcher for HemoCue blood glucose measurement within 40
seconds of pricking the patient’s finger. This method was in accordance with the
HemoCue manufacturer guidelines.

The HemoCue cuvette served as a pipette, reaction vessel, and a measuring
cuvette. The cuvettes contained oxidizing agents, emulsifying agents, and agents that
inhibit glucokinase. These agents worked in concert to stabilize glycolosis of the sample,
thus decreasing the variable of metabolism, or glycolosis, when comparing the SMBG
machine value with the HemoCue value. The HemoCue is factory calibrated with a wet
chemical glucose dehydrogenase method using hemolyzation and deproteinization. The
chemical reactions that take place in the cuvette, including coloration of the material, are
read by the HemoCue device once the cuvette is placed in the cuvette holder on the
machine. After the reaction is complete, the HemoCue quantifies the color of the sample
photometrically with a two wavelength method and displays the blood glucose
measurement on the display (HemoCue Operating Manual, 1991). This method is called
colorimetry.

**Ease of Use Measurement.** The participants rated the SMBG devices with regard
to ease of use using a VAS. A VAS is a straight line measuring from 0 mm to 100 mm in
length, labeled with the extreme values to be evaluated, and used to measure subjective
sensations of patients (Polit & Hungler, 1995). In the context of this study, ease of use was measured by assigning the value of 0 and the descriptor “Very Easy to Use” to the left endpoint of a 100 mm horizontal line and the value of 100 and the descriptor “Very Difficult to Use” to the right endpoint of the same 100 mm horizontal line. Subjects were asked to place a mark on the line corresponding with their perception of how easy the machine was to use. A ruler was then placed on the line to measure how far the mark was from the left end of the line. The distance was measured in millimeters, and the response was scored with that numerical value. For example, a response of 8 mm corresponded to the eighth percentile.

Visual analog scales (VAS) have been demonstrated to be reliable (Price, et al., 1983, 1987), generalizable (Price & Harkins, et al., 1987), and internally consistent measures of patient perception of feelings, namely pain (Price, et al., 1983). The current researcher chose the VAS scale for patient’s ease of use measurement to decrease patient inhibition in assigning a numerical value to their subjective feeling of ease of use of the SMBG devices under study.

**Procedures.** Institutional Review Board (IRB) approval was granted for the conduction of the study from Mississippi University for Women (see Appendix C). Physicians at the endocrinology clinic were contacted (see Appendix D), and permission was granted to conduct the study pending approval from The University of Tennessee, (UT) IRB. UT’s IRB granted approval (see Appendix E) and the study was initiated.

Prior to initiation of the study, patients were required to sign the aforementioned informed consent form, which described the purpose, risks, and benefits of the study. All
five machines used to measure blood glucose, four SMBG devices and the reference standard, were assigned a numerical value, one through five. Numerical assignments were as follows: 1 = Precision QID, 2 = AccuChek Advantage, 3 = One Touch Profile, 4 = Glucometer DEX, 5 = HemoCue (reference standard). The machines, one through five, were randomized so that each participant had a different order in which to obtain blood glucose measurement from each of the machines. The data were collected over a two week period and involved the following procedure:

1. The patient presented to the clinic for his/her scheduled appointment. The study and the VAS rating procedure were explained, and any questions regarding the study were answered. Informed consent was obtained.

2. The SMBG devices were displayed in a linear format with instructions for usage next to each device. A VAS was in place next to each SMBG device as well.

3. The participant read the instructions for the first SMBG device per the random order of assignment for that participant. Then the participant followed the SMBG device’s instructions to obtain a blood glucose measurement. The patient recorded the blood glucose measurement obtained from the SMBG device on the VAS form placed next to the device, on the line labeled “BG Value.”

4. As per random assignment of the five machines, the researcher obtained a sample from the patient's pricked finger using a HemoCue cuvette and placed the cuvette in the cuvette holder of the HemoCue B-Glucose
Analyzer for reference standard measurement. The HemoCue was located adjacent to the conference room in the clinic laboratory.

5. The patient rated the SMBG device with regard to ease of use on the VAS next to each machine and before moving to the next machine.

6. The patient followed steps 3-5 for each SMBG device.

The data were collected as per the above procedure for N = 28 subjects, and the data were analyzed.

Methods of Data Analysis

SMBG devices utilize capillary, or whole, blood for measurement of blood glucose. Capillary blood glucose is 1.12 times lower than plasma blood glucose (Voss, et al., 1996, vol. 27(8)). In older SMBG systems, the value obtained by the SMBG device was multiplied by 1.12 for conversion to plasma glucose for comparison. Now many SMBG devices have an internal conversion (multiplying the value by 1.12), and are referred to as “plasma referenced.” Three of the four SMBG devices used for this study were plasma referenced. The HemoCue, which was the reference standard for this study, reads capillary blood glucose. Therefore, a conversion to capillary blood glucose was necessary for three of the four SMBG devices, which had internal conversions to plasma values. The raw blood glucose measurements obtained by each participant for machines 1, 2, and 4 were divided by 1.12, in order to convert them to capillary, or whole blood glucose values.

