UNIVERSITY OF CALGARY

An Evaluation of Self-Monitoring Blood Glucose (SMBG) Meters

by

Jessica Allyson Jones

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Abstract

Objective: To examine the overall usability of current, commercially available self-monitoring blood glucose (SMBG) meters in order to highlight how the design affects the performance of elderly adults.

Methods: Sixteen younger participants (18-27) and twenty nine elderly participants (65-85) completed two SMBG meter tasks: 1) set date/time and 2) control solution test, using two meters: 1) the Accu-Chek Compact Plus and 2) the One Touch Ultra 2.

Results: Elderly adults struggled to complete the SMBG meter tasks, especially when compared to their younger counterparts. Overall, younger participants were more successful in performing the SMBG meter tasks, were faster and committed fewer errors. All participants completed the set date/time task faster using the One Touch Ultra 2 meter. Elderly participants performed the control solution task faster using the Accu-Chek Compact Plus. Future SMBG meters should be designed with more insight into the needs and specific abilities of the elderly population.
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List of Tables

Table 1.1
Recommendations for SMBG based on type of diabetes from the American Diabetes Association (2012) and the Canadian Diabetes Association (2012e). ................................................................. 9

Table 3.1
Participant demographic data ................................................................. 30

Table 3.2
Participant diagnosis, average daily testing and years of experience ......................... 31

Table 4.1
Type of errors made by meter type and age group. ........................................ 41

Table 5.1
Significant results for meter type x age group interaction. ................................ 66

Table 5.2.
A simple task analysis showing tasks that are performed by the user, the device, or a combination of the user and the device (FDA, 2011). ............................................................... 79

Table 5.3.
A simple task analysis showing tasks that are performed by the user, the device, or a combination of the user and device according to new device design. ............................ 80

Table 5.4.
Problems identified by the current study and a previous heuristic evaluation. ............. 85
List of Figures

Figure 3.1. Picture of the Accu-Chek and One Touch meters.................................................. 33

Figure 4.1. Control solution range indicated on the Accu-Chek meter (left) and on the One Touch meter (right)........................................................................................................ 40

Figure 4.2. Absorbent channel on the One Touch Ultra 2 Test Strip........................................ 43

Figure 4.3. Error screens for the One Touch Ultra 2 meter (left) and the Accu-Chek Compact Plus meter (right). ........................................................................................................... 44

Figure 4.4. The time needed to complete the control solution test for meter type and by age group. Error bars 95% CI........................................................................................................... 46

Figure 4.5. Average number of errors made by younger and elderly groups when using the Accu-Chek and One Touch meters .......................................................................................... 48

Figure 4.6. Buttons on the Accu-Chek Compact Plus meter. “M” is meant to represent memory, “S” is meant to represent settings and the middle button turns the device on/off and releases test strips........................................................................................................ 51

Figure 4.7. Up and down buttons on the One Touch Ultra 2 meter helped participants scroll through information easily........................................................................................................ 51

Figure 4.8. Graphics from the Accu-Chek (left) and One Touch (right) manuals showing users how to compare the results of their control test with the control solution concentration range... 53

Figure 4.9. One Touch test strip with arrow pointing at control solution channel...................... 54

Figure 4.10. One Touch test strip container. ................................................................................ 55

Figure 4.11. Accu-Chek graphic demonstrating how to eject a test strip with the push of the middle button.......................................................................................................................... 56

Figure 4.12. Diagrams taken from the Accu-Chek Compact Plus meter instruction manual (2008) demonstrating how to open the test drum compartment and how to load a new test strip drum.. 56

Figure 5.1. Power button on the Accu-Chek Compact Plus meter. This button also functions as the test strip release................................................................. 68

Figure 5.2. The One Touch Ultra Mini........................................................................................ 72

Figure 5.3. The One Touch main menu screen............................................................................. 74
Figure 5.4. Accu-Chek screen shots. Setting screen (left), memory screen (center) and screen displayed when the test strip release button is pushed (right). .............................................. 74

Figure 5.5. Accu-Chek meter with the year ‘2013’ at the top of the screen. ................................. 75

Figure 5.6. One Touch Ultra 2 test strip (left) and EZ Health meter test strip (right)................... 76

Figure 5.7. One Touch test strip with arrow indicating channel for control solution (left). Incorrect placement of control solution (left). ................................................................. 76

Figure 5.8. Error screens from the Accu-Chek (left) meter and the One Touch meter (right)...... 77

Figure 5.9. One Touch Verio IQ, EZ-Health Oracle, FreeStyle Freedom Lite and One Touch Ultra 2 meters................................................................. 84
Table of Contents

Contents

Abstract ......................................................................................................................... ii
Acknowledgements ....................................................................................................... iii
List of Tables ................................................................................................................ iv
List of Figures .............................................................................................................. v
Chapter 1: Introduction ............................................................................................... 1
Chapter 2: Review of the Literature ............................................................................. 4
  2.1 Defining Diabetes ..................................................................................................... 4
    Type 1 ....................................................................................................................... 4
    Type 2 ....................................................................................................................... 5
    Gestational diabetes mellitus. ................................................................................... 7
  2.2 Defining Self-Monitoring ....................................................................................... 8
    Impact of intensive self-monitoring ......................................................................... 9
    Barriers to proper self-monitoring. .......................................................................... 12
    Device related barriers to self-monitoring. .............................................................. 17
    Age related barriers to self-monitoring. ................................................................... 18
  2.3 Human Factors ....................................................................................................... 21
    Usability testing. ....................................................................................................... 22
  2.4 Human Factors and the FDA ............................................................................... 23
  2.5 Obtaining FDA Approval ..................................................................................... 23
    Premarket notification and usability testing. ............................................................ 23
  2.6 Obtaining Heath Canada Approval ...................................................................... 24
  2.7 Limitations of Current SMBG Research .............................................................. 25
  2.8 Hypotheses .......................................................................................................... 27
Chapter 3: Methods ...................................................................................................... 29
  3.1 Participants ........................................................................................................... 29
  3.2 Study Setting and Materials ................................................................................ 31
    SMBG meters ....................................................................................................... 31
    Experimental scenario and task protocol. ............................................................... 32
  3.3 Procedure ............................................................................................................ 32
Chapter 4: Analysis and Results .................................................................................. 36
  4.1 Study Design and Analysis ................................................................................... 36
  4.2 Generalized Estimating Equation ........................................................................ 37
  4.3 Quantitative Analysis: Categorical Data ............................................................ 38
    Task 1 Results: Set Date/Time .............................................................................. 38
    Task 2 Results: Control Solution Test ................................................................. 38
    Interpretation of the Control Solution Test Results ............................................. 39
    Types of Errors ....................................................................................................... 40
    Time to Complete Each Task ................................................................................. 44
    Task 1: date/time set. .............................................................................................. 44
    Task 2: Control solution test ................................................................................ 45
    Total Number of Errors Made .............................................................................. 47

vii
Chapter 1: Introduction

Diabetes affects more than 371 million, or 8.3% of the global population (International Diabetes Federation [IDF], 2012a). By the year 2025 more people will have diabetes than the current combined populations of the United States, Canada and Australia (Woo, 2008). By 2030 the number of people diagnosed with diabetes is expected to rise to 552 million with diabetes becoming the seventh leading cause of death in the world (IDF, 2011; World Health Organization [WHO], 2011). Worldwide, the cost of diabetes health care has reached US$471 billion per year (IDF, 2012b). In Canada, diabetes rates have doubled over the past decade and today over three million people are living with the disease (Canadian Diabetes Association [CDA], 2012a). By the year 2020 the number of Canadians diagnosed with diabetes is projected to reach 3.7 million and the cost to the Canadian healthcare system will hit $16.9 billion per year (CDA, 2012a). The profound growth of this disease is largely due to the obesity epidemic in Canada and the United States as well as overall world population growth and the aging of populations in many developed countries (Hughes, 2009).

When diabetes is improperly managed or left untreated it can lead to immediate consequences such as hyperglycemia or hypoglycemia. Inability to achieve blood glucose targets can also lead to serious long term complications including heart disease, kidney disease, eye disease, amputation, impotence, difficulties in pregnancy and nerve damage (CDA, 2012b; Florez, Hirschhorn & Altshuler, 2003). To prevent these complications several clinical trials have confirmed that self-monitoring of blood glucose is a key process in effective diabetes management (Diabetes Control and Complications Trial [DCCT], 1993; United Kingdom Prospective Diabetes Study [UKPDS], 1998). Proper self-monitoring permits people with diabetes to determine their blood sugar levels and make the appropriate adjustments to their
insulin levels, diet, and exercise routines in order to effectively manage their diabetes (Rogers, Mykityshyn, Campbell & Fisk, 2001).

To achieve self-management, people with insulin treated diabetes are required to use self-monitoring technologies. The extent to which self-monitoring is successful depends on the person’s ability to use their device as well as the clinical accuracy of the device. Standards defining the specific clinical accuracy for all self-monitoring blood glucose (SMBG) device have been set by multiple organizations including the International Standards Organization (ISO), international regulatory authorities, health care providers and device manufacturers themselves (Ginsberg, 2009). These standards define the specific measurement accuracy for all self-monitoring blood glucose (SMBG devices). However, the usability of SMBG devices is much less standardized. Despite the lack of usability requirements, advertisers of SMBG products recognize the importance of ease of use and spend a lot of money highlighting the simplicity of their products (Heinemann, 2008). They promote their blood glucose meters as “convenient,” “automatic,” and “easy to use” (Abbott, 2010; Johnson & Johnson, 2011; Tremblay Harrison, 2010). However, despite the propensity of these marketing messages, the actual usability of these devices remains largely unknown due to a lack of published research in the common literature. As a result, the ability of people with diabetes to use these devices successfully continues to be a cause for concern and requires further investigation.

This study therefore examines the overall usability of current self-monitoring blood glucose meters. Specifically, on evaluating SMBG meter design issues that affect usability among the elderly adult population (≥ 65 years of age). The research question driving the investigation was: Can adults 65 years and older with diabetes successfully use a current,
commercially available SMBG meter to independently accomplish important self-monitoring tasks?

This thesis will be divided into five primary sections. Chapter 2 presents a review of the literature on diabetes, self-monitoring and human factors evaluation techniques. The study Methods are listed in Chapter 3, the Statistical Analysis and Results are in Chapter 4 and finally, the Discussion and Conclusion in Chapter 5.
Chapter 2: Review of the Literature

2.1 Defining Diabetes

Consistent and proper self-monitoring helps to increase the control that people have over their diabetes (DCCT, 1993). However, even when proper monitoring is employed diabetes can have profound impacts on the everyday lives of those who have been diagnosed (Gebel, 2011).

Diabetes is defined as “a group of metabolic diseases characterized by hyperglycemia (high blood sugar) resulting from defects in insulin secretion, insulin action, or both” (American Diabetes Association, 2010, p. S62). There are three main types of diabetes: Type 1, Type 2, and Gestational Diabetes.

**Type 1.** Type 1 diabetes is a progressive autoimmune disease in which the pancreatic beta cells that produce insulin are destroyed (Florez et al., 2003). Type 1 diabetes accounts for approximately 10% of people with the disease and is usually diagnosed in children and adolescents (CDA, 2012b). Today, the exact cause of what initiates this disease remains largely unknown; however, research suggests that it is a combination of genetic and environmental factors (Florez et al., 2003; Haller, Atkinson & Schatz, 2005).

Family history is an important risk factor in the development of type 1 diabetes. Individuals of European ancestry with a sibling diagnosed with type 1 diabetes have a 6% chance of developing the disease versus a 0.4% chance for those who are not related to someone with the disease (Field, 2002). In the United States, individuals with a first degree relative diagnosed with type 1 diabetes have a 1 in 20 risk of developing the disease, whereas the general population has a 1 in 300 lifetime risk (Haller et al., 2005). Although the role of genetics is definitely present, 85% of type 1 diabetes cases occur in individuals with no family history of the disease (Haller et al., 2005). Therefore, environmental factors and random chance also play a part. Some
of the most cited environmental factors include early nutrition and infection; however, there is no direct evidence to suggest that these play a role in causation (Haller et al., 2005).

Although this disease is not preventable, people with diabetes can properly manage their diabetes using monitoring techniques and insulin therapy treatments (CDA, 2012c). The Canadian Diabetes Association (2012d) recommends that SMBG be carried out four or more times per day for individuals using multiple insulin injections or insulin pump therapy. However, the frequency and specific timing of SMBG should be guided by the individual’s goals and needs.

**Type 2.** People with type 2 diabetes account for approximately 90% of the total diabetic population (CDA, 2012b). Type 2 diabetes is caused when the pancreas produces insufficient insulin or when the body does not use the insulin that is produced effectively (CDA, 2012b). Although type 2 diabetes usually develops in adulthood, there are an increasing number of children and adolescents being diagnosed due to rising levels of childhood obesity (CDA, 2012b). In fact, in countries such as Japan, more children have been diagnosed with type 2 than type 1 diabetes (Dean & McEntyre, 2004). Type 2 diabetes is largely associated with excess body weight, especially around the mid-section, and therefore, can be largely prevented by eating a nutritious diet, exercising regularly and maintaining a healthy body weight (Public Health Agency of Canada, 2012). Family history is also an important risk factor in the development of type 2 diabetes. Those with siblings diagnosed with type 2 have a 30 to 40% risk of diagnosis versus an overall population prevalence of 7% (Florez et al., 2003). Unlike those with type 1 diabetes, the majority of people with type 2 use oral medications to control their disease and do not require insulin treatment in order to survive. However, the American Diabetes Association (ADA, 2007) recommends that people with type 2 diabetes who receive multiple insulin
injections should use a blood glucose monitor. In addition, for those with type 2 who are not using insulin, SMBG is still often recommended as a useful form of self-management for select individuals (ADA, 2012).

The utility of SMBG among people with type 2 diabetes who are not using is currently a topic of much debate. A series of systematic reviews and meta-analyses have reported varying results on the effect of SMBG among people with non-insulin treated type 2 diabetes (Allemann, Houriet, Diem & Stettler, 2009; Breland, McAndrew, Burns, Leventhal & Leventhal, 2013; Farmer et al., 2012; Malanda et al., 2012; McAndrew, Schneider, Burns & Leventhal, 2007). Studies that do not support the use of SMBG among people with non-insulin treated type 2 diabetes and suggest that the overall effect of SMBG is not clinically meaningful, despite finding a consistent drop in HbA$_{1c}$ levels among those using SMBG compared to those who did not (Farmer et al., 2012). These studies suggest that the high financial costs associated with SMBG are not worth the small reductions in HbA$_{1c}$ levels (Farmer et al., 2012; Simon et al., 2008). It has also been reported that the introduction of SMBG among people with non-insulin treated type 2 diabetes was “unlikely to have any significant lifetime health benefits” (Simon et al., 2008, p.6).

Alternatively, studies that support the use of SMBG among non-insulin treated type 2 individuals argue that the reductions in HbA$_{1c}$ facilitated by SMBG are meaningful (Allemann et al., 2009). A meta-analysis by Allemann et al. (2009) demonstrated a significant drop in HbA$_{1c}$ levels among participants using SMBG compared to non-SMBG treated participants. The overall drop in HbA$_{1c}$ levels was translated into a 6% reduction in all diabetes related complications and a 10% reduction in microvascular complications. An additional meta-analysis by Malanda et al.

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1 HbA$_{1c}$ (glycated hemoglobin) is a lab test that is used in the diagnosis of diabetes. HbA$_{1c}$ reflects the average level of blood sugar over the previous two to three months and is a good indicator of how people are controlling their diabetes (Goldenberg, Cheng, Punthakee & Clement, 2011).
(2012) concluded that SMBG was beneficial in lowering HbA1c in individuals with newly diagnosed non-insulin treated type 2 diabetes. However, the same analysis also reported that the effect of SMBG on people with diabetes who had been diagnosed for more than one year were small in the short term (six months) and subsided after one year. Currently there is no consensus on the utility of SMBG in people with non-insulin treated type 2 diabetes. This is largely due to the inconsistent results from randomized controlled trials and observational studies (International Diabetes Federation, 2009). Today, both the American Diabetes Association and the Canadian Diabetes Association suggest that SMBG might be useful as a guide for management for people with non-insulin treated type 2 diabetes however, no specific treatment guidelines have been set (ADA, 2012; CDA, 2012e).

**Gestational diabetes mellitus.** Gestational diabetes mellitus (GDM) is usually a temporary form of diabetes that occurs during pregnancy and tends to disappear after delivery. Gestational diabetes is a form of hyperglycemia and affects approximately 3.7% of all Canadian pregnancies in non-Aboriginal populations (CDA, 2012e). The prevalence of GDM increases up to 18% for First Nations women in Canada (CDA, 2012e). During pregnancy it is normal for women to progressively build up a resistance to insulin. In most women the pancreatic B cells increase their secretion of insulin in an effort to compensate for the resistance. However, in women who develop GDM, there is inadequate compensation due to a defect in their pancreatic B cell functioning (Buchanan & Xiang, 2005). Risk factors for GDM include being a member of a high-risk population (e.g., Aboriginal), being obese, or being over the age of 35 years (CDA, 2012e). The consequences of GDM include an increased risk to the fetus including malformation and an increase in fetal death (WHO, 2012). Babies born from mothers who had GDM also appear to be at a greater risk for acquiring type 2 as an adult (WHO, 2012). Although GDM
usually disappears after birth, women who have had GDM are at an increased risk for developing type 2 diabetes later in life (CDA, 2012e).

