Adoption of Insulin Pumps and Continuous Glucose Monitors: Patient Perceptions of Utility and Usability

by

Isabelle Dutil

A thesis submitted in conformity with the requirements for the degree of Masters of Health Science in Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Masters of Health Science in Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto
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Abstract

This thesis aims to capture patient perceptions of adoption and use of insulin pumps (IP) and continuous glucose monitors (CGM). The first two phases were dedicated to identify barriers and benefits of adoption of IP and CGM respectively. Four themes were identified in the insulin pump study: 1. the lack of value add to management, 2. the psychosocial impact, 3. requirement of a support structure during adoption, 4. need for behavioural readjustment for success. In the CGM phase, three themes were identified: 1. “Use” frustrations, 2. data promotes “power” and proactivity, 3. cost/benefit analysis as a substantial barrier to adoption.

In the third phase, a usability study of the five insulin pumps on the North American market was conducted. Ultimately, the Tandem® pump caused the fewest use errors that could result in significant safety risk. Based on the results, recommendations to manufacturers and for tailoring diabetes training protocols were made.
Acknowledgments

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1 Introduction

1.1 Problem Definition

As of September 2012, approximately 34 million people worldwide suffer from Type 1 diabetes [1]. Type 1 diabetes, formerly insulin-dependent diabetes or juvenile diabetes, is a form of diabetes mellitus that results from the autoimmune destruction of the insulin-producing beta cells in the pancreas. Some 15,000 youth in the United States are diagnosed with Type 1 diabetes every day [2]. To maintain a normal blood sugar, these patients require insulin therapy. Patients with diabetes can administer their insulin manually using a syringe or opt to use of an insulin pump, known as continuous subcutaneous insulin infusion therapy (CSII). In CSII therapy, an insulin basal dose or “background insulin” is delivered continuously while the pump is “on”. A basal dose of insulin is a small, consistent dosage of insulin administered to keep blood glucose levels under control. The user is responsible for administering a bolus dose of insulin before or after a meal. A bolus is taken specifically at meal times to keep blood glucose levels under control and depends on factors such as: 1. the meal itself (carbohydrate amount); 2. the user’s blood sugar level and 3. their blood glucose response to carbohydrate intake and insulin which can be gauged based on experience [3]. Since 2000, over 700,000 T1DM patients have used a CSII device; the majority in the United States [4]. Reported advantages to the use of CSII include tighter glycemic control, a reduction in hypoglycemic episodes (abnormal diminished content of glucose in the blood) and greater precision with insulin dosing [5]. However, despite these published clinical advantages, and notwithstanding financial obstacles, the adoption of an insulin pump is not a given for type 1 diabetes patients eligible for insulin pump adoption. Several studies examining glycemic control of CSII users have shown that some patients improve while on insulin pumps, while others do not and the reasons for this are unclear. Furthermore research has also shown that some patients experience more anxiety during the period of pump adoption than others [6, 7].

Continuous glucose monitors (CGM) are responsible for measuring blood glucose in the interstitial fluid every few minutes via a subcutaneous sensor. The patient receives glucose level updates via an electronic receiver, providing them with the information necessary to take action with regards to insulin administration. However, studies have shown that glucose levels in
interstitial fluid temporally lag behind blood glucose values by between 5 and 10 minutes, which can be significant if the patient is entering what could be a hypoglycemic episode [8]. Despite this revelation, patients using a CGM are more likely to keep their blood sugar in the target range in comparison to type 1 diabetes patients using conventional finger-stick blood glucose testing methods according to Bergenstal et.al [9]. Limited research has been conducted on the use and adoption of CGM since finances pose a barrier to adoption. However, much like insulin pumps, research has shown that some patient groups are more likely to use the device than others and the reasons for this are unclear [10]. Furthermore, some patient groups are likely to experience more anxiety during CGM than others [11].

1.2 Gap in the Literature

The development of the artificial pancreas, a closed-loop system aimed at regulating blood glucose levels without the input of the patient, has raised an issue. There is need for better understanding of patient barriers and barriers to adoption and use of the two components that make up the artificial pancreas: the insulin pump and CGM. Addressing these barriers and understanding why patients may or may not consider these medical devices to be useful can inform the design of new insulin pump and CGM technologies. More poignantly, however, the impact of this gained knowledge can have an immediate effect on patient quality of life if used to inform training protocols for patients at diabetes centres. Furthermore, identifying and addressing the barriers to the adoption of CSII and CGM will likely inform the future design of the artificial pancreas.

1.3 Thesis Roadmap

The next chapter, Study Objectives and Potential Significance, outlines the study objectives and the motivation for the research. Additionally, the study’s significance in adding to researchers’ understanding of the impact of diabetes technology will be explored. The usability study’s likely impact on future training protocols will also be described.