Descriptive statistics were utilized to describe the frequency of occurrence with respect to sex and race of the subjects, as well as the mean age of the subjects. Repeated
measures analysis of variance (ANOVA), or one-within-subjects ANOVA, was used to test the null hypotheses: 1) there is no significant difference among the degree of accuracy of four SMBG devices when compared to a reference standard, and 2) there is no significant difference among the perceived ease of use of four SMBG devices as determined by patient ratings. Repeated measures ANOVA was appropriate because the researcher was testing the difference from the standard for "three or more measures of the same dependent variable for each subject," (Polit and Hungler, 1995, p. 418). Acceptable level of significance was set at $p \leq 0.05$. Following ANOVA, post hoc analyses, Dunnett's t test for accuracy and Tukey's procedure for ease of use, were utilized to determine which machines were different. Please note that exact $p$ values are not reportable under Dunnett's t test or Tukey's procedure. $p$ values are listed as significant below a certain value ($p \leq 0.05$), but no exact values are given per SAS. The frequency of values within the 10% interval of the reference standard was also reported for each device, as per the American Diabetes Association recommendation (ADA, 1995). The recommended error grid analysis was not utilized due to the small sample size of this study. Error grid analysis requires a large sample size for accurate definition of Zones A - E.
Chapter IV

The Findings

The purpose of this descriptive, prospective comparison study was to determine if four SMBG devices differed with respect to their average degree of accuracy when compared with a reference standard. Further, the devices' average perceived ease of use was rated by patients. A description of the sample and results of the data analysis are presented in this chapter. The statistical package used for data analysis was SAS version 7.0 on Windows 98, and statistical significance was defined as $p \leq 0.05$.

Description of Sample

The sample included 28 participants in an endocrinology clinic at The University of Tennessee. Demographic data were collected and analyzed. The SAS frequency procedure and the SAS means procedure were utilized to obtain descriptive statistics. Of the 28 participants, nine were African American (32.14%) and 19 were Caucasian (67.86%). Gender was balanced within the sample with 16 female participants (57.14%) and 12 male participants (42.86%). Ages of the participants ranged from 23 to 69 years, with a mean age of 48.36 years. Hematocrit readings for the participants ranged from 35.5 mg/dl to 44.8 mg/dl. Serum creatinine levels for the participants ranged from 0.7 mg/dl to 1.3 mg/dl.
SMBG Machine Raw Data

Accuracy. The raw blood glucose (RBG) measurements obtained by each participant for machines (1) Precision QID, (2) AccuChek Advantage, and (4) Glucometer DEX were divided by 1.12, in order to convert them back to capillary, or whole blood glucose values, as described in Chapter III. These converted values were referred to as the scaled blood glucose (SBG). The mean SBG values for each SMBG device, as well as the reference standard, are listed in Table 1. The SBGs were tested for normality of data using the SAS univariate procedure. Subjected to the Shapiro-Wilks test, the data did not appear to be distributed normally. Consequently, data were transformed to their natural logarithm. Following transformation, the researcher determined that there were no significant departures from normality (p > 0.05). After SBGs were obtained, they were compared to the reference standard value, blood glucose number 5, for each participant. This was done using a repeated measures ANOVA. The frequency of values within the 10% interval of the reference standard are as follows: machine (1) Precision QID 46.43%, machine (2) AccuChek Advantage 67.86%, machine (3) One Touch Profile 75%, and machine (4) Glucometer DEX 64.29%.

Ease of Use. The mean ease of use values for each SMBG machine are listed in Table 2. No ease of use value is listed for machine 5, the reference standard, since the researcher performed this test on the HemoCue for each subject. Again, the researcher determined using the Shapiro-Wilks test that the data were not distributed normally, and again the natural logarithm transformation was employed. Following the transformation, the data appeared normal (Shapiro-Wilks p values > 0.05).
### Table 1

**Scaled Raw Blood Glucose (BG) Values Expressed as mg/dl Using Descriptive Statistics**

<table>
<thead>
<tr>
<th>SMBG Machine</th>
<th>M</th>
<th>SD</th>
<th>min(^a)</th>
<th>max(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Precision QID</td>
<td>130.93</td>
<td>53.22</td>
<td>56.00</td>
<td>246.00</td>
</tr>
<tr>
<td>2) AccuChek Adv</td>
<td>142.11</td>
<td>57.35</td>
<td>58.00</td>
<td>268.00</td>
</tr>
<tr>
<td>3) One Touch Profile</td>
<td>153.71</td>
<td>73.27</td>
<td>54.00</td>
<td>373.00</td>
</tr>
<tr>
<td>4) Glucometer DEX</td>
<td>152.82</td>
<td>65.47</td>
<td>66.00</td>
<td>374.00</td>
</tr>
<tr>
<td>5) Ref Std (HemoCue)</td>
<td>148.29</td>
<td>70.35</td>
<td>51.00</td>
<td>340.00</td>
</tr>
<tr>
<td>N = 28</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: \(^a\) = minimum BG \(^b\) = maximum BG