### 2.2 Defining Self-Monitoring

Diabetes is an intrusive and inconvenient disease. There is currently no cure for diabetes and in order to achieve proper management, people with diabetes need to be educated and motivated to participate in their own self-care (Gebel, 2011). Self-monitoring of blood glucose is a recommended practice for people with insulin treated diabetes that allows them to achieve a specified level of glycemic control and prevent diabetes related complications (Benjamin, 2002). Self-monitoring requires the individual to test their blood glucose a number of times throughout the day or week, based on an individualized schedule. These tests require the individual to prick his or her finger with a lancing device to obtain an adequate blood sample (0.3-1.0 µl) (Clarke & Foster, 2012). The sample is then applied to a reagent test strip and inserted into the blood glucose meter for an automated reading. The reading results are then recorded in a paper and pen logbook or stored electronically on the monitoring device. Proper self-management requires people with type 1 diabetes, as well as some people with type 2 diabetes, to monitor and maintain their insulin levels using insulin injections or pumps. The recommended number of times to test is based on a variety of factors such as type of diabetes, whether or not the person uses insulin, as well as individual preferences and circumstances (Benjamin, 2002). Recommendations made by the American Diabetes Association and Canadian Diabetes Association can be seen in Table 1.
Table 1.1

*Recommendations for SMBG based on type of diabetes from the American Diabetes Association (2012) and the Canadian Diabetes Association (2012e).*

<table>
<thead>
<tr>
<th>Type of Diabetes</th>
<th>Recommended SMBG (ADA, 2012)</th>
<th>Recommended SMBG (CDA, 2012e)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Yes, ≥ 3 times/day</td>
<td>Yes, ≥ 4 times/day</td>
</tr>
<tr>
<td>Type 2 (insulin treated)</td>
<td>Yes, ≥ 3 times/day</td>
<td>Yes, ≥ 4 times/day</td>
</tr>
<tr>
<td>Type 2 (non-insulin treated)</td>
<td>No specified criteria, may be useful as a guide for management</td>
<td>Some people might benefit from infrequent testing (1-2 times/week)</td>
</tr>
<tr>
<td>Gestational (insulin treated)</td>
<td>Yes, ≥ 3 times/day</td>
<td>Yes, ≥ 4 times/day</td>
</tr>
<tr>
<td>Pre-diabetes</td>
<td>n/a</td>
<td>No, not required</td>
</tr>
<tr>
<td>Newly diagnosed (&lt; 6 months)</td>
<td>n/a</td>
<td>SMBG 1 time/day at different times to learn effects of meals, exercise, medication etc.</td>
</tr>
</tbody>
</table>

**Impact of intensive self-monitoring.** The invention of the self-monitoring blood glucose meter permitted doctors and researchers to determine the impact and importance of intensive self-monitoring. Because of this technology major clinical trials have been able to demonstrate that self-monitoring of blood glucose is a component of effective therapy and a key element in diabetes management (ADA, 2012; Benjamin, 2002; DCCT, 1993; Stetson et al., 2011; UKPDS, 1998). The first large scale study to establish a positive link between aggressive blood glucose control and a reduction in long term complications was the Diabetes Control and Complications Trial (DCCT), which was completed in 1993. This trial followed 1441 people with type 1 diabetes for an average of six and a half years. Participants were randomly assigned to one of two conditions: conventional treatment or intensive treatment. Those in the conventional treatment (control) group were to inject a maximum of two insulin shots per day and test their blood or urine a maximum of twice per day with the goal of avoiding severe high and low
glucose levels (DCCT, 1993). The criteria for the control group were based on the standard of care for the early 1980s.

Those assigned to the intensive therapy (treatment) group monitored their blood glucose levels four or more times per day and required three or more daily injections, which were adjusted by the individual based on their SMBG readings. In addition, participants were to meet with their doctor on a monthly basis (DCCT, 1993). The goal for those in the treatment group was to maintain normal glucose levels. The results of this study demonstrated a significant reduction in retinopathy, nephropathy, and neuropathic conditions. Participants in the intensive treatment group also had a threefold increase in the rate of severe hypoglycemia; however, this risk decreased with increased experience in intensive therapy (DCCT, 1993). In addition, a 1994 follow up study, The Epidemiology of Diabetes Interventions and Complications (EDIC) study, showed that people originally in the intensive treatment group showed a significant reduction in macrovascular events when compared to those originally in the control group (Beaser, 2010).

In Japan, the Kumamoto Study followed the same format as the DCCT study but this time used insulin treated type 2 participants to test the impact of intensive blood glucose control (Shichiri, Kishikawa, Ohkubo & Wake, 2000). Similar results were found. Those in the treatment group showed significant decreases in both micro complications, such as retinopathy and nephropathy, and macrovascular disease (Shichiri et al., 2000). In 1998, the results of another large trial study, the United Kingdom Prospective Diabetes Study (UKPDS), were published. This trial followed a large number of participants with type 2 diabetes for an average of ten years to see if glucose control using intensive pharmacotherapy resulted in clinical benefits (UKPDS, 1998). Specific treatment groups included diet alone, oral therapy or injection therapy. Advantages and disadvantages between different treatment modalities were also studied. Follow
up results demonstrated that participants who received more intense therapy treatments had reduced rates of micro and macrovascular complications 10 years after the study had ended (UKPDS, 1998). These studies demonstrate that early diagnosis and intensive therapies can prevent future complications (Beaser, 2010).

Despite these positive findings, other large scale randomized control trials have uncovered less favorable results. For instance, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study sought to investigate the impact of intensive glucose control on cardiovascular disease (CVD) among people with type 2 diabetes who were at high risk for CVD events (Buse, 2007). This study randomized 10,251 participants to either the intensive glycemic control group (target A1C <6.0%) or the standard glycemic control group (target A1C 7.0-7.9%). In addition, participants were given different combinations of oral medications, insulin and lifestyle interventions. The ACCORD study was halted in 2008 due to increased fatality rates in the intensive glycemic control group compared to the standard group (257 vs 203 deaths over a mean 3.5 years of follow-up) (Dhar, 2009; Skyler et al., 2009). One explanation for the amplified mortality rate in the intensive group was an increase in the number of serious hypoglycemic events among members in the intensive group (10%) compared to those in the standard group (3.5%). Many of the deaths due to CVD were related to severe hypoglycemia (Dhar, 2009).

Similar to the ACCORD, the Veterans Affairs Diabetes Trial (VADT) randomized 1,791 participants with type 2 diabetes to either an intensive or standard glycemic control group (Skyler et al., 2009). Once again, there were more deaths due to CDV in the intensive control group than the standard control (38 vs 29; sudden deaths 11 vs 4). Post-hoc analyses suggested that duration of diabetes (less than 12 years) appeared to have a CDV benefit for those in the intensive group while those who entered the study with a longer diagnosis of diabetes
experienced a neutral or adverse effect of intensive glycemic control (Skyler et al., 2009). Other explanations suggest that severe hypoglycemia within the past 90 days was a strong predictor of CVD mortality.

In an attempt to explain the different results between studies such as the DCCT and UKPDS compared to the ACCORD and VADT, several methodological disparities have been highlighted. For instance, the ACCORD and VADT studies were shorter in duration and tended to enroll older patients (Dhar, 2009). In addition, patients in these studies had been living with diabetes for a longer duration and were at higher risk for CVD. Finally, the treatment strategies used to achieve intensive glycemic control varied between studies and often included complex combinations of medications and interventions, making it difficult to parse out all of the possible effects. The benefits of tight glycemic control on microvascular and macrovascular complications are well established in people with type 1 and type 2 diabetes (Dhar, 2009; Skyler et al., 2009). However, studies such as the ACCORD and VADT demonstrate some important conclusions. For instance, elderly patients with long duration type 2 diabetes and a known history of hypoglycemia might not get CVD benefits from intensive glycemic control. However, patients with shorter duration diabetes who have a longer life expectancy and no significant cardiovascular disease might derive some benefits from tight control (Skyler et al., 2009).

**Barriers to proper self-monitoring.** Since the introduction of insulin into clinical medicine in 1921, compliance to proper self-monitoring has been a major problem (Tattersall, 2009). Adherence rates among people with type 1 and type 2 diabetes have been researched using questionnaires and self-administered surveys. When comparing the rate of recommended daily testing to the rate of self-reported testing, individual adherence ranged from 33% to 52% (Burge, 2001; Karter et al., 2000; Vincze, Barner& Lopez, 2004). This issue persists today and is
often due to variables such as cost, pain, social stigma, inconvenience, inability and self-regulation (Diamond, Massey & Covey, 1989; Heinemann, 2008; Stetson et al., 2011).

**Cost.** Proper diabetes care is expensive. This is especially true for low income Canadians such as seniors who are often on a limited fixed budget. A Canadian with diabetes can incur direct costs between $1,000 and $15,000 per year purchasing monitors, insulin, test strips, medication and other supplies (CDA, 2012a). For people with type 1 diabetes, it is suggested that they test their blood glucose at least four times per day (CDA, 2012d). With test strips in Canada costing an average of 76 cents each (Cameron et al., 2010), expenses accumulate quickly and people often feel the need to decrease the number of times they test. Similarly, it is recommended that lancets only be used once (CDC, 2012f). However, people will often attempt to use the same lancet on multiple occasions to reduce expenses (Heinemann, 2008). In 2006, 1000 participants with diabetes responded to a survey released by the Market Research Company Ipsos in Germany that revealed 10% of people used their lancet only once, 19% used it 2 to 4 times, 22% used it 5 to 7 times, 25% used it 8-10 times and 21% used it 11 times or more (Heinemann, 2008). Multiple usages cause the lancets to become dull and, as a result, inflict a greater amount of pain on the individual. Pain is another deterrent to testing adherence and may cause people to further decrease testing.

Even when diabetes equipment is made more accessible, by lowering costs through public or private healthcare funding, insurance companies are only likely to cover the minimum recommended clinical guidelines for testing, or sometimes less. For instance, in Alberta Canada, the government bases its coverage “on the average cost of twice daily usage of blood glucose tests strips as recommended by the Agency for Drugs and Technologies in Health” (Alberta Health, 2013, para. 2). The coverage is meant to “reduce the cost burden of diabetes,” however
with some individuals testing upwards of ten times per day in order to maintain their glucose levels (Alberta Health, 2013, para.2; Yeaw, Lee, Wolden, Christensen & Groleau, 2012) the cost of testing can remain substantial. The decision to limit testing can in some cases lead to severe consequences including an increased risk of amputation, vision loss, stroke, and death (Rosen & O’Farrell, 2011).

**Pain.** Finger soreness, pain, and fear of needles are three variables that are strongly associated with a low compliance to SMBG testing (Burge, 2001; Lekarcyk & Ghiloni, 2009; Vincze et al., 2004). In fact, a majority of people with diabetes perceive finger sticks from their lancing device as being more painful than insulin injections (Lekarcyk & Ghiloni, 2009). In an effort to enhance adherence and decrease pain, many SMBG devices now offer alternate site testing (AST) (FDA, 2010). Rather than testing on the fingertip, people have the option of lancing their forearm or thigh. Although this is an attractive alternative to many SMBG users, there are problems associated with this form of testing. Evaluations of AST have shown that results can differ greatly from fingertip testing during periods of rapid glucose changes including after meals, exercise or the administration of an insulin shot (Knapp et al., 2009). As a consequence, the inaccuracy of some AST results can increase the potential for a delayed detection of hypoglycemia (Ginsberg, 2002). In spite of the risks involved, AST still seems like an attractive option for those who experience a high level of pain in their fingers. However, various trials have determined that AST does not necessarily increase adherence or frequency of testing (Briggs & Cornell, 2004; Knapp et al., 2009). Future research focused on developing devices that decrease the pain associated with testing is important.

**Social stigma.** Diabetes is a disease that has a high level of social stigma. Overweight individuals and people of lower socioeconomic status tend to have higher rates of diabetes
(Chaufan, 2011). Although diabetes affects many different people for a variety of reasons, the perception of it is still largely associated with laziness, obesity, unhealthy diet, and poor health. In addition, the consequences of diabetes, which may include blindness or amputation, can further increase social stigmatization.

Unwanted disclosure of the disease to friends and acquaintances may result in actual and perceived stigma. As a result, many SMBG users may feel too uncomfortable or embarrassed to test in public environments. If an individual’s SMBG device is too conspicuous for the individual to even attempt to use, then it cannot achieve its intended purpose. An effective SMBG meter should be appealing and unobtrusive so users feel comfortable and confident when it comes time to test. A well-designed device needs to blend aesthetic appeal with ease of use and user safety.

**Inconvenience and inability.** The process of self-monitoring requires a great deal of motivation and effort on the part of the individual. Because many people with diabetes, especially those with type 1, are required to test multiple times per day, it is important that the device facilitate convenience. For nighttime testing, devices should include a backlight so users can see their results without getting out of bed. For users who are constantly travelling, compactness is essential. For those who work in occupations such as construction, temperature can often be a factor and therefore, it is important that the device can withstand both hot and cold temperatures. For elderly individuals meters should include larger screens for easier viewing and larger buttons to account for decreasing dexterity. For children, colour, design, size, and durability should be considered. In addition, sufficient diabetes education is an imperative component to proper self-management.
Proper education should include technical instructions, specifically how to use and interpret the chosen SMBG device, as well as overall diabetes education to help people understand why self-monitoring is an integral part of disease control. National standards outlining proper education for diabetes self-management exist; however, this does not mean that every person with diabetes receives or accepts adequate training (Haas et al., 2012). The widespread availability of SMBG devices through mail, telephone, and internet orders can limit the amount of necessary professional advice obtained by individuals with diabetes. Previous literature has revealed that an overall lack of patient-provider contact time, and thus a lack of sufficient educational opportunity, has served as a major limitation in overall self-monitoring ability (Stetson et al., 2011). A 2002 survey evaluating different aspects of SMBG characteristics and patterns revealed that out of 422 respondents, 51% claimed they were self-educated on the use of their SMBG meter (Skeie, Thue, Nerhus & Sandberg, 2002).

In order to improve the level of diabetes education, researchers have suggested that people with diabetes be given a “drivers’ license” to practice SMBG (Heinemann, 2008, p.715). This would require individuals to go through a process similar to drivers’ education with a final exam at the end. The hope is that people would receive a minimum amount of necessary technical and theoretical training in regards to diabetes and their SMBG device. Although proper education is the ultimate goal for diabetes care, this is not the current reality. Therefore, it is the responsibility of designers to produce SMBG meters that are so intuitive that users can successfully operate them, even without adequate training, which is quite difficult.

**Self-regulation.** Many people with diabetes feel that they do not need to test their blood glucose as often as recommended because they are able to self-regulate (Diamond et al., 1989). These individuals frequently use subjective symptoms such as feelings of fatigue or dizziness to
guide their diabetes management regimen even though studies have found these techniques to be largely unreliable (McAndrew et al., 2007). In a questionnaire looking at symptom perception and subjective estimation of blood glucose, 77% of respondents answered yes to the question “Can you tell just by how you feel, when your sugar is too high?” (Diamond et al., 1989). However, the same study concluded that people largely underestimated their blood glucose levels and that extreme caution should be applied when using subjective symptoms to regulate treatment. To increase the frequency and success of proper SMBG, individuals need to tune their subjective perceptions with objective management. It is the repetitive objective feedback gained from blood glucose testing that is important. However, this task becomes difficult largely due to other barriers of proper self-monitoring including inconvenience, pain, and cost, as already discussed.

**Device related barriers to self-monitoring.** An additional barrier to proper care is related to the level of SMBG meter usability. According to the literature, the number one cause of inaccurate blood glucose readings is user error, not mechanical error (Briggs & Cornell, 2004; Kaye & Chenault, 2002). A panel consisting of the American Diabetes Association, the Food and Drug Administration (FDA), and the National Institute of Health and Center for Disease Control and Prevention reiterated this point stating, “most of the problems with current monitoring systems involve the user and not the system itself” (FDA, 1997, para. 7). A study conducted by Colagiuri et al. (1990) tracked 90 individual with diabetes using two separate SMBG devices for one month and found that 62% of the participants made at least one “clinically significant” error. A clinically significant error indicated that the participant took a medically incorrect action or failed to take a medically appropriate action based on a faulty blood glucose reading. In addition, a survey conducted in 2000 found that over 70% of self-monitoring respondents reported
experiencing problems when using their monitors (Mykityshyn, Campbell, Rogers & Fisk, 2000).