Chapter 3 provides a review of the literature in an effort to explain the motivation of the research in more detail. The literature review explains what research has been previously conducted to
better understand diabetes technology adoption and the impact on patient quality of life. Human factors and the choice to add a simulation phase to the study are also described.

Having established the motivations for the research, Chapter 4 explains the study protocol in detail which includes a description of the three phases that made up the thesis project.

Chapter 5 delves into the first phase of the study where patients with type 1 diabetes mellitus were interviewed in order to better understand motivations and expectations in relation to adoption of an insulin pump. The interview results are presented as well as analysis and discussion.

Chapter 6 delves into the second phase of the study (same format as chapter 5) where patients with type 1 diabetes mellitus were interviewed to better understand motivations and expectations in relation to continuous glucose monitor adoption. The interview results are presented as well as analysis and discussion.

Chapter 7 describes the third phase: the usability study evaluating the 5 insulin pumps available in North America. The experimental setup, results, analysis and discussion of best practices in insulin pump design are included.

Chapter 8 includes the study summary in addition to the final recommendations for how training can be tailored at diabetes clinics in order to better meet the needs of type 1 diabetes patients.

Chapter 8 also highlights future work to further enhance understanding of patients’ perceptions of diabetes technologies.
2 Study Objectives and Potential Significance

Little research exists on the period of adoption of an insulin pump or CGM. No consensus can be reached regarding the burden of care or learning curve that a patient must overcome during initial stages of adoption.

Furthermore, little research exists comparing the usability or ease of use of all existing insulin pumps when tested by novice users. This research team aimed to better understand patient perceptions of the period of adoption and the usability of insulin pump devices for two reasons. The first reason is to fill the gap in the literature that exists in order to better inform diabetes technology design in the future. The second reason was to inform training protocols delivered at diabetes centres in order to better meet the needs of new diabetes technology users.

2.1 Study Structure

In order support these research goals, the study was divided into two parts based upon the two diabetes technologies of interest; the first related to insulin pumps and the second to continuous glucose monitors. The insulin pump study itself was further divided into phases; the first, an interview phase and the second a comparative usability study. The CGM study was comprised of semi-structured interviews. Both the insulin pump and CGM interview phases of this research were based on two theoretical frameworks, the Health Belief Model (HBM) and Technology Acceptance Model (TAM).

Overall, this qualitative study sought to answer these research questions:

- What are the perceptions, barriers and benefits to adoption of insulin pumps and CGM from the perspective of type 1 diabetes patients (both diabetes technology users and non-users)?
- Which of the five insulin pumps allowed for ease of use, and usefulness when used in simulation?
- Ultimately, how can training be tailored to better meet the needs of new users in an effort to lower the burden of care and learning curve?
2.2 Potential Study Significance

The purpose of this qualitative research was to influence the way training is delivered at diabetes centres and to identify best practices in insulin pump design. Very little standardization in training curricula exists to ensure training is delivered in a manner that optimizing diabetes technology use. For example, carbohydrate counting for effective insulin dosing is not taught with the same level of detail at all diabetes centres. Training protocols are developed at the discretion of the clinician leading the diabetes centre and do not go beyond introducing the basic use of a device.

Therefore, it was hoped that through the interviews and usability study, concepts difficult for a new user to grasp would be identified. This would facilitate answering the final research question of how training can be tailored to meet patient expectations and needs.
3 Literature Review

In the past decade, a greater emphasis has been placed on evaluating quality of life in patients with type 1 diabetes in an attempt to understand psychosocial aspects of the chronic disease. In particular, the number of qualitative studies has increased, all with the goal of improving the understanding of behavioural diabetes [12]. Qualitative research explores patients’ motivations, perceptions and expectations; something quantitative research cannot do with the same depth [13]. Understanding perceptions, experiences, behaviors and quality of life as a whole is necessary since they have an effect on perception of health and adherence to treatment [12-14].

The definition of quality of life (QOL) remains broad in the literature. QOL is the combination of life domains that amount to “well-being” which include treatment satisfaction, self-efficacy, anxiety, fear of diabetes complications and treatment expectations [15, 16]. With the introduction of the artificial pancreas to the type 1 diabetes community through clinical trials globally, the research team was interested in looking specifically at quality of life, barriers to adoption and burden of care associated with the components that make up the artificial pancreas: insulin pumps and continuous glucose monitors. A more complete understanding of the QOL domains associated with insulin pumps and continuous glucose monitors will allow designers to better understand users. This would likely inspire better medical device design and training protocols, which will be able to better meet patient needs.