One participant, subject number six, did not rate machine 4 for ease of use; that is, the VAS was left unmarked when the data were reviewed for analysis. Therefore, a repeated measures ANOVA with mean substitution was performed, operating on data with mean replacement for the missing case. The overall average numerical rating for ease of use on machine 4 was 63.2.

### Results of Data Analysis

Data were collected to test two omnibus null hypotheses. The data were subjected to repeated measures ANOVA statistical analyses and post hoc analyses.
Hypothesis $A_{12}$. The first directional hypothesis was: The average blood glucose (BG) values measured by four SMBG devices are identical to the average blood glucose value measured by a reference standard. Since $F(4,108) = 14.34$, ($p < 0.0001$), the researcher determined that significant differences in degree of accuracy existed among the machines. Thus, null hypothesis 1 was rejected (see Table 3). To identify which machines differed from the reference standard, Dunnett’s t test was used to compare the natural logarithm of each machine’s blood glucose readings against the standard (see Table 4). Machine (4) Glucometer DEX had a significantly higher mean BG value, and machine 1) Precision QID had a significantly lower mean BG value than the average reference standard measurement.
Table 3

Analysis of Variance of the Natural Logarithm of Blood Glucose Values of Four SMBG Machines

<table>
<thead>
<tr>
<th>Source</th>
<th>df</th>
<th>MS</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine</td>
<td>4</td>
<td>0.1081</td>
<td>14.34*</td>
</tr>
<tr>
<td>Subject</td>
<td>27</td>
<td>0.8701</td>
<td>115.38</td>
</tr>
<tr>
<td>Error</td>
<td>108</td>
<td>0.0075</td>
<td></td>
</tr>
</tbody>
</table>

*p < 0.0001

Table 4

Dunnett’s t Test for Natural Logarithms of Blood Glucose Values of Four SMBG Machines Compared with the Reference Standard

<table>
<thead>
<tr>
<th>Machine Comparison</th>
<th>Difference Between Means</th>
<th>Simultaneous 95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucometer DEX with Ref Std</td>
<td>0.05869</td>
<td>0.00117 0.11621*</td>
</tr>
<tr>
<td>One Touch Profile with Ref Std</td>
<td>0.04183</td>
<td>-0.01569 0.09935</td>
</tr>
<tr>
<td>AccuChck Adv with Ref Std</td>
<td>-0.01610</td>
<td>-0.07362 0.04142</td>
</tr>
<tr>
<td>Precision QID with Ref Std</td>
<td>0.10025</td>
<td>-0.15778 -0.04273*</td>
</tr>
</tbody>
</table>

*p < 0.05

Hypothesis $A_2$. The second directional hypothesis was: The averages of the perceived ease of use of four SMBG devices, as determined by patient ratings, are equivalent. Since
F(3,81) = 7.97, (p = 0.0001), the researcher determined that perceived ease of use for the four machines differed. Thus, hypothesis 2 was rejected (see Table 5). To specify which machines were nonequivalent, Tukey's pairwise post hoc procedure was employed. The Glucometer DEX, machine (4), was perceived to be more difficult to use than machine (1) Precision QID, machine (2) AccuChek Advantage, and machine (3) One Touch Profile. Machines (1), (2), and (3) were equivalent with regard to perceived ease of use (see Table 6).

Table 5

Analysis of Variance of the Natural Logarithm of Ease of Use Values of Four SMBG Machines

<table>
<thead>
<tr>
<th>Source</th>
<th>df</th>
<th>MS</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine</td>
<td>3</td>
<td>6.7988</td>
<td>7.97*</td>
</tr>
<tr>
<td>Subject</td>
<td>27</td>
<td>1.7204</td>
<td>2.02</td>
</tr>
<tr>
<td>Error</td>
<td>81</td>
<td>0.8531</td>
<td></td>
</tr>
</tbody>
</table>

*p = 0.0001
Table 6

Tukey’s Studentized Range for Natural Logarithms of Ease of Use Values of Four SMBG Machines