Recent data from Health Canada and the FDA further support previous findings on the large number of user centered problems. According to Health Canada (2012), hundreds of consumer complaints, along with product alerts and recalls, continue to be reported in reference to commercial SMBG meters. Similarly, the FDA (2010) receives 12,000 adverse event reports each year in reference to blood glucose meters. Problems that can be directly attributed to the user include: the failure to properly maintain the meter, incorrect techniques and operating procedures, as well as the failure to follow the instructions on meter use (FDA, 1997). More specific examples of user errors include missed or improper coding, improper insertion of test strips, and incorrect date and time input.

**Age related barriers to self-monitoring.** Device related barriers to self-monitoring can cause problems among all types of SMBG users. However, these problems can be further exacerbated among members of the elderly population as complication risk generally increases with diabetes duration (Hewitt, Smeeth, Chaturvedi, Bulpitt & Fletcher, 2011). In the United States 26.9% of people 65 years or older have been diagnosed with diabetes (ADA, 2013). In Canada, 32.4% of the elderly population reported a diagnosis of diabetes (Statistics Canada, 2010). Elderly adults account for the largest proportion of the diabetic population and as a result, the specific needs of this group must be considered when designing SMBG meters (Statistics Canada, 2010). Issues associated with aging include loss of vision and hearing, an increased rate of infirmaries and disabilities, decreases in memory functioning and an increased rate in hypoglycemic events.
Age has been found to be the best predictor for visual impairments and blindness (Fisk et al., 2009). The likelihood of experiencing vision problems after the age of 65 increases even more among people with diabetes, as some degree of retinopathy is common (Deshpande, Harris-Hayes & Schootman, 2008). Diabetic retinopathy causes damage to the blood vessels in the retina and results in over 10,000 new cases of blindness per year. Previous research has found that elder adults have a more difficult time performing a SMBG test due to a decrease in contrast sensitivity, an inability to discriminate between colors on the meter screen and a decrease in ability to perceive small icons or text (McLaughlin, Rogers & Fisk, 2004). In addition to visual decrements, elderly adults are likely to experience hearing loss. Research states that by age 65 approximately 30% of women and 50% of men will experience hearing loss that is serious enough to hinder social interactions (Fisk et al., 2009). Auditory decrements associated with old age include a decrease in ability to distinguish between similar sounds and the inability to understand words or alarms at high frequencies (McLaughlin et al., 2004). Device designers should consider providing verbal instruction options to accommodate users with visual impairments. To account for auditory impairments, SMBG manufacturers should offer meters with increased screen sizes and larger text. Without innovative design adjustments, adults with both visual and auditory impairments are likely to have some degree of difficulty operating the majority of conventional blood glucose meters currently on the market.

An increased rate of infirmaries and disabilities (or co morbidities) such as arthritis and Parkinson’s disease are also experienced by elderly adults (Gardner-Bonneau, 2011). In fact, over 50% of the elderly population has at least one disability that interferes with their ability to perform normal daily tasks (Gardner-Bonneau, 2011). Previous research has shown that older adults often have more difficulty with SMBG testing due to age related changes such as
decreased fine motor control (Carpenter & Mayhorn, 2011). In addition, older adults generally take longer than younger adults to make comparable movements and their movements are much less precise (Fisk et al., 2009). Device designers should consider increasing the size of the buttons and screens to account for a decrease in manual dexterity. In addition, device time out functions should be extended where necessary to ensure elderly adults can complete the task they are attempting before the meter times out and turns off.

Many people over the age of 65 years have little more than a high school education (Gardner-Bonneau, 2011). As a result, the instructions on both the device and peripheral objects and learning materials need to be presented at an appropriate level. In addition, many older adults experience problems with their memory (McLaughlin et al., 2004). It is especially common for older adults to demonstrate a decline in their working memory. Working memory (or short-term memory) allows people to keep a few bits of recent information active and available at one time (Fisk et al., 2009). Elderly people who experience a decline in their working memory often find it difficult to remember all of the steps necessary to perform a proper blood glucose test. The failure to complete any task in the test sequence can result in an inaccurate or incomplete blood glucose reading. For that reason, tasks should be easy to complete, naturally guided by the device and should not require the user to remember large amounts of information. Elderly individuals who experience a decline in their prospective memory (long-term memory) are likely to have problems remembering to complete future tasks such as testing blood glucose at a particular time of day. For elderly adults living alone it is important that reminder alarms and usage dates and times are easy for the user to program into their blood glucose meter. These reminder functions should compensate for a decrease in
prospective memory by properly notifying the user when it is time to test and when tests have been performed.

An additional concern for elderly adults with diabetes is an increased risk of experiencing a hypoglycemic event (Ligthelm, Kaiser, Cora & Yale, 2012). This increased risk is due to factors such as cognitive impairments and a high prevalence of comorbidities. Studies have determined that older adults with diabetes have a greater risk of developing mild cognitive impairments, Alzheimer’s disease and dementia (Cheng, Huang, Deng & Wang, 2012). In addition, recent studies have found that 75% of adults with diabetes have two or more comorbid conditions and are likely to be on multiple medications (Caughey et al., 2010). The use of multiple medications can lead to hypoglycemia through unexpected drug interactions (Ligthelm et al., 2012). To minimize the risk of a hypoglycemic event, insulin treated individuals must adhere to a strict self-regulation regime, this often includes regular blood glucose testing.

Because there is a great deal of variation when it comes to the capabilities and limitations among the elder diabetic population, it is important that designers consider the diversity of their users in the early stages of device development. The failure to consider age and disease related limitations can seriously affect the ability of use and may result in the termination of device use altogether.

2.3 Human Factors

Human factors is an applied science that studies human capabilities, limitations and other characteristics for the purpose of developing tools, machines, systems and environments for safe, comfortable and effective human use (Chapanis, 1996; Rogers & Fisk, 2001). The goal of human factors is to design systems that increase user safety, enhance performance and increase user satisfaction (Wickens et al., 2004). The field of human factors can be leveraged to inform the
design of technologies that are useful to and usable by people of all ages and abilities (Rogers, Stronge & Fisk, 2005). To achieve this goal, human factors research applies a wide range of methods to inspect the usability of a device, system or procedure. For example, one method commonly used in human factors is usability testing.

**Usability testing.** Usability testing is a methodology applied by human factors researchers to determine whether a system or device is easy to use (Wickens, Lee, Liu & Becker, 2004). Usability testing can be employed to verify that the device meets usability objectives (Israelski, 2011). It can determine whether a product or system can cause excessive physical or mental load and it can analyze issues associated with safety and efficiency.

To perform a usability test, participants, or ‘users,’ are asked to interact with a device to identify design flaws that have been overlooked by the designers (Wickens et al., 2004). This usability method employs actual users of the technology being evaluated. In an ideal situation, usability testing should be performed in the early stages of the design life cycle and should continue to aid design decisions throughout the process. However, when the opportunity for usability testing at the beginning of the process is missed, it is still recommended that the method be applied at any stage in development including after development, as a form of device verification and validation (Israelski, 2011).

The benefits of including human factors based techniques, such as usability testing, to healthcare products are extensive and include: increased safety, reduced user error, decreased training time, increased ease of use, improved task performance, enhanced user satisfaction, improved patient outcomes, reduced product liability risks, and increased chance of commercial success (Association for the Advancement of Medical Instrumentation [AAMI], 2009).
2.4 Human Factors and the FDA

Despite the advantages offered by employing human factors techniques, these methods are often overlooked in the development of medical devices. Organizations such as the United States Food and Drug Administration (FDA) have developed and published extensive documents outlining the importance and effectiveness of human factors in medical device use safety (FDA, 2011a; FDA, 1997; Kaye & Chenault, 2002). However, the implementation of these guidelines varies among manufacturers as they are only recommendations, not requirements or standards (FDA, 2011a). In the most recent edition of the FDAs staff guidance document titled, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, its purpose is explicitly stated in the following passage: “FDA’s guidance documents…do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency’s current thinking on a topic and should be viewed only as recommendations…” (FDA, 2011 p.4). Although the FDA has developed strict and enforceable standards for glucose meter accuracy, these devices lack a similar requirement for glucose meter usability. As a result, large differences exist among individual SMBG devices. These differences can make the transition from one device to another difficult. To ensure users feel more confident in the overall quality and consistency of their SMBG meter, an equivalent, enforceable evaluation is required to standardize the evaluation process for device usability (Kaufman et al., 2003).

2.5 Obtaining FDA Approval

**Premarket notification and usability testing.** Although the FDA’s human factors guidance documents are non-binding, SMBG meters still have to pass certain requirements before being released onto the commercial market. In order to meet FDA regulations SMBG devices have to be equivalent, in terms of clinical accuracy and labeling standards, to a pre-
existing FDA approved device that has a similar intended use (FDA, 2010; FDA, 2011b). This process is known as premarket notification or 510 (k) clearance. A complete premarket summary involves an assessment of the intended use of the device, a device description, comparison with predicate devices, an evaluation of clinical performance characteristics, and an evaluation of characteristics not covered under performance characteristics (FDA, 2011b). If any form of usability testing is conducted, it is listed under this final heading (characteristics not covered under performance characteristics) (FDA, 2011b; FDA, 2013).

Devices that have previously been cleared for market use a varying number of participants as well as a variety of usability techniques. For some devices user testing includes a questionnaire given to a group of study participants that assesses label readability and device ease of use (FDA, 2010). Label readability involves an assessment of all device labeling including the user manual, strip insert, quick reference guides, and control inserts to ensure that they are at an acceptable reading level (FDA, 2011b). To assess ease of use, untrained participants are provided with the test kit and are required to complete a questionnaire regarding the clarity of device instructions and overall ease of use (FDA, 2011b). On the spectrum of human factors based user testing methods, relying on a questionnaire is not sufficient to uncover all potential user related hazards or errors. Although the FDA recommends more in depth methods such as expert based heuristic evaluation and usability testing, these are not always performed due to the lack of formal requirement. As a result, it is up to individual manufacturers to determine what user testing methods will be applied (FDA, 2010).

2.6 Obtaining Heath Canada Approval

Health Canada uses a similar method for pre-market testing of SMBG meters. When asked what kind of usability testing SMBG meters are required to go through before release onto
the Canadian market, a regulatory information officer from Health Canada stated that “it is the manufacturer’s responsibility to determine what data should be generated/gathered in order to meet the safety and effectiveness requirements” (C. Foster, personal communication, March 26, 2013). Although it is ultimately up to the reviewers at the FDA and Health Canada to determine what devices have undergone adequate testing, device manufacturers have substantial flexibility to determine what usability methods to utilize. As a result, a general lack of standardization between SMBG meters is likely to persist.

2.7 Limitations of Current SMBG Research

A thorough search was conducted in order to identify all of the relevant literature related to the usability of self-monitoring blood glucose meters. Searches of the following online electronic databases were performed: Medline, PsycINFO, Academic Search Complete and Google Scholar (no date constraints, English-language articles only). Search terms included: blood glucose, blood glucose meter, glucometer, self-monitoring, self-management, usability, human factors, design, elderly and older adult. In depth searches were also conducted on government websites including: Canadian Diabetes Association, American Diabetes Association, Food and Drug Administration, and Health Canada. Additional searches were conducted on the World Health Organization website. Reference lists of identified research articles were also hand searched. Finally, experts identified at the FDA and Health Canada during the review process were contacted to provide additional information on their current human factors guidelines.

The current state of the SMBG usability literature reveals a limited amount of up to date research on this topic. With SMBG meter technology and design continuing to change at a rapid pace, the open literature has failed to keep up. Only a small number of SMBG usability papers have been published in the last couple of years and many of these studies are written by authors
who are affiliated with, or funded by, large diabetes technology companies (Bergenstal et al., 2012; Garg et al., 2004; Ginsberg, 2009; Renda, 2006). The usability of SMBG meters among elderly adults has received even less attention. Carpenter and Mayhorn (2011) and Mayhorn and Carpenter (2012) produced one of the only up to date studies found on the topic of elderly SMBG usability. Their study examined whether participant age or order of exposure to two different SMBG meters affected the accuracy and amount of time it took to complete a control solution test task. Their study used participants who did not have diabetes to simulate newly diagnosed patients. They discovered that younger adults performed more accurately and took less time to complete the control solution test. However, few suggestions as to why this was the case or how meter design could be improved for elderly adult users were discussed. The authors recommended that future research focus on examining the impact of physical design of SMBG testing equipment on usability. This thesis followed up on this recommendation by employing an experimental usability test to ensure that researchers, device manufacturers and users all have access to the most up to date and accurate information on the topic of SMBG meter usability.

For many people, self-monitoring of blood glucose is a key process in effective diabetes management (DCCT, 1993; UKPDS, 1998). However, as this thesis suggests, a number of barriers related to device usability continue to prevent people from achieving proper self-monitoring and tight blood glucose control. A lack of enforced standardization within organizations such as the FDA and Health Canada makes it difficult to determine whether commercial SMBG meters have undergone the appropriate amount and type of user testing among all necessary user groups. This lack of standardization often results in inconsistencies which can make it difficult for users to switch between meters. These difficulties are often exacerbated among adults 65 years and older as this is the age when people often begin to
experience declines in vision, hearing, dexterity and memory. For these reasons it is important that researchers continue to investigate the usability of SMBG meters.

This study is designed to determine the usability of two commercially available SMBG meters. This will be achieved by conducting an experimental usability test in which participants are asked to complete a common SMBG scenario consisting of two separate tasks. In performing this scenario, users will help to identify design issues and potential hazards associated with SMBG meters that impact meter usability. More specifically, this study will determine how the design of SMBG meters affect the performance of elderly participants (65-85) compared to a sample of younger participants (18-27). With elderly adults accounting for the largest proportion of the diabetic population, the specific needs of this group must be considered in the design of SMBG meters (Statistics Canada, 2010). The results acquired will be used to make design recommendations to increase SMBG meter safety, efficiency and usability. In addition, the results of this study will add to the limited literature surrounding SMBG meter safety and usability among the elderly population.

2.8 Hypotheses

1. Adults 65 years and older often begin to experience a variety of age related declines. These declines can affect the individual’s ability to successfully perform a proper blood glucose test. As a result, younger adult participants are expected to have a higher rate of success than older adults on the completion of the self-monitoring blood glucose meter tasks.

a. It is hypothesized that younger adult participants will have: 1) a higher success rate across the usability scenario, 2) will complete each SMBG task faster than the
older participants, and 3) will make fewer errors and will require fewer attempts to successfully complete the task.

2. Based on a combination of pharmacist and nurse educator recommendations, as well as human factors design principles (Fisk et al., 2009), it is anticipated that both older and younger participants will have a higher rate of success when using the One Touch Ultra 2 meter versus the Accu-Check Compact Plus meter.

   a. When using the One Touch meter participants will: 1) complete the tasks faster, 2) make fewer errors, and 3) will require fewer attempts than when using the Accu-Check meter.
Chapter 3: Methods

3.1 Participants

Participants were recruited from July 2013 to November 2013. The primary means of recruitment for the younger adults was through the research participation pool in the University of Calgary’s Department of Psychology. Both younger and elder participants were also recruited through a series of extensive poster (Appendix A) and magazine (Appendix B) advertisement campaigns. Posters were put up around a variety of locations in Calgary including: Foothills Hospital, Richmond Road Diagnostic Centre, Kerby Centre, University of Calgary, Diabetic Depot as well as a variety of churches, coffee shops, community centers, online forums, fitness centers, senior’s homes and public libraries. A poster campaign was also initiated, with permission, at the Junior Diabetes Research Foundation (JDRF) Ride for Diabetes Research fundraiser at Eau Clair Park in September 2013. In addition, a copy of the recruitment poster was placed in the JDRF monthly newsletter at no charge. Paid advertisements were also placed in the Kerby Centre Newsletter and Metro Magazine. Finally recruitment presentations were made to the diabetes educators at the Richmond Road Diagnostic Centre. Participants recruited from the research participation pool were compensated with course credit which was applied to their psychology courses. Participants recruited from the poster or newsletter advertising campaigns received a $25.00 gift certificate as a thank you for their time. In addition parking and transit or taxi fees were covered for each participant.

Table 5.1 shows the demographic information for the 45 participants who completed the study. The division of men and women was approximately equal (51% male, 49% female). Younger participants had a mean age of 20.81 (SD = 3.45) and elderly participants had a mean age of 72.10 (SD = 6.19). Near visual acuity was measured to ensure that all participants had a
minimum of 20/40 vision when interacting with the devices. All younger ($M = 20/19.81, SD = 4.13$) and older participants ($M = 20/29.33, SD = 12.95$) met this criteria. Participants also completed the Mini Mental State Examination (MMSE) (Malloy, Alemayehu & Roberts, 1991), which measured their cognitive ability. A score of 26 to 30 out of 30 indicates normal cognitive ability. All younger ($M = 29.94/30, SD = 0.25$) and older participants ($M = 28.29/30, SD = 1.67$) scored in the normal cognitive range.