3.1 Evaluating Type 1 Diabetes Patients’ Quality of Life

Emphasis on evaluation of quality of life has been predominantly secondary to the main goal of studies conducted on patient transition from multiple injections to insulin pumps and CGM. These particular studies [17-22] evaluate QOL through questionnaires (participant self-reporting) at the beginning and ending of the study period to determine whether the new treatment therapy has had a significant effect on quality of life. Researchers of these studies look to HbA1c levels or body mass index (BMI) to ultimately determine the efficacy of the new treatment therapy. In these studies, control groups often exist, though many evaluations are conducted without adequate controls [no control group in these studies: 18, 19, 23]. A description of participant training in carbohydrate counting and insulin dosage adjustments (important considerations for pump use) and physician or nurse support are rarely disclosed which can often alter quality of life.
life results [24]. Increased training and physician support have been reported as contributing to improved quality of life [24]. Furthermore, inclusion and exclusion data is not often reported. For these reasons, we are left with a limited understanding of quality of life measures since there are no consistent findings. More specifically, we are left with limited understanding of barriers of adoption and burden of care.

### 3.1.1 Insulin Pump Adoption

Some research groups, including Todres, et.al, 2010 [25] and Ritholz, et.al, 2007 [26] conducted interviews and focus groups, respectively, to uncover barriers to adoption of insulin pumps. Todres et.al, 2010 [25] used a qualitative, descriptive phenomenological research design to uncover essential themes from four individual interviews with four patients (two male, two female). The four participants varied in age from 21 to over 51 years of age with pump experience ranging from 5 months to over 11 years. Employment/education among the four participants also varied. Participants identified a number of challenges. They differed between them due to differences in personality and personal history. These included:

1. Adjusting to an increased sense of accountability for the self-management of their condition and the emotional implications of this sense of accountability
2. Learning to trust and accept the benefits of the new treatment regime involved a process of ‘letting go’ of some previous self-management routines and also letting go of the fears that had previously built up about consequences that would now no longer occur
3. Adjusting to others’ perceived views and interactions about pump therapy – adjustments involved working out strategies about how to manage interactions with others and also thoughts about how the pump could be better designed
4. Adjusting to the thought of ‘being on a machine for 24 hours a day’ but quickly followed by a realization of the benefits made this concern redundant [25]

The Ritholz, et.al, 2007 study group generated their own focus group questions and follow-up probes derived from their “clinical experiences” [26]. The group consisted of an endocrinologist, nurse practitioner, clinical psychologist and research psychologist. No conceptual or theoretical framework was reported to have been used to develop the focus group questions. Thirty adults with long-term diabetes participated in five focus groups: two with low mean A1C (6.8 ± 0.4%), one with mid A1C (7.80 ±0.3%) and two with high A1C (9.1±0.5%).
Inclusion criteria was at least 1 year of pump use, age of 18-70 years and type 1 diabetes mellitus. Exclusion criteria included severe depression, pregnancy, blindness and no current enrollment in any pump education program. Three major themes were uncovered, related to self-care practices, emotional reactions to the insulin pump and body image/social acceptance.

The impact the insulin pump had on diabetes self-care differed between the three groups. Participants in the high A1C group reported that they considered the pump to be a ‘miracle’ before they started use and expressed reluctance for performing expected self-care behaviors when they were required to use it on their own. They considered the pump to be more work than expected. Barriers to use for this group included decreased comfort using the technology and a difficulty in grasping how they could improve their glucose control on a pump. The three types of focus groups also differed in terms of emotional acceptance and reactions to the pump. Low A1C level participants reported that the pump made them more accepting of their diabetes while high A1C members described their pump experience in a more negative way. The mid A1C level participants shared the same opinions as both the high and low A1C level participants. Female members in all groups related to body image and social acceptance issues more so than men.

3.1.1.1 Insulin Pump Adoption and Training

In a study by Wheeler, et.al [27], family perceptions of adverse events and confidence in dealing with them was investigated. Families with adolescents less than 19 years of age on a pump were asked to participate in a 16- week study. Before the study began, the investigators surveyed the participants and found there to be 53 adverse events/100 person-years related to the insulin pump, whether it was due to mechanical or set-related failure. Of the mentioned adverse events, 8% reported hospitalization as a result of the pump complication.
Participants were followed for 12 months and asked to report on adverse events. At the end of the study, participants were also asked to comment on confidence and education. The study investigators found that there was an association between older age and pump malfunction (site/set problems excluded). There was no indication that infusion/set problems were related to age, duration of diabetes or duration of time on insulin pump. According to Wood et.al [28], difficulties with sites were the reason for permanent pump discontinuation in 21% of cases, while another study [29] reported cannula failure resulting in cannula replacement before expiration in 8-9% of insertions was the cause of discontinuation.

Education of these participants was also examined as mentioned above. Families commented on training issues and education, show in Table 1. Despite the initial and subsequent training, families were least confident about disconnecting the pump. The research group hypothesized that a more formal action plan for when things go unexpectedly may allow families to be more confident in their child’s diabetes management. This indicates a need for revised training protocols better able to meet patient and patient family’s needs.