<table>
<thead>
<tr>
<th>Machine Comparison</th>
<th>Difference Between Means</th>
<th>Simultaneous 95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucometer DEX with Precision</td>
<td>0.8407</td>
<td>0.1932</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.4883*</td>
</tr>
<tr>
<td>Glucometer DEX with One Touch</td>
<td>0.9951</td>
<td>0.3475</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.6426*</td>
</tr>
<tr>
<td>Glucometer DEX with AccuChek</td>
<td>1.0663</td>
<td>0.4188</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.7139*</td>
</tr>
<tr>
<td>Precision with One Touch</td>
<td>0.1543</td>
<td>-0.4932</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.8019</td>
</tr>
<tr>
<td>Precision with AccuChek</td>
<td>0.2256</td>
<td>-0.4220</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.8731</td>
</tr>
<tr>
<td>One Touch with AccuChek</td>
<td>0.0712</td>
<td>-0.5763</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.7188</td>
</tr>
</tbody>
</table>

*p < 0.05
Chapter V

The Outcomes

Researchers have established that close monitoring of blood glucose in patients with DM, with the goal of near euglycemia, decreases the risk of complications. Daily use of SMBG devices is a way of life for many patients with DM. Treatment decisions are made based on the results produced by these devices. It follows, then, that health care providers, including physicians and nurse practitioners, have a responsibility to understand the SMBG devices prescribed for these patients. This understanding includes knowledge of how accurate these machines are and how easy (or difficult) they are to use.

Although studies have been done comparing SMBG devices for both accuracy and ease of use, previous researchers have not utilized patients with diabetes in the testing process. In a meticulous review of the literature, the researcher found no studies in which patients themselves were asked to test the SMBG machines to obtain their own blood glucose (BG) or to rate the machines for ease of use.

The current researcher aimed to determine if there was a difference among four SMBG devices with respect to accuracy as compared to a laboratory standard and ease of use as determined by patients' ratings. Pender's Health Promotion Model (HPM) was utilized to guide this comparative study.

This chapter includes a summary and discussion of the findings of the study.
Conclusions, implications for nursing, and recommendations for future research also are presented.

Summary of Findings

The sample consisted of 28 participants diagnosed with DM and followed by staff at an endocrinology clinic associated with the University of Tennessee (UT). The age range of the participants was 23 to 69 years. Ethnicity was predominantly Caucasian (67.86%), and gender was balanced (57.14% female, 42.86% male). Hematocrit (HCT) readings and renal function (SrCr) were within the range as per SMBG machine requirements for accurate results, (HCT range of sample = 35.5 mg/dl to 44.8 mg/dl; SrCr range of sample = 0.7 mg/dl to 1.3 mg/dl).

The One Touch Profile had the highest number of blood glucose (BG) values within the 10% interval of the reference standard, with 75% falling within this range. The frequency of the other SMBG devices’ values within this range were as follows: AccuChek Advantage 67.86%, Glucometer DEX 64.29%, and Precision QID 46.43%.

Both null hypotheses were rejected, indicating that there was indeed a difference among the four SMBG devices with respect to both comparative accuracy and ease of use. The first directional hypothesis was: the average blood glucose values measured by four SMBG devices were identical to the average blood glucose value measured by a reference standard. Dunnett’s t test was used to compare the natural logarithm of each machine’s BG readings against the standard. Glucometer DEX had a significantly higher mean BG value, and the Precision QID had a significantly lower mean BG than the mean BG measured by the reference standard. The second directional hypothesis was: the
averages of the perceived ease of use of four SMBG machines were equivalent. Tukey’s pairwise post hoc procedure was employed to identify the machine(s) which were different. The Glucometer DEX was shown to be the most difficult SMBG device to use, according to patients, with the other three machines equally easy (or difficult) to use.

Discussion

The findings from this study led the researcher to believe that there was variability among SMBG devices with respect to accuracy and ease of use. A comparison of previous studies validates these findings, and evokes further discussion. The greatest gap in knowledge regarding SMBG device performance is the patient’s experience with the use of these machines. For comparison studies of SMBG devices to be truly meaningful, use of patients in the evaluation of these machines is essential, in order for the results to be applicable to real life situations (Chan, et al., 1997; Voss, et al., 1996, vol. 27(8)). Ease of use, or user-acceptability, of SMBG devices, as perceived by patients, will likely facilitate adherence to SMBG, which will decrease the risk of complications associated with DM.

Noteworthy is the variability within prior studies with respect to the accuracy of SMBG devices as measured using two or more methods of comparison. For example, Chan, et al. (1997) found the Companion 2 SMBG device to be accurate when using the ANOVA comparison, but only 56% of the Companion 2 blood glucose measurements fell within the 10% interval of the reference standard. Also, Glasmacher, et al. (1998) determined that 41% of blood glucose values measured by the One Touch II SMBG device fell within 10% of the reference standard, as compared to Chan et al.’s (1997) finding of 56.8% for this device. The current researcher found less variability between the
two methods used in this study to determine SMBG device accuracy. The Glucometer DEX, which was determined to have significantly higher average BG readings than the reference standard, also was found to have the third lowest percentage of SMBG readings within the 10% interval. The Precision QID's readings were significantly lower than the reference standard and produced the lowest percentage of BG values within the 10% interval. Finally, the AccuChek Advantage and the One Touch Profile were determined to be relatively accurate using Dunnett's t test and because they produced the two highest percentage of readings within the 10% interval of the reference standard. The results found by the current researcher do not clarify the issue of variability regarding the accuracy of SMBG machines. These results do, however, add to the scientific knowledge base regarding accuracy for newer meters with increased storage capabilities when BG is measured by patients on these machines.