Table 3.1

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Male (%)</th>
<th>Female (%)</th>
<th>Mean Age (SD)</th>
<th>Visual Acuity (20/x) (SD)</th>
<th>MMSE (x/30) (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young (18-27)</td>
<td>16</td>
<td>6</td>
<td>10</td>
<td>20.81 (3.45)</td>
<td>20/19.81 (4.13)</td>
<td>29.94/30 (.25)</td>
</tr>
<tr>
<td>Elderly (65-85)</td>
<td>29</td>
<td>17</td>
<td>12</td>
<td>72.10 (6.19)</td>
<td>20/29.33 (12.95)</td>
<td>28.29/30 (1.67)</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>23(51%)</td>
<td>22(49%)</td>
<td>53.87 (25.40)</td>
<td>20/25.94 (11.57)</td>
<td>28.87/30 (1.56)</td>
</tr>
</tbody>
</table>

While all of the younger participants had a type 1 diagnosis, the elderly group had diagnoses of type 1 diabetes (10.3%), type 2 (86.2%) and pre-diabetes (3.4%) (see Table 5.2). On average, younger participants tested their blood glucose more times per day ($M = 5.09, SD = 1.47$) than those in the elderly group ($M = 2.02, SD = 1.76$). However, the younger participants had fewer years of SMBG experience ($M = 8.94, SD = 4.75$), on average, than the elderly participants ($M = 13.10, SD = 9.80$).
Table 3.2

Participant diagnosis, average daily testing and years of experience

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Diagnosis (%)</th>
<th>Avg. # Tests Per Day (SD)</th>
<th>Years of SMBG Experience (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young (18-27)</td>
<td>16</td>
<td>Type 1 (100%)</td>
<td>5.09 (1.47)</td>
<td>8.94 (4.75)</td>
</tr>
<tr>
<td>Elderly (65-85)</td>
<td>29</td>
<td>Type 1 (10.3%)</td>
<td>2.02 (1.76)</td>
<td>13.10 (9.80)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Type 2 (86.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pre-diabetes (3.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>Type 1 (42.2%)</td>
<td>3.11 (2.22)</td>
<td>11.62 (8.54)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Type 2 (55.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pre-diabetes (2.2%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2 Study Setting and Materials

Experimental sessions took place in the Healthcare Human Factors Simulation Laboratory (HHFSL) at the W21C Research and Innovation Centre. The HHFSL consists of two rooms: 1) the simulation room where the participants took part in the study session and; 2) the control room where the researcher observed the participant throughout the experiment. A one way mirror separated the two rooms. Four video cameras and microphones mounted in the ceiling of the simulation room allowed the researcher to record each session in detail. All study sessions were video recorded using Noldus Recorder, and later coded with Noldus Observer XT (v. 9.0).

**SMBG meters.** In this study, participants interacted with two self-monitoring blood glucose meters to complete a series of common SMBG tasks. The meters used in this study were chosen based on a number of criteria including: market share research, pharmacist recommendation, patient recommendation and human factors design principles. The Accu-Chek Compact Plus and the One Touch Ultra 2 meters were evaluated in this study. The Accu-Chek meter is manufactured by Roche diagnostics; Roche accounts for the largest percentage of world
glucose monitoring sales (26.48%) with a 2011 total of US$3.01 billion (Kalorama Information, 2012). The One Touch Ultra 2 Meter is manufactured by Life Scan; Life Scan accounts for the second largest percentage of world glucose monitoring sales (23.37%) with a 2011 total of US$2.65 billion.

**Experimental scenario and task protocol.** Participants were provided with a standardized scenario and task protocol (Appendix E). This protocol consisted of a mock SMBG scenario along with all of the instruction and details needed to complete two SMBG meter tasks. The first task required the participant to set the proper date and time on the meter. The correct entry of date and time might seem like a straightforward task however; a study examining the use of blood glucose meters with users’ memory capabilities found that 40.4% of users had the wrong date and time setting input into their meters (Bergenstal, 2008). When this information is entered incorrectly it can cause user and practitioners to misinterpret the users’ blood glucose patterns and this data becomes largely meaningless. The second SMBG meter task asked participants to perform a control solution test. This task is important because it allows the user to determine the status and reliability of their meter and test strips. Although this task might appear to be easy because it so closely resembles a blood glucose test, previous research has found contrary evidence. In a study measuring SMBG procedures, diabetes nurse educators observed the technique of 280 participants with diabetes and found that 62% of the participants were unable to perform a control solution test correctly (Bergenstal et al., 2000).

### 3.3 Procedure

Upon arrival at the W21C Research and Innovation Centre, participants were given an informed consent form (Appendix F) and a demographic questionnaire (Appendix G). The questionnaire assessed demographic details such as type of diabetes, age of diagnosis and level
of education. The Standardized Mini Mental State Examination (SMMSE) was used to screen all participants for possible cognitive impairments (Malloy et al., 1991). No participants were excluded based on the SMMSE cognitive impairment criteria. Before arriving at the HHFSL, participants were systematically assigned to one of two groups using an alternating assignment method (Shadish et al., 2002). For example, participant one was assigned to use the Accu-Chek meter and then the One Touch meter. Participant two was assigned to use the One Touch meter and then the Accu-Chek meter and so on for each participant. Those assigned to group one interacted with the Accu-Chek and then the One Touch meter (Figure 3.1), whereas those in group two interacted with the One Touch and then the Accu-Chek meter. The device order was counterbalanced in an attempt to prevent order effects (Shadish, Cook & Campbell, 2002).

![Figure 3.1. Picture of the Accu-Chek and One Touch meters](image)

Before participants began to interact with the first meter, a standardized verbal protocol was read to them that outlined what was expected of them throughout the experimental session. Participants were instructed to begin the session by briefly scanning through all of the written informational aids that accompanied the device. For instance, they were advised to scan through
the written instruction manual and quick reference booklets as well as the control solution and test strip packaging. All participants were given five minutes to complete this portion of the study. Participants were told that they would be able to refer back to the instructions at any time throughout the experimental session. Next, participants were presented with a standardized Scenario and Task Protocol Form (Appendix E), which specifically described the tasks that they were to perform with the meter. Tasks were presented to participants one at a time with each one on a separate page. Participants were asked to try and complete each of the tasks independently.

The tasks presented on the protocol form were written as follows:

Usability Task Part 1: You have just purchased a new self-monitoring blood glucose meter. To ensure that the meter is providing the correct information for the blood glucose readings please set the proper **date** and **time** on the meter. When you are finished please record the date and time you set in the meter.

Usability Task Part 2: You have just purchased a new self-monitoring blood glucose meter. To ensure that the meter is providing correct blood glucose readings please perform a control solution test. Please try to complete this task independently using the meter you were provided. When you are finished please record the results of the control solution test on this form.

Usability Task Part 2 also required participants to read through two questions related to the control solution task which they answered after completing the control test: 1) Are the results of the control solution test within range?, and 2) How have you determined whether or not the control solution results are within range?

Once the participant finished reading through part one of the Scenario and Task Protocol the researcher provided them with the first SMBG meter and they were told to begin the scenario. Once the participant completed both tasks for the first SMBG meter this process was repeated for the second device. Finally, participants were asked to take part in a structured interview regarding their experience during the usability scenario (Appendix H). Any questions or concerns that the participant had were addressed during this time. Participants were then
debriefed (Appendix I), assigned course credit, or given a $25.00 gift certificate as compensation for their time, and thanked for their participation.
Chapter 4: Analysis and Results

4.1 Study Design and Analysis

This study used a mixed measures design. There were two independent variables: Age (young, elderly) represented the between subjects variable and meter type (Accu-Chek, One Touch) represented the within subjects variable. There were a number of dependent variables that were analyzed separately. Categorical dependent variables included: task results (success or failure) and type of errors made. Categorical variables were analyzed using a combination of Chi Square Analysis, Fishers Exact Tests, as well as the Generalized Estimating Equation (GEE) (see below for a brief explanation). Continuous dependent variables included: time to complete each task, total number of errors made and total number of additional attempts. Continuous variables were analyzed using the GEE. All quantitative data was analyzed using Predictive Analytics Software (SPSS v.20). Throughout the analysis a p value of $\leq .05$ was considered significant.

Qualitative data obtained from participant interviews was analyzed using a classic content analysis (Hsieh & Shannon, 2005). Qualitative statistical software NVivo (v.10) was used to manage, sort and organize qualitative data. The think aloud method, which requires participants to verbalize their actions as they complete a task, was considered for qualitative data collection. This method is useful because it avoids reliance on participant explanations that are usually offered after the completion of the study tasks (Fisk et al., 2009). However, previous research has found that because verbalization requires additional cognitive processing it can cause participants to perform more slowly rendering all task based time measures inaccurate (Fisk et al., 2009). In addition, for elderly adults who may have diminishing cognitive abilities, the process of verbalization can create a dual task situation (Pashler, 1994). This means that talking aloud acts as an additional task that must be performed causing a detriment in
performance on the original task. For these reasons, the think aloud method was not used in the current study.

4.2 Generalized Estimating Equation

The generalized estimating equation (GEE) was developed by Liang and Zeger (1986) as an extension of the generalized linear model (GLM) that allows for the analysis of repeated measures data, or other correlated observations (Ghisletta & Spini, 2004; IBM, 2011). While the GEE remains somewhat unknown within the area of social sciences, it has had increasing use in the fields of biology and epidemiology for the last decade (Ghisletta & Spini, 2004).

Within the GEE model all independent variables are assumed to be categorical, while any included covariates are assumed to be scale. The GEE equation also assumes that all cases are to be dependent within subjects and independent between subjects (IBM, 2011). The GEE approach was chosen in place of the repeated measures analysis of variance (RM ANOVA) to better accommodate the data collected in this study. First, the GEE is very well suited to address repeated measures variables and correlated data; this study includes the repeated measure ‘meter type.’ Second, the GEE can integrate various forms of response data including continuous (e.g., task times), count (e.g., number of additional attempts made) and binary (e.g., mistake made (y/n)). Third, the GEE can be applied when there is incomplete or missing data because individual observations are treated as missing completely at random (Ghisletta & Spini, 2004). Finally, additional advantages offered by the GEE include: 1) consistent, asymptotically normal, unbiased standard errors; and 2) the GEE implies no strict distribution assumptions.
4.3 Quantitative Analysis: Categorical Data

Task 1 Results: Set Date/Time

*Success or Failure.* Success was achieved if the participant was able to set the proper date and time without assistance. Failure to complete the task occurred if the participant was unable to complete the task within 30 minutes, if the participant gave up on the task before the end of the session or if the participant required assistance from the researcher to complete the task. Researcher assistance was provided when the participant explicitly asked for help, if the participant was unable to make any progress or did not interact with the device for a period of ten minutes, or if the participant was becoming obviously frustrated. Researcher assistance was provided to ensure that participants could progress through the device scenario and entire session. Assistance was offered to preserve the participants’ confidence and to prevent heightened frustration.

Task completion was coded as 1 = Success, 0 = Failure. The data was analyzed using the Chi Square Test. When expected cell values were less than five, Fishers Exact Test was used (Siegel & Castellan, 1988). As expected, the statistical analysis found a significant difference between the younger and elderly groups when using the Accu-Chek meter, $\chi^2 (1) = 18.64, p < .001$. Eighty-eight percent of younger participants successfully completed the set date/time task, whereas only 21% of those in the elderly group did. When using the One Touch meter, all of the younger participants and 79% of the elderly participants completed the date/time set task. The difference approached significance, $\chi^2 (1) = 3.82, p = .058$.

Task 2 Results: Control Solution Test

To successfully perform blood glucose monitoring, patients with diabetes must be able to: 1) successfully operate their blood glucose meter and 2) successfully interpret their blood
To test whether participants could successfully perform blood glucose monitoring, two similar tasks were tested: 1) performing a control test and producing a result and 2) interpreting the control test reading.

**Success or failure.** Success when performing a control test was achieved if the user was able to obtain an in-range reading using the control solution. If the participant was unable to complete the task without assistance or if the participant was unable obtain an in-range reading using the control solution, their performance was scored as a failure. Because some cell frequencies were less than five, the Fishers Exact test was used to analyze this data.

When using the Accu-Chek meter, the difference between younger and elderly groups approached significance, $\chi^2 (1) = 3.22, p = .090$. All of the younger participants and 82% of elderly participants completed the control test task. When participants used the One Touch Ultra 2 meter to complete the control task, the younger group performed significantly better than the elderly, $\chi^2 (1) = 9.03, p = .002$ All of the younger participants successfully completed the control test task, whereas only 59% of those in the elderly group did so.

**Interpretation of the Control Solution Test Results**

**Success or failure.** To achieve success on the control test interpretation task, participants were required to locate the proper control solution range and then answer two interpretation questions correctly. The two questions were:

1) Are the results of the control solution test within range? Please circle one: YES or NO.

2) How did you determine whether or not the control solution results were within range?
The location of the control solution range on the Accu-Chek meter could be found on the outside of the test strip drum container. For the One Touch, the range was found on the outside of the test strip vial. Please refer to Figure 4.1.

![Control solution range on Accu-Chek and One Touch meters](image)

**Figure 4.1.** Control solution range indicated on the Accu-Chek meter (left) and on the One Touch meter (right).

Participants who correctly answered both of the interpretation questions without assistance were categorized as successful. Those who did not answer both questions correctly were classified as having failed the interpretation task. Results were coded as a 1 when a participant was successful and a 0 when they failed. The results of the interpretation task were analyzed using the GEE. Younger and older participants significantly differed when interpreting the control solution results, $\beta = 2.06^2$, $p = .003$. Younger participants were significantly more likely to complete the interpretation task successfully than participants in the elderly group.

**Types of Errors**

Three categories of errors were captured during the set date/time and control solution tasks: 1) test strip errors, 2) control solution application errors and 3) error codes (see Table 4.1).

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2 The score of 2.06 is interpreted according to the original coding scheme with 1=success and 0=failure. Higher scores are associated with a higher probability of success. A high score of 2.06 for the younger group means they were more successful than those in the elderly group.
A Chi-Square test was used to analyze this data. When cell frequencies were less than five, Fisher’s Exact test was used.

Table 4.1

*Type of errors made by meter type and age group.*

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Accu-Chek</th>
<th>One Touch</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Younger</td>
<td>Elderly</td>
</tr>
<tr>
<td>Test Strip Errors</td>
<td>44%</td>
<td>83%</td>
</tr>
<tr>
<td>Control Solution Errors</td>
<td>6%</td>
<td>24%</td>
</tr>
<tr>
<td>Meter Error Codes</td>
<td>13%</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Test strip errors.* Test strip errors included the following: 1) accidental ejection of test strips (participant pressed the eject button by accident or unknowingly), 2) use of additional test strips (participant used, released or discarded the original test strip before completing the task and had to use and insert a new one), 3) improper test strip insertion (participant inserted the wrong end of the test strip into the meter or participant attempted to insert test strip into wrong device (e.g., lancing device), and 4) insertion of test strip during the wrong task (e.g., when setting date/time).

As expected, younger participants made fewer errors than those in the elderly group with either meter, $\chi^2 (1) = 7.32, p=.007$. When using the Accu-Chek meter, significantly fewer younger participants (44%) made test strip errors compared to those in the elderly group (83%). The most common test strip error made by both the younger and older participants was the
accidental ejection of a test strip before completing the task. Eighty three percent of elderly participants and 44% of younger participants accidentally or unknowingly ejected a test strip. A similar pattern of results was found when using the One Touch meter, $\chi^2 (1) = 11.78, p = .001$. Younger participants made fewer test strip errors (6%) compared to elderly participants (59%). When using this device, the most common test strip error was the use of additional test strips. Ninety-four percent of elderly participants and 45% of younger participants used two or more test strips per task.

**Control solution application error.** Any method or technique of applying the control solution that resulted in a failure to produce a control test reading was classified as an application error and included: Applying the control solution on the wrong end of the test strip or applying the solution to the incorrect location on the test strip. For example, when using the One Touch meter, the control solution must be applied to the tip of the test strip so it can absorb into the proper channel (see Figure 4.2). If the participant did not put the control solution directly into the channel then the meter gives no reading. Control solution application errors were not significantly different between younger (6%) and older participants (24%) when using the Accu-Chek meter, $\chi^2 (1) = 2.26, p = .226$, although absolute percentages were in the expected direction. When using the One Touch meter, older participants (72%) had significantly more errors than did younger participants (6%), $\chi^2 (1) = 18.06, p < .001$. 
Error codes. Error codes that were displayed on either meter during the set date/time and control solution tasks were also recorded and analyzed. Figure 4.3 shows two examples of error codes displayed during the tasks. While the One Touch error screen is somewhat self-explanatory, the Accu-Chek error screen provides users with a code number and no indication of what is wrong or what actions should be taken. According to the Accu-Chek instruction manual, the E-5 code indicates a series of possible errors including: 1) the blood was applied to soon, 2) the test strip was bent prior to testing, 3) the measurement window was dirty or 4) there was moisture in the meter. The frequency in which error codes were displayed did not significantly differ between younger (13%) and elderly (14%) groups when using the Accu-Chek, $\chi^2(1) = .015, p = .642$. A similar pattern of results were found when using the One Touch meter, $\chi^2(1) = 1.77, p = .258$. None of the younger participants and 10% of elderly participants received an error code when completing the two tasks.
Time to Complete Each Task

The focus of this analysis was to determine if participants could complete common SMBG meter tasks in a timely manner. Task completion times are one of the most commonly used metrics in human factors (Wickens et al., 2004). The clock started once a participant finished reading the task instructions, the participant questions were answered and the researcher left the room. Once a participant completed all tasks and associated questions, the participant said “finished” and/or visually signaled their completion (e.g., the participant gave the thumbs up), when the participant gave up, or when the researcher felt the participant could not continue (e.g., the participant became visually or verbally frustrated), the clock was stopped.