3.1.2 CGM Adoption

Studies addressing quality of life associated with the adoption of continuous glucose monitors (CGM) predominantly followed the same protocol as studies addressing adoption of insulin pumps. Participants were randomly assigned to CGM treatment or the control group (if there

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replaced battery cap every 6–12 months*</td>
<td>33/225 (15%)</td>
</tr>
<tr>
<td>Average duration for set/site change ≤ 3 days</td>
<td>183/227 (81%)</td>
</tr>
<tr>
<td>Longest interval for set/site change ≥ 5 days</td>
<td>78/226 (35%)</td>
</tr>
<tr>
<td>Insulin pump settings documentedb</td>
<td>118/228 (52%)</td>
</tr>
<tr>
<td>All equipment needed for injectionsb</td>
<td>212/230 (92%)</td>
</tr>
<tr>
<td>Called diabetes service in the last 12 months</td>
<td>77/230 (34%)</td>
</tr>
<tr>
<td>Called pump company in the last 12 monthsa</td>
<td>78/230 (34%)</td>
</tr>
</tbody>
</table>

*According to the pump manufacturer’s specifications.
bIn anticipation of total pump failure and conversion to injection therapy.
aPump company technical support.

Table 1: Education and training issues [27]
was one) and were asked to completed QOL questionnaires at baseline and at the end of the study [21, 22, 30]. Similar to the insulin pump studies mentioned above, no consensus was reached as to whether CGM improves quality of life.

Two research groups, Tansey et.al, 2011 [31] and Ritholz et.al, 2010 [32] addressed barriers to adoption and use of CGM. Tansey et.al. [31] distributed the Continuous Glucose Monitoring Satisfaction Scale Questionnaire at baseline and at the conclusion of a 6-month study to 224 adults and 213 youth (8-18 years old) of which 81% were insulin pump users. Each participant used a CGM for one week before randomization. Users of the CGM over the 6 month study period identified barriers to monitoring included insertion pain, system alarms and body issues (size of transmitter and insertion site) while benefits including glucose trend data, opportunities to self-correct out-of-range glucose levels and to detect hypoglycemia. Youth had least favourable scores for questions related to hassles of using CGM. Participants that used the CGM more frequently to monitor their blood glucose (6 days/week) had higher overall scores on the Satisfaction Scale questionnaire (higher benefit and lower hassle scores) compared to infrequent users (fewer than 4 days/week). However, in this study, participants were provided CGM devices and sensors at no cost, which could have been a factor affecting satisfaction.

Ritholz et.al, 2010 [32] conducted semi structured interviews with 20 adults (aged 45 ± 15 years, diabetes duration 25 ± 19 years, 50% female) separated into three focus groups: HbA1c responders who demonstrated an improvement in glycemic control with CGM (baseline HbA1c >7%, reduction greater than or equal to 0.5%), hypoglycemia responders (baseline < 7%) who demonstrated decreased time <3.9mmol/l while remaining within target HbA1c, and HbA1c non-responders (baseline HbA1c greater than or equal to 7%, HbA1c reduction less than 0.5%). Three themes were identified where responders differed from non-responders:

1. Coping with frustrations with various mechanical features associated with CGM (alarms, calibrations, glucose discrepancies and inaccuracies)
2. Use of CGM information; responders watched trends while non-responders reported not being able to manage excessive amount of retrospective data
3. Significant other/spousal involvement; non-responders’ spouses described lack of participation with and/or understanding of CGM by significant other while responders
described significant other as being interested and understanding, as well as engaged with their diabetes.

The theme of body image concerns was identified in all three groups. Participants described feeling “kind of like a machine” [32]. The study was, however, limited by a small, well-educated and homogenous sample of selected subjects (100% white, 85% in significant relationships and 90% on insulin pump). These participants willingly participated in two consecutive research studies with the authors of the study. This suggests that participants were interested in diabetes self-care and more educated in their use of CGM, which may have skewed results.

CGM has been used in a number of studies with type 2 diabetes patients as a means of observing whether improvements in overall “control” can be seen as a result of interventions such as adjusting exercise regimes [33-37]. In a study by Allen et.al [38] where type 2 diabetes patients were put on a CGM while they participated in a regimented exercise program, participants were also included in a focus group interview to describe their perceptions of the technology.

Participants wore the Minimed CGMS (Medtronic) for 3 days total while also wearing an accelerometer (See Figure 1). At the end of the study, they were asked to participate in a one-hour, tape-recorded focus group interview.