When interpreting the results of this study, the researcher is mindful that other variables may have impaired the accuracy of the results. Prior studies used technicians or other trained health care personnel to measure BG of patient blood samples on SMBG devices, whereas the current researcher used patients for this measurement. Additionally, there may have been variability in the quality of the test strips used, even though the lot number was the same. Lastly, although remote, there may have been variability between machines of the same brand; that is, within brand consistency was not studied.

The method chosen to assess the accuracy of these SMBG devices is controversial and has not been standardized. Based on findings from their evaluation of four statistical methods used to evaluate five SMBG devices for accuracy, Poirer, et al. (1998) suggested
that the coefficient of correlation and the Wilcoxon’s paired test, statistical methods commonly used to evaluate these devices, were inappropriate. Poirer, et al. (1998) recommended the use of the error grid analysis, developed by Clarke and colleagues, and the percentage of blood glucose values measured by the SMBG device that fall within the 10% interval of a reference standard blood glucose measurement. The current researcher used the repeated measures ANOVA, and the percentage of values within the 10% interval, which was addressed by Poirer, et al. (1998). The error grid analysis method was considered, but was determined by the researcher to be inappropriate due to the small sample size of this study. SMBG devices are used by millions of patients with DM every day, and many make decisions regarding insulin dosage based on the results of these machines. The researcher believes this underlines the rationale for ensuring that these machines provide accurate readings and for identifying which ones are inaccurate.

Accuracy of SMBG machines leads to correct dosing of insulin, which leads to better control of DM and less chance for complications. The scientific and medical community have a responsibility to come to an agreement regarding which statistical methods are appropriate to determine the accuracy of SMBG devices.

Regarding the ease of use of SMBG devices, Chan et al. (1997) evaluated the user-acceptability of six SMBG devices, none of which were studied by the current researcher. However, Chan, et al. (1997) used diabetes educators to determine ease of use, rather than patients, and recommended that future studies use patients to evaluate the devices. The current researcher evaluated four SMBG devices and found three to be equally easy to use as rated by patients, with the Glucometer DEX rated by patients to be more difficult
to use than the other three meters. To the researcher's knowledge, the current study is the only study in which patients with DM were asked to measure their own BG on several SMBG machines for comparison to a reference standard and to rate the machines for ease of use. Thus, these findings cannot be accepted nor refuted. In an attempt to decrease any bias from the researcher, no orientation to the machines was given to the subjects. Rather, the researcher had the subjects read and follow the instructions for each device. There may have been variability among subjects' ability to read and understand instructions, as well as in their ability to use the information to perform the BG test. However, each subject had an unlimited amount of time in which to do the required task, and all were given the same manufacturer instruction booklets and cards to read. The researcher determined that there was variability among patient ratings of ease of use of the meters within machines using the VAS tool, with standard deviations ranging from 26.0% to 30.73% for the meters studied. This variability may indicate poor validity of the tool for SMBG measurements. Future researchers may want to incorporate a qualitative portion in their studies, to include patient comments regarding features that make an SMBG device more difficult or easy to use.

Pender's Health Promotion Model (HPM) (1987) was used as the theoretical basis for this study. The HPM is used to identify factors that influence individuals' decisions to participate in health-promoting behaviors, such as SMBG, based on a cue to action. Cues to action could be meter accuracy and ease of use. Cognitive-perceptual factors, or primary motivational mechanisms, influence behavior. The belief that a particular SMBG device is accurate will lead a health care provider to prescribe that machine for his/her
patients. Conversely, a patient’s belief that an SMBG is accurate may lead that individual to request a certain SMBG from his/her provider. In the current study, the researcher noticed that patients began asking what the reference standard reading was and making comments regarding the machines’ accuracy, as compared to the standard. In addition, the researcher noticed that when patients believed that a machine appeared easy to use, they were less hesitant to sit down, read the instructions, and use the machine for BG testing. This observation led the researcher to believe that accuracy and ease of use may indeed be modifying factors in a DM patient’s decision to adhere to SMBG testing.

Findings from the current study support the HPM since the determination of accuracy and ease of use of SMBG devices assist the FNP in encouraging competent self-care for their patients through prescription of and instruction regarding accurate, easy-to-use SMBG devices. Increased adherence to SMBG, due to accurate, easy-to-use meters will lead to better glycemic control, therefore decreasing patients’ risk of complications.