Task 1: date/time set. The GEE was used to analyze this data. A normal probability distribution and an exchangeable correlation matrix were used to accommodate the continuous nature of this data. As in RM ANOVA, this structure represents homogeneous correlations between elements (IBM, 2011). When analyzing the results for the date/time set task, the variable ‘years of experience’ (how many years’ participants had been testing their blood glucose) was included as a covariate. Significant main effects were found for age group, $p = .043$, and meter type, $p = .026$. All results are reported in seconds unless otherwise stated.
**Age group.** As hypothesized, participants in the younger group completed Task 1: set date/time, significantly faster ($M = 137.01s$, $SE = 585.80s$) than participants in the older group ($M = 428.49s$, $SE = 266.09s$). On average, younger participants completed the set date/time task 4 min and 9 seconds faster than those in the elderly group.

**Meter type.** Participants completed Task 1: set date/time significantly faster, ($M = 179.04s$, $SE = 323.30s$) when using the One Touch meter than the Accu-Chek meter ($M = 386.46s$, $SE = 428.25s$). On average, when using the One Touch meter participants completed the task 3 minutes and 46 seconds faster than when using the Accu-Chek.

**Task 2: Control solution test.** The GEE was used to analyze the control solution time data. A normal probability distribution and an exchange correlation matrix were applied. Again, the covariate, ‘years of experience’, was included in this analysis. A significant interaction was found for age group x meter type, $p = .048$ (Figure 4.4). The main effect of age group approached significance, $p = .072$. Pairwise comparisons were conducted to explore the interaction.
Figure 4.4. The time needed to complete the control solution test for meter type and by age group. Error bars 95% CI.

*Age group x meter type.* Pairwise comparisons found that when using the Accu-Chek meter elderly participants performed the control test task faster ($M = 373.40s$, $SE = 328.07s$) than when using the One Touch meter ($M = 432.50s$, $SE = 412.63s$). On average, elderly participants performed the control test task 59 seconds faster when using the Accu-Chek meter than when using the One Touch meter. In contrast, younger participants performed the control test task faster when using the One Touch meter ($M = 137.34s$, $SE = 610.44s$) than the Accu-Chek meter ($M = 211.57s$, $SE = 644.08s$). On average, younger participants completed the control task 1 minute and 24 seconds faster when using the One Touch meter compared to the
Accu-Chek meter. Overall, younger participants performed the control test task using the Accu-Chek meter 2 minute and 39 seconds faster than the elderly participants. When using the One Touch meter, younger participants performed the control test task, on average, 5 minutes and 32 seconds faster than the elderly participants.

**Age group.** The main effect for age group approached significance, \( p = .072 \). Younger adults (\( M = 174.45s, SE = 594.34s \)) performed the task faster than the elderly adults (\( M = 402.95s, SE = 312.05s \)). On average, participants in the younger group performed the control solution task 3 minutes and 8 seconds faster than the elder adults.

**Total Number of Errors Made**

The total number of errors made by the participants for tasks 1 and 2 were categorized and analyzed based on error definitions described previously (see Type of Errors). The GEE was used to analyze this variable. A negative binomial regression model was used due to the nature of the data. This model is generally recommended when analyzing count data (e.g., number of errors made) (IBM, 2011). The negative binomial regression model also provided the best fit when compared to the Poisson model.

A significant main effect was found for age group (\( p < .001 \)), which confirmed the original hypothesis that younger participants would commit fewer errors. Those in the elderly group committed significantly more errors (\( M = 2.07, SE = .25 \)) than the younger group (\( M = .48, SE = .19 \)). On average those in the elderly group made an additional 1.59 errors than those in the younger group. A non-significant main effect was found for meter type, (\( p = .888 \)), indicating neither meter was necessarily inferior. See Figure 4.5.
Figure 4.5. Average number of errors made by younger and elderly groups when using the Accu-Chek and One Touch meters.

Additional Attempts Made

When participants tried to perform the same task step a number of times with either meter it was recoded and analyzed. Additional attempts were defined as all subsequent activation attempts made after the participant had initially activated the blood glucose meter. For example, an additional attempt was counted each time the meter was turned off and then back on or if the meter timed out and the participant had to restart it in order to complete the task. Again, the GEE
was used to analyze the total number of additional attempts made. A negative binomial regression model provided the best goodness of fit for this analysis.

**Task 1: Set date/time.** Significant main effects were found for both age group (\(p = .018\)) and meter type (\(p < .001\)). Participants in the younger group made fewer additional attempts (\(M = .31, SE = .15\)) than those in the elderly group (\(M = 1.09, SE = .23\)). On average, elderly participants made an additional .78 attempts to complete the set date/time task than those in the younger group. Participants also required more additional attempts when using the Accu-Chek meter (\(M = 1.90, SE = .36\)) than when using the One Touch meter (\(M = .18, SE = .09\)). On average, participants required an additional 1.72 attempts when using the Accu-Chek meter to set the date/time compared to the One Touch meter.

**Task 2: Control solution test.** No significant main effects were found for age group (\(p = .062\)) or meter type (\(p = .140\)). Younger participants required fewer attempts (\(M = .17, SE = .09\)) than those in the elderly group (\(M = .50, SE = .12\)). Participants in the elderly group required an additional .33 attempts when compared to those in the younger group. More additional attempts were required when using the Accu-Chek meter (\(M = .46, SE = .15\)) than when using the One Touch meter (\(M = .18, SE = .09\)). On average, participants required an additional .28 attempts when using the Accu-Chek compared to the One Touch.

**4.4 Qualitative Analysis**

A classic content analysis was used to analyze the participant interview data (Hsieh & Shannon, 2005). Participant interviews were recorded, sorted and organized using qualitative statistical software NVivo (v.10). To begin, all participant interviews were transcribed and uploaded into one list in NVivo. Next, the interview data was reviewed and chunked into small
passages based on common themes, and then a code was assigned to each chunk. The data was reviewed and coded several times to ensure saturation of topics. This is the point when the researcher was no longer identifying any new concepts or themes from the data (Glaser & Strauss, 1967). Finally codes were grouped together to form broader categories. The number of participant references made for each category was calculated in NVivo. Categories that received the largest number of participant references were used to specify descriptive design recommendations, which are provided in the Discussion.

A total of 20 codes were identified at the point of data saturation (Appendix J). Once codes were grouped based on relationships and data linkages, three major categories emerged: 1) device related barriers to proper self-monitoring; 2) age related barriers to self-monitoring; and 3) additional barriers to self-monitoring. Data analysis was inductive and therefore no pre-defined categories or structures were used to analyze participant interview data.

**Most Frequent Themes**

**Device related barriers to proper self-monitoring.** This category received the largest number of references (418) from study participants across all of the structured interviews. Within this category the most referenced codes included: meter buttons, meter instructions and meter size, which are elaborated.

**Meter buttons.** Participants did not like the buttons on the Accu-Chek meter. The majority of participants claimed that they had difficulty understanding what the buttons meant and called the buttons “unintuitive”, “confusing” and “abstract” (Figure 4.6). Several participants could not figure out how to turn the device on or off and many wasted test strips because they did not know that the middle button functioned as a test strip release button. In addition, several
participants complained that they had a difficult time depressing the buttons on this device. They said the buttons tended to stick and required a very firm push to activate.

Figure 4.6. Buttons on the Accu-Chek Compact Plus meter. “M” is meant to represent memory, “S” is meant to represent settings and the middle button turns the device on/off and releases test strips.

Overall, participants preferred the buttons on the One Touch (Figure 4.7). Specifically, they liked the up/down arrows as they were “intuitive” and allowed the participants to scroll easily through the date/time set task options.

Figure 4.7. Up and down buttons on the One Touch Ultra 2 meter helped participants scroll through information easily.
**Meter instructions.** Participants liked the booklet format that was used to present the Accu-Chek instructions. They also liked the table of contents in the booklet as well as the “Quick Guide” instructions, which is a one-page fold out with graphics. However, the information on the Quick Guide was thought to be less than satisfactory. The main instruction manual was described as “confusing”, “overwhelming” and “complicated.” Many participants commented on the amount of information in the 218 page manual saying, “it’s too much information to read,” “too difficult,” and “it’s a lot of unnecessary information.” Several participants said the instructions in the manual were unclear and noticed that the instructions did not always correspond with certain aspects of the meter. For example, the presentation of the sequence of steps required to set the date and time on the meter in the manual did not correspond to the sequence of steps needed to actually perform the task.

Participants preferred the type of and amount of graphics that were used in the One Touch instructions (Figure 4.8). They also liked the layout of information and found that the One Touch instructions were presented in a more “logical order.” Finally, participants felt that the One Touch instructions were more concise than the Accu-Chek instructions. Participants disliked the size of the One Touch instruction sheet. They said the physical size was too big (80cm x 64cm).
Figure 4.8. Graphics from the Accu-Chek (left) and One Touch (right) manuals showing users how to compare the results of their control test with the control solution concentration range.

**Meter size.** Participants from both groups preferred a meter that was slim, small and could easily fit into a purse or fanny pack. The size of the meter was largely equated with convenience and practicality, the smaller, the better. When evaluating the two SMBG meters, the majority of participants disliked the size of the Accu-Chek. They described the meter as “awkward”, “bulky”, “cumbersome” and “clumsy.” Several participants stated that they would not carry around a meter the size of the Accu-Chek because it was too large. Most of the participants preferred the size of the One Touch meter calling it “handy”, “convenient”, “light” and “compact.”

**Age related barriers to proper self-monitoring.** This category received the second largest number of references (80) during the structured interviews. Within this category, the highest frequency of codes included: vision, dexterity and memory.

**Vision.** Participants complained that the size of text on the meter screen, and in the meter instruction manuals, was too small. Specifically, elderly participants who used the Accu-Chek meter said that the display background was too dark, which made it challenging to see the text on
screen. One participant said the screen text was so small and difficult to see that it prevented him from completing the date and time setting task. When using the One Touch meter, a number of participants said they had difficulty placing the control solution into the correct channel on the test strips because the channel was so difficult to see (Figure 4.9). Several participants indicated that the size of print in the instructions for the One Touch was too small. Participants liked the size and clarity of the One Touch screen and said the backlight function would make testing at night much easier.

![Image of One Touch test strip with arrow pointing at control solution channel.]

_Figure 4.9._ One Touch test strip with arrow pointing at control solution channel.

**Hands/dexterity.** Thirteen percent of the elderly participants said that they had difficulty grasping and manipulating small objects due to arthritis or essential hand tremors. When using the Accu-Chek meter, participants said that the buttons were too close together (see Figure 4.6 above). Because the buttons were close together, participants accidentally pressed the test strip ejection button when trying to press one of the other buttons. Other participants had difficulty pushing the buttons with sufficient force to activate them. When using the One Touch meter, several participants liked the size and shape of the meter and said that it fit nicely into their hands. However, some suggested that a rubber grip should be added to the smooth surface on the back and sides of the meter to assist with holding and manipulating.
Many of the elderly participants with arthritis had difficulty opening the One Touch test strip container (see Figure 4.10) because the lid required substantial force to pull open. Once the container was opened, pulling out just one test strip was difficult. To solve this problem, participants would dump out a number of test strips onto the table surface, pick up one and put the rest back in the container. Others licked their finger before trying to pull out a test strip so that the strip was more likely to stick to their finger. Because the Accu-Chek meter contains a drum of test strips where one strip is ejected with a single button push (see Figure 4.11), it could be expected that elderly participants would prefer this function. However, this was not the case. Participants complained that they had difficulty locating the test strip compartment and several participants lacked the strength to open this compartment and had to ask the researcher for assistance with completing this task (Figure 4.12).

*Figure 4.10. One Touch test strip container.*
**Figure 4.11.** Accu-Chek graphic demonstrating how to eject a test strip with the push of the middle button.

**Figure 4.12.** Diagrams taken from the Accu-Chek Compact Plus meter instruction manual (2008) demonstrating how to open the test drum compartment and how to load a new test strip drum.

**Memory.** There were two sub themes within the topic of memory. First, when participants were asked the question “What barriers prevent you from testing,” some answered that it was simply forgetfulness. On occasion, participants from both the younger and older groups admitted to getting caught up in their day-to-day activities and forget to perform tests. Device manufacturers have tried to address this issue with a number of alarm settings on their meters. However, many users said that they never used these advanced functions on their own meters. Second, several of the elderly participants found that the Accu-Chek and One-Touch
instruction manuals presented too much information. When discussing the Accu-Chek instructions one participant commented, “By the time I get to the back of these instructions, I can’t remember what I read in the front.” It was suggested that the meter instructions should be condensed and re-organized so that information could be found and used more easily.

**Additional barriers to proper self-monitoring.** This final group of coding categories is composed of the third most referenced (79) themes and include meter complexity, cost and additional barriers.

**Meter complexity.** Participants found the Accu-Chek meter especially complex and confusing when compared to the One Touch. After initial contact with the Accu-Chek meter many participants commented that it was “not user friendly” and was “unintuitive”. Several participants could not even figure out how to turn the device on. In addition, the lack of a main menu screen, or primary starting point of any kind, made the set date/time task especially difficult for participants. Participants felt that there was too much learning required to use this device and that it was too technical for the average person. Finally, many participants, especially those in the elderly group, felt there were too many extraneous features (e.g., additional alarm settings) that made the meter seem overwhelming. Due to the perceived complexity, several participants said that they would never purchase or use this meter. When participants were asked to choose which of the two meters they found easier to use 98% chose the One Touch. When asked which meter they would recommend to other people, 91% of participants chose the One Touch meter.

**Cost.** Participants admitted that the cost of test-strips prevented them from testing as often as they would like. One participant, who usually tested 2-3 times per day, revealed that she
had not tested in over a week because of the cost of test strips. In addition, numerous participants said that instead of using each lancet once, as recommended (CDC, 2012f), they used them for a month at a time, for economic reasons. When participants were asked to explain why they would consider switching from one meter to another, many said that their decisions were based on price. If a certain brand of test strips went on sale at their pharmacy, they would switch meters, which are often offered at no cost, to obtain the deal.

Participants disliked the potential for test strip wastage when using the Accu-Chek meter. When performing the two tasks, 82.8% of elderly participants and 43.8% of younger participants accidentally or unknowingly ejected a test strip. When using the One Touch many participants found it difficult to insert the control solution into the proper channel on the test strip, others failed to insert the proper amount of solution. With each mistake, participants would use an additional test strip. Participants revealed that they preferred meters with test strips that allowed for the addition of blood, if the blood was not applied to the proper location or if the right amount was not applied on the first attempt.

Additional barriers. In addition to meter complexity and cost, social stigma, convenience, self-regulation, pain and frustration were given as additional barriers to proper self-monitoring. In regard to social stigma, participants were asked if they felt comfortable testing their blood glucose in public environments. Out of 45 participants, 16 (33.5%) said that they did not feel comfortable doing so. These participants said that their discomfort was due to others and they did not want to make other people feel uneasy. Many participants admitted to testing in public washrooms to obtain privacy. Others simply limited their testing to when they were at home so they would not have to deal with public testing. Convenience was another barrier to
testing. A number of participants did not like to carry around their meter and supplies and preferred to only test at home.

Some participants chose to decrease the number of times they tested per day/week because they felt that their diabetes was under control. Others said that they could feel whether their blood glucose was either too high too low. As a result, they felt that they did not need to test as often as was recommended. A few participants limited testing due to the pain involved with repeatedly poking their fingers. These participants said that if a device was available that did not require them to constantly prick their fingers then they would test more often. Finally, many expressed a lot of frustration with the process of blood glucose testing. Some participants decreased the number of times they were supposed to test because they were sick of being reminded that they had diabetes. Others were frustrated with their blood glucose meters and lancing equipment. Some found the meters too complex and, although every participant in this study had at least a month of independent SMBG experience, some were still not proficient with the steps involved in performing a proper blood glucose test.

**Observational Summary**

In addition to the classic content analysis, observational data was collected throughout each of the study sessions. This data consisted of interesting participant performances as well as salient quotes and was a valuable supplement to the participant interviews. Some noteworthy observations are listed below.

Prior to interacting with each of the SMBG meters, participants were given five minutes to review all of the device instructions. During this time several of the younger participants took a quick glance at the instructions and then sat patiently or decided to occupy themselves with another task. In contrast, the majority of elderly participant used the entire time to scan through
the instructions and several even took notes. Once the five minutes was over and participants began to perform the SMBG tasks, the observational data allowed the researcher to perceive the different strategies used by participants to complete the tasks. Elderly participants were, once again, very reliant on the instruction manual. Many of them continued to read for several minutes before attempting to turn the meter on. In contrast, younger participants rarely referred to the instruction manual and instead attempted to complete the tasks using a trial and error approach. Many candid quotes were also obtained through the observation data. In reference to the One Touch instruction manual a participant said, “You’d have to be a surgeon to read these, so complicated.” While reading the instructions for the Accu-Chek meter another participant commented, “The Accu-Chek can go in the garbage.”