![Continuous glucose monitoring system](Figure 1)

The focus group was guided by open-ended questions such as ‘What was it like to wear the CGMS?’ and ‘What were your thoughts when you saw CGMS graphs?’ [38]. The focus groups
were transcribed verbatim and put through thematic analysis. The take-away message from the transcripts was ‘a picture is worth a thousand words’ [38]. Participants felt that graphical information was more meaningful than discussion. Four major themes were identified regarding CGMS feedback [38]:

1. Made the need for behavioural change real
2. Reinforced diet and exercise program
3. Showed the effect and interrelatedness of exercise, diet and stress on glucose levels
4. Individualized feedback was valuable for behavioural change.

Overall the study investigators gathered that the CGMS technology was easy to use, reliable and provided meaningful data for their participants (n=9). However, participants did identify issues with calibration: related to the frequency of calibration required and related to actually inputting blood glucose readings/event data into the machine. In terms of physical burden, participant identified an issue with the length of the monitor cord, saying it was either too long or too short depending on the patient’s weight (See Appendix A) [38]. This issue is no longer relevant as the sensor and monitor in existing CGM technologies communicate via radiofrequency. However, patient comfort with wearing technology remains an unresolved issue. Wearing the device at night was also a comfort-related concern for patient participants. Skin irritation and pinched skin when bending over were also identified as inconveniences by participants who wore the monitors.

Ives, et.al [39] and his team at Yale University and the Yale Children’s Diabetes Program (YCDP) sought to devise a checklist of sorts to help patients and their families in choosing a CGM. Based on their experiences with clinicians and patients at the YCDP, they considered the important ‘practical characteristics’ of the CGM devices to be: the number of components, size of components, length of time the sensor can be worn, sensor insertion process and user friendliness [39]. The number of components led users to refer to “device burden” as patients were required to carry insulin administration supplies as well as a blood glucose meter and receiver. The second insertion site was also considered burdensome.

Difficult or painful insertion as well as poor adhesion and skin irritation were mentioned by a large number of patients in this study. Patients also reported frustration when they found the
sensor did not agree with their blood glucose meter readings or when false alarms interrupted daily activities. The study investigators attributed this to patient’s poor understanding of “lag time”, alarm fatigue and ineffective calibration technique [39]. The study investigator hypothesized that alarm fatigue can be attributed to patients setting unrealistic alarm thresholds. Though the authors aimed to address these misunderstandings through better training, the design of the technology and its contribution to the errors would need to be addressed in order to successfully mitigate safety issues. Shivers, et.al [40] mentioned the ramifications that accompany alarm fatigue and discussed the merits of sound quality (vibrate vs. beep) and volume [40].

Patients at the YCDP were also asked about calibration and there was a tendency for patients to believe that “more is better”; meaning that they calibrated the CGM more than necessary. This led to the sensor malfunctioning. An improvement of manufacturer instructions regarding the calibration strategy was emphasized by the patients who participated in this study. The authors concluded that careful training and discussion of troubleshooting strategies would likely ensure patients and families have a positive experience with CGM. This further emphasizes the need for improved training protocols at diabetes centres.

### 3.1.2.1 CGM Adopters

There has been some discussion in the literature regarding who is most suitable for CGM adoption, meaning which patients make good candidates and are likely to be successful [41]. According to Klonoff, et.al [42], patients with HbA1c levels of approximately 7% and above, able to use devices on a daily basis are ideal for CGM adoption. Furthermore, according to the Evaluation of Active Implants in Diabetes (EVADIAC) Sensory study, patients on insulin pumps have been seen to show greater improvement on CGM than patients using multiple daily insulin injections [43]. This may be attributed to insulin pump patients being more likely to make online adjustments to the delivery of insulin according to CGM data.

Other patients, such as new-onset TIDM patients are less likely to see improvements on CGM compared to self-monitoring blood glucose. CGM has also be seen to be less effective in younger patients between 8 and 17 years old according to 6-month JDRF study, attributed to infrequent use of the device [44].
Furthermore, the frequency with which the CGM is used is also a point of debate among clinicians and was addressed in the EVADIAC study [41, 43]. Two approaches were taken in this study: patient self-management vs physician–prescribed use of sensors [43]. In the first group, patients were advised to use the CGM continuously while the second group was prescribed the CGM by the physician depending on their glucose outcomes. The patients in this second group started with 15 days of sensor use per month for three months. At the three month mark, some remained at the same 15 days of use while others (HbA1c >7.5%, more than 4 mild hypoglycemic episodes per week or at least one severe hypoglycemic episode) extended their use beyond the original limits. After 1 year, the HbA1c decrease between the two groups was found to be similar though the physician prescribed group used fewer sensors that the patient-led group [41, 43].

3.1.2.2 CGM Training

Previous studies have shown that the amount of data available via CGM can be overwhelming to patients. The EVADIAC Sensor study saw to it that patients received specific education on how to retrospectively analyze and apply CGM data. Patients’ skills were assessed quarterly during the study through a questionnaire (see Table 2). Education was considered successful if all questions were answered positively. Those who did so also showed greater improvement in HbA1c compared to others. The study team deemed structured education to be essential to success on CGM.