Limitations

Generalization of the results must be done with caution, as some shortcomings are associated with the methodology of this study. First, the small sample size limited the choice of statistical methods appropriate for comparing the SMBG devices. The small sample size also impacted the representation of each glycemic range (hypoglycemic, normoglycemic, and hyperglycemic) in the study. Each range of values was represented, but the majority of the samples were in the normal and moderately hyperglycemic range. Similarly, a larger sample size would have provided more statistical power to assess the ease of use of the SMBG devices by patients. Considering the parameters of time and
patient access, the researcher maximized resources to accomplish this pilot study. The researcher found it to be unacceptable to ask the subjects to lance their fingers more than four times, leading to an inability to measure blood glucose values in duplicate for each SMBG device. This decision may affect the repeatability of the measures. The extraneous variables of time since last meal, user error, and glycolysis between measurements on SMBG machines may affect accuracy and reliability of the measurements. The researcher used the control of time to decrease the chance of the interference of glycolosis. The reference standard was measured within 40 seconds of one of the blood glucose readings done by the subject, as per random order for each subject. The presence of medications whose effect on blood glucose monitoring has not been established may be an unknown extraneous variable. Due to the current researcher’s inability to request extra lab studies to be done, the range of time in which hematocrit and serum creatinine were measured was within 1 week to 6 months prior to the study implementation. Stricter control of time frame between obtaining these lab values and conducting the study would be more desirable for study strength.

Conclusions

In conclusion, the Precision QID and the Glucometer DEX were considered inaccurate, with Precision QID values measuring lower than the reference standard and Glucometer DEX values measuring higher than the reference standard. The One Touch Profile and AccuChek Advantage were considered acceptable by this method. Using the 10% interval comparison method for accuracy, the One Touch Profile had the highest percentage of values in the 10% interval, with a value of 75%. The AccuChek Advantage...
was the second most accurate machine using this comparison, with 67.9%, followed by Glucometer DEX at 64.3%, and finally Precision QID with 46.4% of measurements within the 10% interval. Also, the Glucometer DEX was considered to be the most difficult SMBG machine to use, as determined by patient ratings using ANOVA comparison and Tukey's Procedure. Since prior researchers have used different machines and statistical analyses for their comparison studies, these conclusions cannot be supported nor refuted. The HPM is an appropriate model for application to SMBG. In the encouragement of SMBG for DM patients, nurse practitioners want to prescribe accurate and user-friendly meters to decrease barriers to this health-promoting behavior. Since the One Touch Profile and the AccuChek Advantage were found to be accurate and easy to use, the researcher recommends the prescription of these two meters for nurse practitioners in their practice when encouraging the self-care behavior of SMBG for their patients.

Implications for Nursing

The findings from the present study have implications for nursing research. No previous studies were found which utilized patients in the evaluation process of SMBG machines; therefore, the current study may evoke future researchers to build upon its findings. Considering the millions of finger sticks performed daily by patients with DM in an attempt to decrease the risk of complications through improved glycemic control, further research investigating the accuracy and ease of use of SMBG machines is clearly warranted. This further research must involve patients, as they are the users of these machines.

Nursing education should address this important aspect of self-care, SMBG, with
respect to the patient with DM. The current study’s findings provide information regarding several relatively new SMBG devices which have not been studied in many previous studies: Precision QID, Glucometer DEX, and One Touch Profile. This information could be included in the curriculum taught to graduate, as well as undergraduate, nursing programs. Continuing education regarding SMBG for nurse practitioners in practice would also be appropriate and useful.

Implications for nursing theory and practice from this study are interconnected. One aspect of Pender’s HPM of particular interest is the concept of promotion of competent self-care in individuals through education (Pender, 1987). Pender’s model can be used to help patients with DM identify and understand their beliefs about SMBG and factors affecting their level of participation in SMBG. The family nurse practitioner may use his/her knowledge of the patient’s beliefs and influencing factors to encourage the patient to commit to a plan of action regarding SMBG which is individualized to meet the patient’s needs (Tillett, 1998). The family nurse practitioner prescribes SMBG devices for his/her patients with DM in practice. The findings from this study add to the family nurse practitioner’s knowledge base for writing these prescriptions.

Some of the primary motivational mechanisms a family nurse practitioner may encounter with their patients are importance of health, perceived benefits of health-promoting behaviors, and perceived barriers to health-promoting behaviors. For example, some patients with DM may be very motivated to engage in SMBG because they hold their health in high value and want to avoid complications of DM by keeping their glucose in tight control. Those same patients may find that competing demands, such as multiple
young children in the home, hinder their adherence to SMBG. For some, accuracy and ease of use of their SMBG device could be considered either a benefit or barrier to engaging in the activity of SMBG.