This data was also useful in highlighting problems that were common among participants. For instance, when completing the set date/time task on the Accu-Chek meter it became clear that participants were struggling with the task because they were pressing the wrong button. Instead of pressing the ‘s’ (setting) button which would allow them to enter the appropriate screen to begin the set up process, a large number of participants were pressing the ‘m’ (memory) button. Once in the memory screen they were unable to perform the proper steps and appeared confused as to what to do next. When conducting the structured interviews at the end of each session participants often had a difficult time recalling and/or articulating why they were unable to complete the set date/time task or where they encountered problems. The observational data provided additional information and helped to clarify where and why participants were having issues.
Chapter 5: Discussion

The purpose of this study was to carry out a thorough evaluation of two current, commercially available SMBG meters to determine if they are as easy to use as the marketers claim. More specifically, this study focused on evaluating SMBG meter design issues that affect usability among the largest diabetic demographic, elderly adults 65 years and older (Statistics Canada, 2010). To examine how the design of SMBG meters affect the performance of elderly adults, an elderly group was compared to a sample of younger participants (18-27). The goal was to investigate whether adults 65 years and older with diabetes can successfully use a SMBG meter to accomplish important self-monitoring tasks? To answer this question, a set of measures were used that included: success or failure in completing tasks (set date/time, control solution test, interpretation of control test results), task completion times, frequency and type of errors made and number of attempts required to complete each task.

5.1 Age Group

Overall, age group influenced all of the dependent variables. As expected, younger participants were more successful in performing the SMBG meter tasks, were faster, committed fewer errors and made fewer additional attempts throughout the experimental session.

Task Performance

The purpose of performing a control solution test is to identify problems related to the meter or test strips (Bergenstal, 2008). In addition, the control solution task closely mimics a blood glucose test and can provide insight into whether users can perform many of the necessary steps involved in blood glucose testing. In the current study, younger participants performed the control solution task with a success rate of 100% while the elderly group failed to produce a
successful reading 18 to 21% of the time. A previous study that measured the performance of 280 ambulatory patients with type 1 and type 2 diabetes, who were not in an emergency situation, found an even higher rate of failure with 62% of participants’ unable to accurately perform a control test (Bergenstal et al., 2000).

Although participants showed improved performance over the participants in Bergenstal et al.’s (2000) study, these results are still concerning for a number of reasons. First, the participants in the current study were all experienced SMBG users who performed blood glucose tests an average of three times per day. For this reason it was expected that participants would be comfortable performing a task that so closely mimics blood glucose testing. Second, the study by Bergenstal et al (2000) assessed thirteen different aspects of blood glucose meter techniques and found that the inability to perform a control solution test was the second most significant barrier to proper blood glucose testing. This suggests that if a person with diabetes cannot perform a successful control solution test they may have similar problems performing an actual blood glucose test. Accurate blood glucose testing is necessary to make appropriate self-management decisions. The inability to perform a proper blood glucose test can lead to immediate consequences such as hyperglycemia or hypoglycemia. Elderly adults are at an increased risk of experiencing a hypoglycemic due to factors such as cognitive impairments and high prevalence of comorbidities (Ligthelm, Kaiser, Cora & Yale, 2012). The inability to achieve blood glucose targets, based on incorrect testing, can also lead to long term complications including eye disease, amputation, impotence, difficulties in pregnancy and nerve damage (CDA, 2012b; Florez et al., 2003).

Elderly participants had even less success when completing the set date/time task with an average failure rate of 61%. A previous study reviewed the date and time setting for 151 patients
with diabetes and found similar results (Meneghini & Arce, 2005). Only 40% of the patients had input their date and time settings within an hour of the actual time. The incorrect entry of the date and time is not inconsequential. When the wrong information is entered into a patient’s meter, it can cause the patient and their practitioner to misinterpret blood glucose patterns rendering the meter readings largely meaningless (Bergenstal, 2008). If the incorrect date/time goes unnoticed this could affect management as the practitioner could prescribe an inappropriate insulin regime based on incorrect patterns.

Elderly participants were also significantly less successful in interpreting the results of the control solution test than the younger participants. However, this was largely because participants were unable to locate the control solution results range (refer to Figure 4.2), as opposed to a lack of knowledge on proper blood glucose targets. When participants were unable to locate the control solution range they usually answered the interpretation questions based on their knowledge of what was considered to be a normal reading for them. For example, a participant produced a control solution result of 8.3mmol/L and concluded that the results were within range. When asked how she determined whether or not the control solution results were within range she answered, “I checked my blood before I came, it’s [the control solution result] pretty close.”

**Task Times and Task Errors**

The time it took participants to complete the set date/time and control solutions tasks was important because typical users have limited patience and are not willing to invest large amounts of their time to learn to use a device, or to execute a task that is marketed as being simple (AAMI, 2009). If a task takes too long to learn or complete, this can result in the termination of device use all together. In this study younger adults completed the set date/time and control
solution test faster than the older adults. These results are in line with current research, which supports the trend that older adults have a more difficult time than younger people when it comes to the use and operation of various technologies (Czaja et al., 2006; Rogers & Fisk, 2010). Studies comparing older and younger participants on a variety of time-based tasks consistently demonstrate performance differences, as younger adults yield faster task times (Carpenter & Mayhorn, 2011; Mykityshyn, Fisk & Rogers, 2002; Ng, Tao & Or, 2013). A rule of thumb provided by Fisk et al., (2009), states that older adults (defined as ≥ 60) are 1.5 to 2 times slower than their younger counterparts when completing novel tasks or tasks involving movement. This is largely due to the general age related decreases in sensory, cognitive and motor functioning (Fisk et al., 2009). The results of the current study are in agreement with Fisk et al.’s (2009) rule of thumb. While performing the set date/time task older adults took 1.6 times longer than the younger participants. Similarly, when completing the control solution test, older adults took 1.9 times longer. The current results also duplicate the trend found in Carpenter and Mayhorn (2011) and Mayhorn and Carpenters (2012) studies which examined the performance of younger and older participants, who did not have diabetes, on the control solution task. Younger participants finished the task 2.2 times faster than those in the older group. The tradeoff between speed and accuracy may provide an additional explanation as to why the elderly participants took longer than the younger participants to complete the SMBG tasks. The speed accuracy tradeoff proposes that part of the reason elderly adults perform more slowly than their younger counterparts, is because they place a greater emphasis on accuracy (Salthouse & Somberg, 1979). Based on this logic, the results of the current study should reveal longer task times and lower error rates for the elderly participants. However, in addition to longer task times, elderly participants also made significantly more errors when compared to the
younger participants. These results are once again in accordance with Carpenter and Mayhorn (2011) who found that older participants made significantly more errors than younger participants when completing the control solution task. The best explanation for the current study results is likely a combination of individual differences in ability and task familiarity, age related declines and meter design flaws.

5.2 Meter Type x Age Group Interaction

In general, participants who had higher success rates also completed tasks faster, made fewer errors and required fewer additional attempts when using the One Touch meter. However, due to a significant interaction between meter type (Accu-Chek) and age group (elderly adults), there were some interesting exceptions. For instance, when the elderly participants used the Accu-Chek meter to perform the control solution task, they had a higher rate of success (82%) than when using the One Touch meter (59%). Similarly, elderly participants completed the control test faster when using the Accu-Chek meter (373.4 s) compared to the One Touch meter (432.5 s). The elderly group also made fewer errors when completing the control test task and required fewer attempts on the control test task when using the Accu-Chek meter. Significant results for meter type by age group interaction are presented in bold in Table 5.1.
Table 5.1

Significant results for meter type x age group interaction.

<table>
<thead>
<tr>
<th></th>
<th>Young</th>
<th>Elderly</th>
<th>One Touch Ultra 2</th>
<th>Young</th>
<th>Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accu-Chek Compact Plus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Set Date/Time Task Success</td>
<td>88%</td>
<td>21%</td>
<td>Date/Time Set Task Success</td>
<td>100%</td>
<td>79%</td>
</tr>
<tr>
<td>Control Solution Task Success</td>
<td>100%</td>
<td>82%</td>
<td>Control Solution Task Success</td>
<td>100%</td>
<td>59%</td>
</tr>
<tr>
<td>Time to Complete Set Date/Time Task</td>
<td>222.7s (627.7s)</td>
<td>550.3s (399.0s)</td>
<td>Time to Complete Date/Time Task</td>
<td>51.4s (605.9s)</td>
<td>306.72s (213.7s)</td>
</tr>
<tr>
<td>Time to Complete Control Solution Task</td>
<td>264.2s (637s)</td>
<td>373.4s (328.1s)</td>
<td>Time to Complete Control Solution Task</td>
<td>157.6s (613s)</td>
<td>432.5s (412.6s)</td>
</tr>
<tr>
<td>Number of Errors</td>
<td>.62 (.21)</td>
<td>1.5 (.21)</td>
<td>Number of Errors</td>
<td>.37 (.26)</td>
<td>2.8 (.45)</td>
</tr>
<tr>
<td>Set Date/Time Task Additional Attempts</td>
<td>1.6 (.55)</td>
<td>2.3 (.34)</td>
<td>Date/Time Set Task Additional Attempts</td>
<td>.06 (.06)</td>
<td>.52 (.19)</td>
</tr>
<tr>
<td>Control Solution Task Additional Attempts</td>
<td>.44 (.27)</td>
<td>.48 (.14)</td>
<td>Control Solution Task Additional Attempts</td>
<td>.06 (.06)</td>
<td>.52 (.19)</td>
</tr>
</tbody>
</table>

This significant interaction is contrary to the original hypothesis. Based on a combination of pharmacist and nurse educator recommendations as well as human factors design principles (Fisk et al., 2009) it was anticipated that all participants would be more successful, complete the tasks faster, have fewer errors and additional attempts when using the One Touch meter compared to the Accu-Chek meter. One potential explanation for the meter by age interaction is the Accu-Chek meter design, specifically the automated test strip release system. Previous research has suggested that meters that do not require individual test strip handling may be more helpful for older users with dexterity or arthritis issues (Renda, 2006). Many of the steps involved in performing a control solution test with a meter similar to the One Touch require additional strength and fine motor skills which could lead to increased difficulties. For example, difficulties may include: 1) opening the test strip case, 2) selecting a single test strip from among
many, and 3) accurately inserting the test strip into the small meter opening. The Accu-Chek meter allows participants to bypass all of these steps by releasing a test strip with a single button push.

Even though elderly users had a higher level of success, completed the control solution task faster and with fewer errors, there were still a number of problems with the test strip drum technology. For example, participants had a difficult time locating and opening the test strip compartment, found the test strip mechanism loud and also disliked the small number of test strips (17) contained in each drum.

5.3 Design Recommendations

Based on the quantitative and qualitative results of this study and a thorough review of previous literature, a number of design recommendations for SBMG meters are made with respect to meter buttons, meter instructions, meter size, meter accessibility, meter complexity, vision and test strips.

1. Meter Buttons

*Increase consistency and standardization.* Consistency and standardization of labeling should be employed across devices to decrease the user’s reliance on long term memory (Wickens, Lee, Liu & Becker, 2004). Users should not have to wonder whether different symbols or words mean the same thing. For example, the One Touch meter uses the standard power (standby) symbol (■) while the Accu-Chek meter uses an obscure symbol shown in Figure 5.1. In order to improve consistency on the Accu-Chek meter, the standard power (standby) symbol should be used in place of the current, ambiguous power symbol. This symbol, (◇), is recognized by the International Electrotechnical Commission (IEC 5009) as the
standardized symbol for use when labeling power switches on medical devices such as blood glucose meters (PMC, 2002). Because this symbol is identified by international standards it could be argued that the largest number of users worldwide would be able to identify and interpret its meaning, as opposed to the symbol used on the Accu-Chek meter. In addition, a standardized power button would decrease the number of test strips wasted, as well as the number of additional attempts made by users, as the purpose of the on/off button would be more apparent.

![Image of Accu-Chek Compact Plus meter power button]

*Figure 5.1.* Power button on the Accu-Chek Compact Plus meter. This button also functions as the test strip release.

**Ensure labels are unambiguous.** The purpose of a label is to “unambiguously signal the identity or function of an entity, such as a control, display…or other system component” (Wickens et al., 2004, p. 193). When abbreviations are used they need to perceptually link the button to a verbal label (Wickens et al., 2004). To increase the overall usability of the Accu-Chek device, the buttons need to be meaningful. One way to increase meaning is by presenting a written label beside or underneath the abbreviated key. When discussing the Accu-Chek meter some participants did suggest that the use of “actual words” would be helpful in decreasing the button ambiguity. Previous research has found that older native language speakers prefer text to symbols or icons in certain contexts (e.g., medical labeling) (Fisk, Rogers & Charness, 2009). However, because blood glucose meters have such a compact interface the text labels would need to be very small and may not be legible for many of the older users. This solution would
also be ineffective for non-English speaking users. Instead, the inclusion of buttons with icons similar to ones used on the One Touch meter (refer to Figure 4.9) would be more meaningful and useful for the largest number of users.

**Increase button size, button spacing and minimize required force.** Dexterity and strength tends to decrease with age and for people with arthritis, Parkinson’s disease, tremors or essential tremors, simple actions such as pressing a meter button can become uncomfortable. As a result, meter designers should consider increasing the size of the meter buttons as well as the spacing between buttons and should minimize the force required to depress the buttons. According to the FDA’s (1997) draft document on portable blood glucose monitoring, meter buttons should be 12-15 mm in size to ensure that they are large enough for users to employ the necessary amount of force without slipping. It is also suggested that meter buttons use tactile cues by employing textured button surfaces or by using a concave shape to better fit the users’ finger. Several participants in the current study had trouble physically targeting the buttons on the two meters due to conditions such as arthritis. In addition, some participant experienced difficulty depressing the meter buttons, specifically on the Accu-Chek, due to a lack of applied force.

Input devices such as touch screens or the use of a stylus could also be considered as a solution to these problems. Previous research has reported that touch screen technologies can improve performance and acceptability among older adults when compared to other forms of input (e.g., mouse) (Findlater, Froechlich, Fattal, Wobbrock & Dastyar, 2013). Touch screens have also demonstrated many advantages over other input devices (e.g., mouse, trackball), including easier hand-eye coordination, faster target acquisition and decreased cognitive demands (Capriani, O’Connor & Gurrin, 2012; Taveira & Choi, 2009). The use of a touch screen
would also remedy the problem of ambiguous button abbreviations as the actual word could be written on screen in full and an icon could be included.

Despite these potential benefits, with the small size of current handheld blood glucose meters, it might be difficult to accommodate the visual and motor capabilities of the elderly population. In addition, for those with vision problems, the haptic feedback provided by the traditional push buttons would be lost. A new form of redundant feedback such as an auditory signal would need to be implemented to accommodate these users.

2. Meter Instructions

Reduce the length of the instruction manual. Learnability and efficiency are two attributes that are used to determine the usability of a product (Fisk et al., 2009). Learnability asks the question, how easy is it to learn to use the device? Efficiency is attained if the user can achieve their intended objective within a reasonable amount of time.

When analyzing the qualitative data for this study it was determined that participants did not find the meter instructions for the Accu-Chek to be high in learnability or efficiency. Participants from both age groups found the 219 page user manual overwhelming and complicated however, older adults had the most trouble. One reason that older adults may have encountered more difficulties is because they were more likely to use the instructions. These results are in accordance with previous research by Cifter and Dong (2010) who found that older participants were more likely to review the instructions prior to attempting SMBG tasks. In contrast, younger participants were more likely to use a trial and error approach and only referred to the instructions if necessary. Because older adults relied more heavily on the manual and spent more time reviewing the document they found the amount of information to be more overwhelming than their younger counterparts. In addition, as people age they experience
declines in their working memory (ability to store and retrieve new information) and their procedural memory (knowledge about how to perform a task) (Fisk et al., 2009). When older adults are presented with an instruction manual containing large amounts of information, their working memory can become overloaded and this will result in decreased efficiency. If the user cannot learn to use the device then they will not be able to achieve their intended purpose.

In an effort to increase learnability and efficiency the Accu-Chek instruction manual should consider the following suggestions. First, the length of the manual and the volume of information should be decreased. One potential solution is to divide the information into two smaller manuals (FDA, 1993). The first manual should contain basic information such as meter set up and the steps required to perform a blood glucose test. The second manual should present more advanced features such as how to set a meter alarm. Dividing the information into two books will permit users to focus on the information that is relevant to them without becoming overwhelmed. Alternatively, the FDA (1993) document on home medical device instruction manuals recommends the use of tabbed manuals with separate sections for the lay user and medical professionals. It is suggested that tabs are created out of thick paper that is color coated and carefully labelled.