Table 2: Evaluation of patient's education in EVADIAC Sensor Study [41]
3.1.3 Insulin Pump and CGM Adoption Combined in STAR 3 Study

The advantages of pump therapy and CGM separately have been documented considerably in the literature and this led to the Sensor Augmented Pump Therapy (SAPT) for A1C Reduction 3 (STAR 3) trial. This particular study combined the sensor augmented pump with optimal conventional therapy in a large population over 1 year (n=485). The study [45] aim was to assess factors likely to affect patient acceptance of SAPT, being health related quality of life (HRQOL) and treatment satisfaction in adult and pediatric patients and their caregivers. As mentioned above, a number of studies have shown pump therapy is favored over MDI for perception of general health and quality of life [46, 47]. However, a 6-month trial study by the JDRF Research Foundation Study Group [48] found there was little change in HRQOL when CGM was introduced. The STAR 3 set itself apart from Rubin, et.al [45] by looking at generic and diabetes specific HRQOL (hypoglycemia fear scale) and treatment satisfaction (using insulin delivery system rating questionnaire).

The primary outcomes after 1 year showed that A1c had decreased more in the SAPT group compared to the MDI group. However, the rate of severe hypoglycemia and weight gain in the SAPT group did not differ significantly compared to the MDI group [49].

After 52 weeks, there was no significant change among adults in either group in the measure of the generic HRQOL. There was a significant change in one measure of the generic HRQOL in children in the MDI group. There were no significant changes among caregivers.

Both measures of hypoglycemia fear improved significantly in all the SAPT groups (adults, children and caregivers). One measure of hypoglycemia fear improved significantly in the MDI group among children [45].

In the SAPT arm treatment satisfaction was significantly improved for adults, children and caregivers with a few measure exceptions. In the MDI group, there was some significant improvement among five measures: BG burden, efficacy, worry, social burden and overall preference in adults but not in children or caregivers [45]. The authors concluded that making a switch between MDI to SAPT is safe and feasible for motivated patients seeking to improve blood glucose control. The authors suggested that future research lies in comparing intermediate
technology platforms: IP with regular blood glucose monitoring and MDI with CGM. Of particular interest would be the observation of the tradeoff between the clinical benefits and the subjective benefits (i.e. improved diabetes control vs. appearance).

3.2 Previously Evaluated Training Protocols and Human Factors

This section will outline what research has been done in order to inform training of diabetes technologies for new adopters. Following this will be a description of the use of human factors methods to inform training.

3.2.1 Pump Training Protocols

In 2010, the American Association of Clinical Endocrinologists convened a panel to formulate a consensus statement regarding insulin pump (IP) management [50]. The group looked to characterize which patients are suitable for IP use and which are less likely to be successful. They also sought to better understand who in a patient care team, should look after patients on insulin pumps. Patient diabetes education and pump training protocols were recommended for implementation periodically in order to address patient gaps in knowledge that develop over time.

The characterization of which patients are suitable for IP therapy is beyond the scope of this research. However, the AACE considers an ideal candidate to be one performing 4 or more insulin injections per day, motivated to improve their blood glucose control, and willing to both mentally and physically commit to the challenges of pump therapy. Self-management is essential and a patient must be capable of this. Patients with reservations regarding the pump’s usage interfering with ‘lifestyle’ are not encouraged to adopt the pump. Furthermore, those not motivated to check blood glucose multiple times per day (>4 times), nor interested in tighter management are not expected to be successful on the insulin pump. These criteria are shared by a number of other research groups [50, 51, 52].

In terms of provider selection, the AACE [50] discussed the implications around there not being any standard guidelines as to which providers can be involved in insulin pump therapy prescription and training. The suggestion by Skyler et.al [53], is that only providers with the necessary knowledge, skills and resources, should be authorized to provide patient education,
training and follow-up. The implementation of provider certification was suggested. Provider selection is beyond the scope of this research but warranted mention.

In terms of patient education, evidence suggests that US clinics spend too little time on initial pump training and provide little support on the other end of the phone following the initial training, leading to negative patient outcomes [50]. This is in comparison to France and the United Kingdom, where patient education is a high priority [54, 55]. The AACE recommended extensive training on the technical aspects of insulin pump use which include [56]:

1. proper catheter insertion
2. meaning of pump alarms, especially those implicated with insulin delivery interruption (e.g. battery failure)
3. packing of extra supplies in case of emergency

What was emphasized and perhaps of meaningful importance was the mention that patient education and training be conducted periodically to maximize the value of the pump and to ensure continued patient safety.