Implications for nursing administration gleaned from this study include addition to the knowledge base from which decisions are drawn with respect to which SMBG devices to use in hospital settings or in outpatient office settings. Caution should be used with this implication, as hospital settings often use different models of SMBG devices than those intended for home use.

Recommendations

**Research.** Recommendations for future research in the area of SMBG devices include:

1. Replication of this study with controlled time frames between measurement of lab values required for eligibility for the study and data collection, and use of a tool which allows for qualitative measurement of ease of use.

2. Conduction of research involving cohorts for each SMBG device, with a follow-up study one month after patients' use of the SMBG device at home.

3. Replication of this study with a larger sample size, inclusion of a correlation of the values within the 10% range and the repeated measures ANOVA statistical method, as well as the error grid analysis method. A larger sample size would also allow for representation, in larger numbers, of each glycemic range of values (hypoglycemic, normoglycemic, and hyperglycemic).

**Practice.** Recommendations for family nurse practitioners in practice include:
1. Continuing education for nurse practitioners in practice that includes study findings regarding accuracy and ease of use of SMBG devices to assist nurse practitioners in choosing the appropriate SMBG device to prescribe for different patient groups.

2. Inclusion of comparison study findings regarding the accuracy and ease of use, as well as features of these machines and cost, in curriculum for family nurse practitioner students.

3. Application of Nola Pender’s HPM to assess DM patients’ beliefs about health and to encourage competent self-care. This will include assessment of patients’ cues to action and their perception of SMBG, including perceived barriers and benefits of this self-care tool. If patients are prescribed accurate, easy-to-use SMBG meters, they will be more likely to have success with adherence to SMBG, thus improving their quality of life.
References


APPENDIX A

INFORMED CONSENT
A COMPARISON OF SELF-MONITORING BLOOD GLUCOSE DEVICES FOR ACCURACY AND EASE OF USE
Principal Investigator: Kelly K. Pfrommer, 3834 Kenwood, Memphis, TN 38122

INTRODUCTION

I give my permission to Kelly K. Pfrommer, RN, BSN and Dr. Kitabchi to participate in the research study to be conducted on diabetic patients. I understand that I will only be asked to participate in this research while I am attending my regularly scheduled clinic.

The purpose of the study is to compare several blood sugar machines for accuracy and to determine which one is easier for me to do my finger stick blood glucose readings.

There will be approximately 30 subjects enrolled in the study. The research will be conducted at the UTMG Endocrinology Clinic, 920 Madison, Suite 300.

PROCEDURES TO BE FOLLOWED

I understand that I will be asked to:

1. read instructions on how to use four machines, one at a time,
2. check my blood sugar on each different machine using a finger stick method,
3. record the blood sugar on a piece of paper next to the machine,
4. rate each machine for ease of use using a scale which has been shown to me, and finally
5. wash my hands with antibacterial soap before I begin testing the machines, and after I finish testing the machines.

I understand the decision to participate in the study in no way changes my care, medications, or relationship with the clinic.

RISKS ASSOCIATED WITH PARTICIPATION

I understand that there is a small chance for infection from the needle used to stick my finger, which will be decreased by handwashing with antibacterial soap before and after testing the machines. I also understand that there will be some discomfort from the needle sticks.

BENEFITS ASSOCIATED WITH PARTICIPATION

No direct benefits will be available to me except knowledge of the use of the SMBG machines and later, upon publication of the study results, the comparative accuracy of each machine.

Participant’s Initials ____________
CONFIDENTIALITY

I understand that all patient information will be kept completely confidential, and initials will be used, rather than names, for data analysis. I understand that the investigators of the study and the UT Memphis Institutional Review Board will have access to confidential data which identifies the participant by name.

COMPENSATION AND TREATMENT FOR INJURY

I understand that I am not waiving any legal rights or releasing the University of Tennessee or its agents from liability or negligence. I understand that, in the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, the University does not provide for treatment or reimbursement for such injuries.

QUESTIONS

I understand that if I have any questions regarding this study I may contact Kelly Pfrommer (901) 324-2788 or Dr. Abbas Kitabchi (901) 448-5802 or (901) 448-5882.

If I have any questions concerning my rights as a participant in this study or rights as a research subject, I may contact Dr. Clair Cox, UT Memphis, IRB Chairman at (901) 448-4824.

PAYMENT FOR PARTICIPATION

I understand that I am participating in this study as a volunteer and there will not be payment for my participation in this study.

COSTS OF PARTICIPATION

I understand that there will be no monetary cost to me for participation in this study.

VOLUNTARY PARTICIPATION

I understand that my participation is voluntary, and I can decide to quit the study at any time, without it affecting my status as a patient at the clinic.

APPROVED

MAY 3 1999

Participant’s Initials __________

UT IRB
A COMPARISON OF SELF-MONITORING BLOOD GLUCOSE DEVICES FOR ACCURACY AND EASE OF USE  
Principal Investigator: Kelly K. Pfrommer

CONSENT OF SUBJECT

I have read or have had read to me the description of the research study as outlined above. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts, side effects and adverse reactions as well as the possible benefits of the study.