*Use clear, non-technical language.* In order to reach the widest audience, the FDA recommends that all user instruction manuals should avoid formal language and should be written at a sixth to seventh grade reading level (FDA, 1993). In the current study, participants felt that the Accu-Chek instructions were written in a technical manner that was inappropriate for the average user. One participant said, “I had to re-read [the instructions] multiple times, they were not written for the average lay person.” In addition, the language used to describe different tasks should be standardized across SMBG meters to reduce potential confusion among users.
(e.g. ‘performance check’ should be referred to as ‘control solution test’). One participant commented, “Performance check, why call it this…it’s not logical.”

Present instructions in booklet format. When possible, the FDA (1993) suggests that manuals should be formatted in a standard size either 8 ½ inches by 11 inches or 5 ½ inches by 8 ½ inches to facilitate convenience and portability. If the page size of the instruction is too large, as was the case for the One Touch meter (80cm x 64cm), the manual becomes too cumbersome to use and is difficult to store. While participants in this study preferred the content and organization of the One Touch meter instructions they did complain about the size of the large fold out sheet and preferred the format of the Accu-Chek instruction booklet.

3. Meter Size

Size meter for convenience and discretion. Participants equated meter size with convenience; the bigger the meter, the less convenient. Participants from both age groups disliked the size of the Accu-Chek meter and favored the size of the One Touch. Many participants, (44% young, 23% elder), preferred meters that were even smaller than the One Touch and opted for miniature sized versions of their meter such as the One Touch Ultra Mini shown in Figure 5.2. The ideal size was described by participants as a meter that could easily fit in a pocket, fanny pack or purse. This was especially important for participants who travelled frequently. The size of the meter was also an important feature for the 34% of participants who said they did not feel comfortable testing in public environments as a smaller meter has the potential to be more inconspicuous.

Figure 5.2. The One Touch Ultra Mini.
4. Meter Accessibility

*Incorporate test strip drum technology.* Despite complaints made in regards to the Accu-Chek test strip release system, older participants performed the control solution test faster when using the Accu-Chek meter compared to the One Touch meter. Elderly participants also made fewer errors and required less additional attempts when using this meter to complete the control solution test. For these reasons the test strip drums should be considered in future device design. However, for this kind of system to be successful the size of the test strip drum will need to be decreased to ensure the overall meter size remains small. Additionally, the process of opening the drum compartment as well as loading and unloading the test strip drums must be made easier for older adults, especially for those with dexterity issues.

5. Meter Complexity

*Include a main menu for easy navigation.* A well designed menu will help to inform users about the current state of their meter through the display of information (Zhang, Johnson, Patel, Paige & Kubose, 2003). A menu also reduces the amount of memory load required from the user by providing relevant prompts. The One Touch meter included a simple main menu which participants liked because it helped them to navigate through the tasks (Figure 5.3). In contrast, the Accu-Chek meter did not include a main menu, or a primary starting point of any kind. Instead, the Accu-Chek meter provided users with three start-up options (see Figure 5.4). 1) Press the ‘s’ button. This button allows the user to access and change settings however, this is not necessarily portrayed by the initial screen. 2) Press the ‘m’ button. This option allows the user to retrieve results stored in the meters memory. 3) Press the middle button. This button releases a test strip and also flashes an icon of a test strip and blood drop on the meter screen to
signify to the user that they should perform a blood glucose test. This method provided no natural guidance throughout the tasks and required participants to remember large amounts of information.

![Main Menu Screen](image)

*Figure 5.3. The One Touch main menu screen.*

![Screen Shots](image)

*Figure 5.4. Accu-Chek screen shots. Setting screen (left), memory screen (center) and screen displayed when the test strip release button is pushed (right)*.

6. **Vision**

*Increase font size, reposition important information and include a backlight.* To account for poor lighting, as well as the degrading eye sight of older adults, a minimum font size of fourteen should be used for all instructional information (FDA, 2001). A sans serif font style should also be applied to increase overall clarity (FDA, 1993). Even though the older participants included in this study met the visual acuity requirements (required to have 20/40 and average visual acuity for elderly participants was 20/29.33) many of the older adults still found the size of both the meters instructions to be difficult to read. In addition, some elderly adults had problems seeing pertinent information on the Accu-Chek screen when it was located in their visual peripheries. For example, one participant said that he gave up on the date and time task.
because he could not see the year “2013” blinking at the top of the screen and, as a result, could not proceed with subsequent task steps (see Figure 5.5). It is recommended that all important information be presented in the center of the users’ visual field, as many older adults have deficits in their peripheral vision (AAMI, 2009). Designers should also avoid the use of blinking text or images as adults have a difficult time with temporal change, or the ability to see flashing images (McLaughlin et al., 2004). Finally, blood glucose meters should provide a backlight for middle of the night testing so users can see their results without having to get out of bed.

![Figure 5.5. Accu-Chek meter with the year ‘2013’ at the top of the screen.](image)

**7. Test Strips**

*Improve test strip design.* Individual test strips should include an arrow or some form of indicator to clearly convey which end is to be inserted into the device and which end is to be used for blood/control sample. Figure 5.6 displays a One Touch test strip which has a cluttered design and provides users with no indication of which end goes into the meter. Alternatively, the test strip for the EZ Health meter (not evaluated in this study) employs a clean, simple design as well as an arrow indicating which end to insert into the meter.
To avoid blood glucose testing errors, and prevent the wastage of test strip, designers should consider increasing the size of the blood sample site. Enlarging the size of the area that receives blood would make it easier to target, thus helping users with vision and/or dexterity problems.

To perform a successful control solution test using the One Touch meter, the solution must be inserted directly into the narrow channel which is located on the tip of the test strip (Figure 5.7). Many participants made control solution errors because they were unaware of where to deposit the control solution sample.

*Figure 5.6.* One Touch Ultra 2 test strip (left) and EZ Health meter test strip (right).

*Figure 5.7.* One Touch test strip with arrow indicating channel for control solution (left). Incorrect placement of control solution (left).
Allow multiple blood applications. The cost of test strips was a concern for many of the study participants (20%), particularly for elderly adults living on a limited, fixed income. To prevent the use of additional test strips and save on cost, users should be able to add blood to the same test strip if an insufficient amount of blood, or control solution, was applied on the first attempt. This same suggestion was expressed over a decade ago by participants in Rogers et al. (2001) evaluation of self-monitoring blood glucose meters and yet many SMBG meters still do not provide this option.

Provide clear and meaningful feedback. Self-monitoring blood glucose meters should indicate more user feedback to facilitate increased understanding and interpretation. For example, the Accu-Chek meter uses error codes such as E21, shown is Figure 5.8, to express test strip problems. However, this technical code conveys little meaning to the user and provides no information on how to fix the problem. The Accu-Chek error code is supposed to indicate that not enough blood was applied to the test strip and the user should release a new test strip and provide a larger sample of blood. In order to gain any understanding of the error the user must refer to the instruction manual. Useful error messages should be written in plain, ‘user-centered’ language and should provide the user with meaningful feedback on what to do next (Molich & Nielsen, 1990). The One Touch meter provides a more helpful error message that explains the problem in simple language and provides a course of action.

Figure 5.8. Error screens from the Accu-Chek (left) meter and the One Touch meter (right).
8. ‘Outside of the Box’ Design

The previous seven design recommendations have been made on the basis of current trends in SMBG meter technology. However, it is important to think outside of the box and consider what could be done to elevate the design of SMBG meters and reduce user errors. With unlimited funding and no technological barriers, what would the optimal SMBG meter really look like and how would it function?

**Meter Buttons.** Instead of changing ambiguous labels or increasing the surface area of each button, why not get rid of the buttons all together? Future SMBG meters could implement voice activation technology (assuming this technology has been perfected!). Users could simply verbalize the actions they would like to perform and the meter would respond accordingly.

**Meter Tasks.** To eliminate the problems associated with setting the date and time, future SMBG meters should eliminate the manual set up requirement. Similar to current cell phones, the date and time on SMBG meters should be automatically set and maintained by connecting via Bluetooth to the users’ computer or cellular device. Similarly, the meter could link to a cellular device or computer the same way as a USB stick to download meter results and upload updated setting information.

**Test Strips.** Test strips are expensive and, as demonstrated in this study, consumers often have to use more than one strip to complete a test because of issues related to poor design or the complicated testing process. To eliminate these issues, a potential solution is to get rid of conventional test strips all together. A new technology that incorporates a lancet and test strip in one could save on cost while also reducing the number of tasks required by the user during testing. To demonstrate how this would work, the user would be required to load a cartridge of 50-100 of the new test strips into their device. Each test strip would contain a lancet with a
hollow inside filled with fiber optic technology. When testing the user pricks their finger and the lancet will automatically absorb the blood sample, analyze the sample and provide a visual and audio reading. The user will then eject the test strip and the testing process is complete. Table 5.2 provides a simple task analysis conducted by the FDA (2011), which demonstrates the steps involved in a conventional blood glucose test as well as a breakdown of whether each task is performed by the user, the meter or a combination of the two. Table 5.3 provides a simple task analysis demonstrating the steps required for the updated meter technology. The new meter technology eliminates three tasks, two of which required performance by the user. The user is no longer required to place the sample on the test strip or fit the test strip in the device, eliminating the potential for errors such as placing the blood sample in the incorrect location on the test strip or inserting the wrong end of the test strip into the meter. The option of redundant feedback through visual and auditory channels can assist those with vision issues. Because the meter links with the users’ smart phone, tablet or computer additional web-based feedback can be provided to assist the user in interpreting their test results.

Table 5.2.

A simple task analysis showing tasks that are performed by the user, the device, or a combination of the user and the device (FDA, 2011).

<table>
<thead>
<tr>
<th>Task</th>
<th>Device</th>
<th>User</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Patient’s finger is lanced with automatic lancing device</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2 Blood sample is place on test strip</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>3 Test strip is placed in device</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>4 The sample is allowed to react with reagents in the test strip for a specific time</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>5 Blood glucose level in the sample is measured</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>6 The resulting value is displayed</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>7 The displayed value is read, interpreted and acted upon</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
Table 5.3.

*A simple task analysis showing tasks that are performed by the user, the device, or a combination of the user and device according to new device design.*

<table>
<thead>
<tr>
<th>Task</th>
<th>Device</th>
<th>User</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Patients finger is lanced with automatic lancing device, blood sample is absorbed simultaneously</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>2 Sample is analyzed</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>3 Resulting value is displayed and/or verbalized. Meter provides visual and auditory interpretation feedback</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>4 The displayed value is read, or heard by the user and acted upon</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>

5.4 Contributions of the Current Study

This research adds to the limited literature on SMBG usability by providing a non-biased up to date evaluation of current, commercially available blood glucose meters. It also contributes to the literature on medical technology and aging. In addition, this study extends previous research by Carpenter and Mayhorn (2011) by examining the impact of the physical design of SMBG testing equipment on usability among adults with diabetes. These results also have practical significance for patients, healthcare providers and SMBG device companies. Elderly adults can use this information to help them choose a suitable self-monitoring blood glucose meter. The errors and common concerns of elderly users identified in this study can be used by pharmacists and other health care workers to provide more directed training and education to elderly patients. Finally, device manufacturers could implement the suggested design recommendations to improve the overall safety, efficiency and usability of future SMBG meters.

5.5 Limitations

The results of this study suggest that current SMBG meters may not consider some of the capabilities and limitations of their largest demographic, those 65 years and over (Statistics
Canada, 2010). It is possible that these results underestimate the potential problems that older users might encounter when using their meters, as the participants in this study are not necessarily representative of the older, diabetic population. The elderly participants in this study had above average eyesight, cognition and education for people with diabetes in their age demographic. In Canada, 23% of people with type 1, and 14% of people with type 2 diabetes on insulin therapy are affected by retinopathy (CDA, 2012). In the current study, none of the elderly participants reported any diagnosis of retinopathy. Elderly adults with diabetes are also at a greater risk for developing mild cognitive impairments, Alzheimer’s and dementia (Cheng et al., 2012). However, all participants in this study scored in the normal cognitive range on the MMSE. In Canada, the average years of education achieved by adults is 12.5 (Hazell, Gee & Sharpe, 2012). The elderly participants in this study had an average of 15.6 years of education. In addition, all of the participants willingly signed up for this study indicating that they may be more motivated and involved with the treatment of their disease than the average individual with diabetes. Finally, while some of the study participants had physical disabilities such as arthritis, essential tremors and neuropathy, they were all mobile and healthy enough to make it to the study session. As a result, relevant issues for people with diabetes who are experiencing more serious side effects may have been overlooked.

Health literacy and self-efficacy are important measures that can be used to help determine a person’s motivation to maintain their health. The Public Health Agency of Canada (2011) defines health literacy as “the ability to access, comprehend, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the life course.” In Canada, 60% of adults and 88% of seniors are not health literate. A lack of health literacy is associated with less knowledge of chronic disease processes, higher hospital
admission rates and poorer mental and physical health (Bostock & Steptoe, 2012). Self-efficacy is “the belief in one’s capabilities to organize and execute the courses of action required to manage prospective situations” (Bandura, 1995, p.2). Low self-efficacy can result in decreased levels of motivation and overall performance (Bandura & Locke, 2003). Although there is evidence to suggest that the participants in the current study were higher than average in health literacy (based on years of education), as well as self-efficacy (volunteered to participate in the study), measures such as the Test of Functional Health Literacy in Adults (STOFHLA) (Baker, Williams, Parker, Gazmararian & Nurss, 1999) and the Diabetes Management Self-Efficacy Scale (DMSES) (Stanford Patient Education Research Center, 2014) could have been used to verify this assumption and gain a better understanding of the participants health care abilities and confidence in self-management. In addition, the inclusion of these tests would have helped to determine whether levels of health literacy and self-efficacy differed significantly between the younger and elderly participants.

This study could also have been limited by the tasks that were chosen for the participants to complete. Unfortunately, it is not possible to capture the full context of use of the device under evaluation while also trying to accommodate practical considerations such as ethics, hygiene and time constraints. For instance, the control solution test was included in this study because it closely simulates a blood glucose test without requiring participants to provide an actual blood sample. However, because participants were not required to lance themselves and produce a drop of blood this removed a critical, and often painful, step from the task. This could have resulted in a decrease in study realism.

Participant performance could have also been altered due to the study environment. First, participants were asked to perform the SMBG tasks in an unfamiliar setting. For those who test
in a variety of public locations, this likely would not have had a large effect. However, for those who only test at home it could have affected their performance (Gifford, 2007). Second, the lab space provided optimal lighting as well as a quiet environment for testing, which may not replicate the participants’ home or everyday surroundings. Third, participants were aware that a researcher was observing them throughout the study scenario. As a result, participants may have felt more anxious when trying to complete the task or they may have been more diligent when reading the device instruction (Heiman, 2002). Conversely, participants may have given up on some of the tasks sooner knowing the researcher would come in to assist them if necessary. Finally, the small sample size and the small number of SMBG meters evaluated could have further limited the validity and generalizability of the study.

5.6 Generalizability

On average, elderly participants had 13 years of experience performing blood glucose tests with a self-monitoring meter. These participants were practiced users. When the variable ‘years of experience’ was included as a covariate in the analysis of time based tasks, it was non-significant. Meaning, participants with ten years of experience did not perform significantly better than those with two or three years of experience. Based on this information, there is reason to believe that the problems participants had with the SMBG meters during the half hour study session could linger in subsequent use. In addition, many of the issues that were discovered in this study (e.g., issues related to vision and dexterity) are not problems that can be remedied with time; these are issues of human limitation. For instance, an elderly woman with essential hand tremors is always going to experience difficulty opening her test strip case, selecting an individual test strip and inserting the strip into the small test strip opening. Her hand tremors are
not likely to go away. The solution is not practice or time. The solution is in the design of the meter.

This study used two blood glucose meters to comment on the overall usability of common, commercially available SMBG meters. Can the results of this study really generalize to other current meters? What about future models of SMBG meters? The answer is yes. Many of the design problems discovered in the current study were also found in a previous heuristic evaluation (Jones, 2013). In this study six experts assessed four commercially available SMBG meters: The One Touch Verio IQ, EZ-Health Oracle, FreeStyle Freedome Lite and One Touch Ultra 2 (also evaluated in the current study) (Figure 5.9). Table 5.1 highlights the overlap in problems identified by the current study and the previous heuristic evaluation. These overlaps demonstrate that similar issues persist across a breadth of SMBG meters.

![Figure 5.9. One Touch Verio IQ, EZ-Health Oracle, FreeStyle Freedome Lite and One Touch Ultra 2 meters.](image)
Table 5.4.