A review of educational components and strategies revolving around insulin pump therapy was conducted by Jayasekara, et al [57] in 2011. The authors sought to answer the question: What are the most effective strategies for delivering education for adults with type 1 diabetes either using or initiating insulin pump therapy (IPT)? Effectiveness was defined as the extent to which an intervention, when used appropriately, achieves the intended effect [58]. A total of 142 studies were identified as possibly relevant. After an initial review of abstract, 24 papers were considered suitable for evaluation of methodological quality. At this stage, 20 papers were excluded. With one additional paper found in a list of references, the authors examined 5 papers to better understand the effectiveness of training on outcomes.

After examining the 5 papers of interest, the authors concluded that drawing any ‘take-aways’ from this study was difficult as there is a lack of high-quality comparative studies, sample sizes were too small and there was too great a variability between methods of reporting among authors. However, the descriptive studies did explore a range of uses that may be related to effectiveness of IP therapy and education. Based on the results, the authors listed recommendations for practice [57, 59-63]:

17
1. Education and training is important for successful initiation
2. Multidisciplinary teams form effective teams for delivering education
3. Mixture of group and individual teaching can be effective
4. Take-home materials may be useful for education and training (e.g. teaching and learning materials like a training pump)
5. Blood glucose monitoring, carb counting, adjusting insulin dose (basal, bolus) as well as practical aspects such as identification of malfunctions, prevention and management of acute complications should be addressed in education and training programs
6. Longer duration training with multiple sessions may be more effective than short term sessional training
7. Duration and frequency of follow up for optimal management should be adapted to individual needs [57]

Another study, published in 2013 by Meade et.al [64] sought to assess insulin pump use and to shape ongoing education based on its findings. In order to reach this goal, the study team implemented a pump assessment questionnaire (closed questions) in an endocrinology office designed to evaluate aspects of IP therapy such as: pump operations, infusion set failure, management of acute complications, and usage of advanced features [64]. The questions were designed based on a review of the literature regarding pump therapy. With the help of a diabetes educator, 89 participants completed and reviewed the questionnaire. This allowed the diabetes educator to uncover training opportunities. The participants were split between type 1 diabetes patients (80%) and type 2 diabetes patients (20%) and were all Medtronic insulin pump users. The study was conducted between January 2008 and February 2011 and all patients had to be using a pump for at least 1 year. During regular office visits, patients were asked to complete the questionnaire in the waiting room. (The questionnaire can be found in Appendix B.)

A number of issues highlighted by patients are beyond the scope of this literature review such as not checking for urine ketones when applicable (56%) and the lack of antiemetic prescription for sick day intervention (52%) [64]. However, of particular relevance is the use of manual bolus instead of the bolus calculator (51%) and perhaps the absence of a back-up insulin syringe if the pump stopped working (68%). Another interesting revelation was that the square wave bolus (an insulin bolus delivered over an extended period of time) and alarm clock were the two least
utilized functions on the pump while the most utilized related to adjusting temporary basal rates [64]. Other issues identified by participants are shown in Appendix B.

With these results, the study investigators recommend continual assessment of knowledge techniques and behavior to ensure optimal safety and use of the insulin pump. Particularly relevant was the idea of further educating patients on the benefits of using a bolus calculator rather than bolusing manually.

3.2.1.1 One Insulin Pump Manufacturer’s Training Protocol: Tandem t:slim

At the 7th Annual Advanced Technologies and Treatments of Diabetes (ATTD) International Conference in 2014, Tandem (a sponsor of the event) presented the results of its research and showed that faster training times and fewer errors were found when using the Tandem t:slim over the Medtronic Minimed insulin pump. This randomized usability study included participants (n=72) not currently using pump therapy, who were engaged to perform seven of the most common tasks on either the Tandem and the Medtronic pumps. Participants were trained and asked to return two days later to perform the tasks without assistance. The authors, report that the t:slim took 27% less time to train than the Medtronic pump (17.6 min vs. 24.1 minutes) and that these same users failed fewer tasks (0.8 errors versus 2.3 errors). In an exit survey, participants reported that the t:slim was easier to understand, the screen had clearer contrast, was better sized, was easy to program and more “enjoyable to use” [65]. This data was provided in a press release and therefore further information was not available at the time of this review.

Reported at the same conference were preliminary findings, showing that patients using the t:slim, saw decreases in HbA1c after 3 months (n=289). This patient population was made up of both previous pump users and non-users (n=78).

3.2.2 Examples of the Use of Human Factors to Inform Training

It is difficult to find explicit examples of human factors informing training directly in healthcare. However, it’s very likely that implicitly, human factors have been utilized in creating training programs.
In the field of aviation human factors (HF) have successfully been employed to better understand how humans can most safely be integrated with technology. This understanding has been explicitly translated into better design, training and policies in order to encourage better human performance [66]. HF has also contributed to accident reporting and future accident prevention through training in the offshore oil industry [67]. Though these findings do not necessarily set an exact precedent for this work, they do show potential for the use of human factors to inform training protocols.