I freely volunteer to participate in the study. I understand that I do not have to take part in the study and that my refusal to participate will involve no penalty or loss of rights to which I am entitled. I further understand that I am free to later withdraw my consent and discontinue participation in this study at any time. I understand that refusing to participate or later withdrawing from the study will not adversely affect my subsequent medical care.

______________________________
Signature of Participant

______________________________
Signature of Witness

______________________________
Signature of Principal Investigator

______________________________
Date

______________________________
Date

______________________________
Date

APPROVED
MAY 13 1999
UT IRB
APPENDIX B

VISUAL ANALOGUE SCALE
VISUAL ANALOGUE SCALE

Please place an ‘X’ on the line to rate the machine

Patient’s study # ______

Device # ______
Blood Glucose Value ______
APPENDIX C

LETTER OF APPROVAL FROM MISSISSIPPI UNIVERSITY FOR WOMEN ON USE OF HUMAN SUBJECTS IN EXPERIMENTATION
March 22, 1999

Ms. Kelly K. Pfrommer
c/o Graduate Program in Nursing
Campus

Dear Ms. Pfrommer:

I am pleased to inform you that the members of the Committee on Human Subjects in Experimentation have approved your proposed research as submitted provided the doctor's introductory letter be expanded to include more detailed information about the proposed study, provided the findings remain confidential, and provided participants understand that they may withdraw from the study at any time.

I wish you much success in your research.

Sincerely,

Susan Kupisch, Ph.D.
Vice President
for Academic Affairs

SK: wr

cc: Mr. Jim Davidson
    Dr. Mary Pat Curtis
    Dr. Bonnie Lockard
APPENDIX D

LETTER OF PHYSICIAN AGREEMENT
Dear Dr. XXX:

I am a graduate nursing student enrolled at Mississippi University for Women in Columbus, MS. As partial fulfillment of the Master's of Science degree in Nursing, graduate students are required to complete a thesis. The title of my proposed research is “A Comparison of Self-Monitoring Blood Glucose Devices for Accuracy and Ease of Use.”

The purpose of the proposed study is to evaluate several self-monitoring blood glucose devices for accuracy and ease of use. I believe the results of the study will benefit your practice by providing information as to the accuracy of the machines and their ease of use by your patients. I would like your assistance and written permission to utilize your clinic patients in my proposed study.

I will ask the participants to use the MediSense Precision QID, Lifescan One Touch Basic, Boehringer Mannheim Accucheck Advantage, and Bayer Glucometer DEX to measure their blood glucose and rate each machine for ease of use.

Patients will be included on a voluntary basis, with the understanding that they may withdraw from the study at any time. All subjects will be informed as to study purpose, risks and benefits; and consent forms will be signed prior to patient admission to the study.

I am enclosing a duplicate of this letter for your records. Please return the signed original to me in the enclosed envelope.

If you have any questions or comments, please do not hesitate to contact me. Thank you in advance for your help in this research.

Sincerely,

Kelly K. Pfrommer, RN, BSN
APPENDIX E

LETTER OF APPROVAL FROM THE UNIVERSITY OF TENNESSEE
INSTITUTIONAL REVIEW BOARD
May 13, 1999

Kelly K. Pfommer, RN, BSN
Department of Medicine/Endocrinology
College of Medicine
335M Bowld Hospital
UT Memphis

Dear Ms. Pfrommer:

On May 13, 1999, the UT Memphis Administrative Section of the Institutional Review Board reviewed your application entitled “A Comparison of Self-Monitoring Blood Glucose Devices for Accuracy and Ease of Use” (IRB #6860) which includes human subjects and/or tissue for investigative purposes.

The administrative section of the IRB determined your application to fall under the guidelines of expedited review, therefore your application was approved in this regard as complying with proper consideration of the rights and welfare of human subjects, the risk involved, and the potential benefits of the study. Therefore, this letter constitutes full approval of your application and consent form, stamped IRB approved ‘May 13, 1999’, from the Institutional Review Board for the above referenced study.

In the event that volunteers, either subjects or patients are to be recruited by means other than usual and standard patient care practices, the board must approve of any such solicitation materials (i.e., advertising copies or posters, etc.).

Any further alterations in the protocol must be promptly reported to and approved by the UT Memphis Institutional Review Board. In addition, annual reapproval is required by the IRB, and it is the responsibility of the Principal Investigator to initiate the request for reapproval regardless of the time the activity has been approved by the sponsoring agency.

You have individual responsibility for reporting to the board in the event of adverse reactions.

Sincerely,

Clair E. Cox, M.D.
Chairman
Institutional Review Board
APPENDIX F

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