*Problems identified by the current study and a previous heuristic evaluation.*

<table>
<thead>
<tr>
<th>Meter Problem Identified In Current Study</th>
<th>Meter Problems Identified in Heuristic Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Verio IQ</td>
</tr>
<tr>
<td>Meter Buttons (e.g., ambiguous)</td>
<td>✓</td>
</tr>
<tr>
<td>Meter Instructions (e.g., size, information)</td>
<td>✓</td>
</tr>
<tr>
<td>Test Strips (e.g., unclear design)</td>
<td>✓</td>
</tr>
<tr>
<td>Vision (e.g., small font, screen contrast, no backlight)</td>
<td></td>
</tr>
<tr>
<td>Dexterity (e.g., difficulty opening test strip container)</td>
<td></td>
</tr>
<tr>
<td>Error Messages (e.g., lack of feedback)</td>
<td>✓</td>
</tr>
<tr>
<td>Meter Complexity (e.g., lack of menu)</td>
<td>✓</td>
</tr>
</tbody>
</table>

**5.7 Future Directions**

As previously mentioned, due to practical implications such as funding, ethics, and hygiene, participants in this study were not required to lance their finger or provide an actual blood sample. However, finger soreness and pain caused by lancing are two variables that are strongly associated with low compliance to SMBG testing (Burge, 2001; Lekarcyk & Ghiloni, 2009; Vincze et al., 2004). There are also design issues that affect the usability of lancing. For example, do users prefer a single needle to a multi needle lancing device? Do users favor a lancing device that is attached to the meter or a device that is separate? Do elderly adults with arthritis have a difficult time loading and detaching individual lancets from their lancing device? In an effort to enhance adherence and ease of use while also decreasing pain, researchers should conduct evaluative tests in which participants perform the entire blood glucose test, including lancing. Lancing is an integral step in the testing process and it is important that elderly users’ preferences and limitations are considered.
To determine if the results of this study are generalizable among all SMBG users, future studies should conduct evaluative testing with peripheral, non-diabetic SMBG users such as caregivers, partners, teachers and parents. Certain groups of people with diabetes, such as those with serious physical or cognitive impairments and young children, require assistance when testing their blood glucose. As a result, it is important to ensure that those administering care can properly operate a blood glucose meter and interpret the results of a blood glucose test. In addition, a longitudinal study design could be implemented to experimentally confirm whether or not some of the problems participants encountered with the SMBG meters in the current study persist over a period of continued use.

5.8 Conclusion

The results of this study demonstrate that elderly adults, even those with above average vision, cognition and education, struggle to use blood glucose meters when completing common SMBG tasks. Because the consequences of improper self-management can be very serious it is critical that device manufacturers incorporate the specific needs and limitations of elderly adults in the design of future SMBG meters. While there is not a single meter that will meet the individuals needs of the entire diabetic population, elderly adults may benefit from choosing a device with the following features: 1) clear, unambiguous buttons, 2) large, well-spaced buttons that require limited force to depress, 3) clear, step-by-step instructions, 4) a meter that is sized for convenience and portability, 5) a meter with a main menu for easy navigation and 6) a meter that accommodates visual deficits and 7) test strips with large, clearly marked test sites.
References


Buse, J. (2007). Action to control cardiovascular risk in diabetes (ACCORD) trial: design and


Diabetes Control and Complications Trial Research Group (DCCT). (1993). The effect of
intensive treatment of diabetes on the development and progression of long term
329(14), 977-986.


Deshpande, A., Harris-Hayes, M., & Schootman, M. (2008). Epidemiology of diabetes and
diabetes-related complications. *Journal of American Physical Therapy Association*,


Collins Publishers Ltd.

(2012). Meta-analysis of individual patient data in randomized trials of self-monitoring of
blood glucose in people with non-insulin treated type 2 diabetes. *British Medical
Journal*, 344, 1-11. doi: http://dx.doi.org/10.1136/bmj.e486

in performance with touchscreens compared to traditional mouse input. Proceedings from
Pg. 343-346.


64(9), 38-43.


IBM Corp. (Released 2011). *IBM SPSS advanced statistics, version 20*. Armonk, NY.


Johnson & Johnson. (2011). One Touch Verio IQ blood glucose monitoring system [Meter
Box Label]. Zug, Switzerland.


Proceedings of UPA (pp.1-10).


Tremblay Harrison. (2010). *EZ Health Oracle blood glucose monitoring system [Meter box*


Participants Needed For Study

Participants needed to take part in a study evaluating Blood Glucose Meters

$25.00 gift certificate as compensation for your time + paid parking

Single session study. Approximately 1 hour

To Qualify:

- Must be 18-35 years
- Must be diagnosed with T1 or T2 Diabetes
- Must have experience using a blood glucose meter

For more information or to participate please contact:

Jessica Jones @ jonesja@ucalgary.ca or 403-210-7453

This study has been approved by the conjoint Health Research Ethics Board, Ethics ID 25083
Appendix B Metro Magazine Advertisement

Participants Needed For Study
Participants needed to take part in a study evaluating Blood Glucose Meters

$25.00 gift certificate as compensation for your time + paid parking
Single session study. Approximately 1.5 hours

To Qualify:
• Must be between 18-35 years or 65 years and over
• Must be diagnosed with T1, T2 or pre-diabetes
• Must have experience using a blood glucose meter

For more information or to participate please contact:
Jessica Jones @ jonesja@ucalgary.ca or 403-210-7453

This study has been approved by the conjoint Health Research Ethics Board, Ethics ID 25083
Appendix D Standardized Mini-Mental State Examination

Cognitive Impairment in the Elderly – Recognition, Diagnosis and Management
Revised January 30, 2008
Usability Scenario Part 1: You have just purchased a new self-monitoring blood glucose meter. To ensure that the meter is providing the correct information for blood glucose readings please set the proper **date** and **time** on the meter.

When you finished please record the date and time you set in the meter.

Date: _______________

Time: _______________

When you have finished this portion of the usability scenario please say “finished.”
Usability Scenario Part 2: You have just purchased a new self-monitoring blood glucose meter. To ensure that the meter is providing correct glucose readings please perform a control solution test/performance check. Please try to complete this task independently using the SMBG meter you were provided.

When you are finished please record the results of the control solution test/performance check on this form. Please dispose of the used test strips into the garbage provided.

Control Solution Test/Performance Check Result: ________________

Please answer the following questions:

Are the results of the control solution test within range? Please circle one: YES or NO

How did you determine whether or not the control solution results were within range?
__________________________________________________________
__________________________________________________________
__________________________________________________________

Please dispose of the test strip.

When you have finished the usability scenario and answered all of the questions please say “finished.”
Appendix F Consent Form

Evaluating Self-Monitoring Blood Glucose (SMBG) Meters
Ethics ID #E-25083

**TITLE:** Evaluating Self-Monitoring Blood Glucose (SMGB) Meters

**PRINCIPLE INVESTIGATOR:** Dr. Jeff Caird, Professor
Human Factors and Simulation Lab
University of Calgary
jkcaird@ucalgary.ca or 403.220.8441

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

**BACKGROUND**

Advances in home healthcare technologies such as self-monitoring blood glucose (SMBG) meters have allowed patients to take a more active role in their diabetes management. Proper self-monitoring allows patients to determine their blood sugar levels and make the appropriate adjustments to their insulin levels, diet and exercise routines in order to effectively manage their diabetes (1). Although SMBG devices have made great progress in regards to their overall measurement accuracy and compliance with acceptable standards, little has been done to determine their overall usability (2). Several past research studies have suggested that additional research be conducted to examine the physical design and overall usability of SMBG devices (2)(3)(4)(5). In addition, as blood glucose monitors are changed and adapted to fix prior problems, new usability issues may be presented (4). Therefore, continuous usability testing is required to ensure safe and efficient devices.

The goal of this research study is to determine how usable current self-monitoring blood glucose meters (SMBG) really are among a variety of SMBG users. In order to determine the overall usability of a variety of current SMBG meters, a usability test will be performed. The usability test will determine whether the device can be used in a safe and effective manner. It will highlight the problem areas that users encounter when interacting with these devices. Information obtained from the usability tests will be used to make recommendations that will hopefully be used in the design of future SMBG meters.
References


WHAT IS THE PURPOSE OF THE STUDY?
The purpose of this study is to examine whether a number of commercially available blood glucose meters are safe and usable among a variety of current SMBG users.

WHAT WOULD I HAVE TO DO?
The first thing you will be asked to do is complete a Mini Mental State Exam (MMSE)\(^3\). This is a brief questionnaire that is used to screen for possible cognitive impairments. You will then be asked to participate in a usability scenario in which you will be asked to complete a common self-monitoring blood glucose meter task. Once you have completed this task you will be invited to take part in a structured interview regarding your experience during the scenario. Your participation in the study will take approximately one and a half hours.

WHAT TYPE OF PERSONAL INFORMATION WILL BE COLLECTED?
Should you agree to participate in this study your interactions with the self-monitoring blood glucose device will be videotaped and audio recorded for data analysis. Your participation is completely voluntary and confidential. No one except the researchers and their supervisors will be allowed to view or listen to any of the data.

WHAT ARE THE RISKS?

There should be no physical or emotional risks that result from your participation in this study. Participants are not required to lance their finger or produce a blood sample during this study. Participants will be given a control solution to use in place of an actual blood sample.

WILL I BENEFIT IF I TAKE PART?

Participants diagnosed with Type 1 or Type 2 diabetes will gain additional experience/practice using a blood glucose monitor. In addition participant comments and feedback will be used to make design recommendations that might benefit users.

DO I HAVE TO PARTICIPATE?

Your participation in this study is entirely voluntary and you are free to discontinue the study at any time and for any reason. In addition, you are free to ask questions about your participation at any time in the study, before or after you sign this agreement. If the researcher believes it is in your best interest, or if you fail to cooperate with requirements and procedures, you may be asked to leave the study.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

Participants recruited from the University of Calgary, Department of Psychology’s SONA system will be compensated with course credit to be applied to their psychology courses. All other participants will receive a $25.00 gift certificate as a token of appreciation for participating. In addition, participant parking will be covered.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, the Ward of the 21st Century Research and Innovation Centre, the Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Jeff Caird: (403) 220-8441
If you have any questions concerning your rights as a possible participant in this research, please contact The Chair, Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

________________________________________  ______________________________________
Participant’s Name                        Signature and Date

________________________________________  ______________________________________
Investigator/Delegate’s Name              Signature and Date

________________________________________  ______________________________________
Witness’ Name                            Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.
## Appendix G Demographic Questionnaire

Please answer the following demographic and experience questions.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>What is your age? _______</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What is your marital status? Single □ Common Law □ Married □ Separated □ Divorced □ Widowed □</td>
</tr>
<tr>
<td></td>
<td>What is your gender? Male □ Female □</td>
</tr>
<tr>
<td></td>
<td>What is your ethnicity?</td>
</tr>
<tr>
<td></td>
<td>What is your height?</td>
</tr>
<tr>
<td></td>
<td>What is your body weight?</td>
</tr>
<tr>
<td></td>
<td>What is your highest level of completed education, including all post-secondary?</td>
</tr>
<tr>
<td></td>
<td>What is your current occupation?</td>
</tr>
<tr>
<td></td>
<td>How many years have you worked in your current occupation?  _______</td>
</tr>
<tr>
<td></td>
<td>How old were you when you were diagnosed with diabetes?  _______</td>
</tr>
<tr>
<td></td>
<td>What is your specific diagnosis (Type 1/Type 2)  _______</td>
</tr>
<tr>
<td></td>
<td>How old were you when you started testing your blood glucose with a self-monitoring blood glucose meter?  _______</td>
</tr>
<tr>
<td></td>
<td>On average, how many times per day do you test your blood glucose levels?</td>
</tr>
<tr>
<td></td>
<td>Please list the name of your current blood glucose meter:</td>
</tr>
<tr>
<td></td>
<td>What blood glucose meters have you used in the past?</td>
</tr>
<tr>
<td></td>
<td>If you have ever switched meters, what were your reasons for doing so?</td>
</tr>
<tr>
<td></td>
<td>Have you ever received any training/education on blood glucose meters? If so, please describe</td>
</tr>
</tbody>
</table>

### The following is to be completed by the Researcher

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>20/_____</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hearing Assessment</strong></td>
<td>1. Do you have any uncorrected hearing impairments? _______</td>
</tr>
<tr>
<td></td>
<td>2. Do you have difficulty distinguishing a voice over the telephone or following a conversation in a loud setting? _______</td>
</tr>
</tbody>
</table>
Appendix H Structured Interview

Background

1. Does anyone else in your immediate family suffer from diabetes? Type 1/Type 2

2. Do you suffer from any other medical conditions?

3. What is your regular method of treatment for dealing with your diabetes? (SMBG, diet, exercise, oral medications etc.)

4. How many times per day/week are you supposed to test?

5. How many times per week do you test?

6. What barriers prevent you from testing? (Social stigma, cost etc.)

7. Do you feel comfortable testing in a public environment?
   a. If no, why don’t you feel comfortable?

SMBG Meter History

8. What blood glucose monitor brands have you used in the past?

9. What were the reasons that you switched monitors (features, ease of use, price etc.)

10. What is your current blood glucose meter?

11. What do you like about your current meter?

12. What do you dislike about your current meter?

SMBG Meter Instructions and Training

13. How did you learn to use your current blood glucose meter?
   a. Do you think you were provided with sufficient training?

14. Have you ever performed a control test before?
   a. If so, when? How often?

Accu-Chek Compact Plus

15. When you were attempting to use the Accu-Chek Compact Plus Meter, did you find the instructions helpful?
If yes, which aspects did you find most helpful and why?
If no, what would you do to make this information more helpful?

What else could be included to aid you in the usability of this device?

Accu-Chek SMBG Meter Usability

16. What did you like about the Accu-Chek meter?
17. What did you dislike about the Accu-Chek meter?
18. What design aspects made the Accu-Chek meter particularly difficult to use?
19. What design aspects made the Accu-Chek meter particularly easy to use?
20. If you could change one thing about the Accu-Chek meter, what would it be?

Specific Task

21. What difficulties did you have, if any, in setting the date and time on the Accu-Chek meter?
22. Could you have performed this task without referring to the instructions?
23. What difficulties did you have, if any, in performing the control test task with the Accu-Chek meter?
24. Could you have performed this task without referring to the instructions?
25. What difficulties did you have, if any, in interpreting the results of the control test using the Accu-Chek meter?
26. What difficulties did you have, if any, in finding the control test solution normal range information for the Accu-Chek meter?
27. On a scale of 1 to 10, with 1 being not easy and 10 being very easy, how would you rank the Accu-Chek meter compared to other meters you have used in the past?

On a scale of 1 to 10, with 1 being not satisfied and 10 being very satisfied, how would you rank the Accu-Chek meter compared to other meters you have used in the past?
Appendix I Debrief Form

Evaluating Self-Monitoring Blood Glucose (SMBG) Meters
Ethics ID #E-25083

TITLE: Evaluating Self-Monitoring Blood Glucose (SMGB) Meters

PRINCIPLE INVESTIGATOR: Dr. Jeff Caird, Professor
Human Factors and Simulation Lab
University of Calgary
jkcaird@ucalgary.ca or 403.220.8441

Thank you for participating in our study. Your participation will help us to determine the overall usability of a variety of current SMBG meters. The objectives of this study are to identify possible user related SMBG meter design issues and hazards and to ensure that these meters can achieve their stated purpose (accurate blood glucose measurement). In addition, we will use the information we have collected to make recommendations on the design of the blood glucose meters which we hope will be used to improve future SMBG meters.

Diabetes affects an estimated 285 million people worldwide (1). Currently, over three million Canadians are living with diabetes and it is projected that by 2020 diabetes will cost the Canadian healthcare system 16.9 billion per year (1). At the individual level, diabetes maintenance can be invasive, painful and extremely costly. Canadians with diabetes can incur direct costs from purchasing monitors, insulin, test strips and other supplies averaging $1000.00-$15,000 per year (1).

Although SMBG devices have made great progress in regards to their overall measurement accuracy and compliance with acceptable standards, little has been done to determine their overall usability (2). Several past research studies have suggested that additional research be conducted to examine the physical design and overall usability of SMBG devices (2)(3)(4)(5). In addition, as blood glucose monitors are changed and adapted to fix prior problems, new usability issues may be presented (4). Therefore, continuous usability testing is required to ensure safe and efficient devices.

Should you have any questions or concerns regarding this study please contact either Jessica Jones, Master’s Student, at jonesja@ucalgary.ca or Dr. Jeff Caird, Professor at jkcaird@ucalgary.ca. Once again, thank you for your participation.
References


2. Kaufman, D.R., Patel, V.L., Hilliman, C., Morin, P.C., Pevzner, J., Weinstock, R.S.,


### Appendix J N’Vivo Codes

<table>
<thead>
<tr>
<th>Node #</th>
<th>Node Name</th>
<th>Sources</th>
<th>References</th>
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<td>1</td>
<td>Meter Buttons</td>
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<td>Meter Size</td>
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<td>All in One (Accu-Chek)</td>
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<td>Complexity</td>
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<td>Cost</td>
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<td>Hands_Touch_Dexterity</td>
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</tr>
<tr>
<td>10</td>
<td>Lack of Start Menu (Accu-Chek)</td>
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<td>14</td>
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<td>11</td>
<td>Disability</td>
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<td>12</td>
<td>Control Solution Errors</td>
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<td>Additional Testing Barriers</td>
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<td>Hearing</td>
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<tr>
<td>20</td>
<td>Self-Regulation</td>
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<td>3</td>
</tr>
</tbody>
</table>

Green= Device related barriers to proper self- monitoring  
Red= Age related barriers to proper self- monitoring  
Purple= Barriers to appropriate self-monitoring