3.3 Perceptions of Diabetes Technologies: Use of Theoretical and Conceptual Frameworks

Though the studies above generated a list or themes of barriers to adoption, there was limited ability to produce conclusive evidence. The way in which interview questions were generated was not divulged and it is possible that the measures of quality of life for example were subjective and therefore unreliable. The use of a validated measurement scale or theoretical model is needed to better guide interviews and questionnaires for this study. Models such as the Technology Acceptance Model (TAM) and Health Belief Model (HBM), among others described below, have validated scales for specific variables such as perceived usefulness and perceived ease of use. These fundamental determinants of user acceptance are likely to predict and explain system use with greater practical value [68]. However, there may arise some rigidity when using a conceptual framework as it can provide some guidance in certain areas, while not accounting for other factors that influence health behaviours. For example, the models do not account for health-related behaviours for reasons unrelated to health (e.g. exercising for aesthetic reasons) nor do they account for environmental factors outside an individual’s control.

3.3.1 Technology Acceptance Model

The Technology Acceptance Model (TAM) was first validated in 1989 by Fred Davis in a study examining user acceptance of new computer systems and electronic mail to improve job performance. The TAM was based on two concepts: perceived usefulness and perceived ease of use. Perceived usefulness is described as the degree to which a person believes that the new system will enhance job performance. Perceived ease of use is described as the degree to which a person believes that using the new system would be free of effort. Since 1989, “trust in the
new system’ has been added to the two previous concepts; this new model is referred to as the adapted TAM [69].

The van Bon et.al, 2010 [70] artificial pancreas (AP) study group used the TAM as the basis of their study and investigated the future acceptance of an AP and its determinants. This study [70] attempted to increase the predictive value of TAM by extending the variables of perceived usefulness and ease of use. Determinants of perceived usefulness were social influences and cognitive instrumental processes. Social influences included peer pressure, conformity and persuasion. Cognitive processes included judgments and evaluation. These were further subdivided as seen in Figure 2. Perceived ease of use was also improved with: perceptions of internal control (self-efficacy to perform a task), perceptions of external control (facilitating conditions such as specific training), intrinsic motivation (openness to process) and emotion (computer anxiety). This framework allowed the authors to identify the major barriers to adoption: concerns associated with the number of components that must be worn and issues of trust regarding the technical accuracy of the AP, particularly during exercise.

![Figure 2: Visual Representation of Technology Acceptance Model, van Bon et.al, 2010 [70]](image)

3.3.2 Health Belief Model

The Health Belief Model (HBM) was first described in the 1950s by a group of social psychologists seeking to understand why people refused screening tests for early detection of asymptomatic diseases [71]. The model was later used to understand a patient’s response to symptoms followed by an attempt to understand compliance with prescribed medical regimens.
The HBM model is composed of two variables in the context of health-related behavior: (1) the desire to avoid illness (or if ill, to get well), and (2) the belief that a specific health action will prevent or improve illness. The HBM consists of the four dimensions (Figure 3):

1. Perceived susceptibility: refers to one’s subjective perception of the risk of contracting a condition
2. Perceived severity: refers to feelings concerning seriousness of contracting an illness (or of leaving it untreated)
3. Perceived benefits: refers to beliefs regarding the effectiveness of the various actions available to reduce the disease threat
4. Perceived barriers: refers to negative aspects of a particular health action that might impede the undertaking of a recommended action or behavior

The original authors of the HBM hypothesized that the levels of susceptibility and severity provide the “energy to act” and that perception of benefits provide a path of action. Furthermore, some stimulus is necessary to trigger the decision-making processed, called a “cue to action” which can be internal (symptoms) or external (media, health care providers, etc).

![Figure 3: Visual Representation of the Health Belief Model, Glanz et.al, 2002 [72]](image)

To date, the HBM has inspired or has been used explicitly as a framework in a number of studies related to diabetes mellitus including evaluation of diabetes management behavior, and observation into the relationship between diabetes and compliance to insulin administration in both adults and youth starting in the 1980s [73- 76].
3.3.3 Theory of Planned Behavior

The concept of the Theory of Planned Behavior (TPB) was proposed by Icek Ajzen in the 1970s to improve the predictive power of an existing theory: The Theory of Reasoned Action. The theory of planned behavior states that an individual’s behavioral intentions and behaviors (Figure 4) are driven by [77]:

1. Behavioral beliefs and attitude toward behavior: an individual’s belief about consequences of particular behavior; based on positive or negative evaluation of self-performance
2. Normative beliefs and subjective norms: an individual’s perception about the behavior which is influenced by judgment of significant others or others’ beliefs that he or she should or should not perform such behavior
3. Perceived behavioral control and control beliefs: an individual’s perceived ease or difficulty of performing a behavior (based on control beliefs which refer to beliefs about presence of factors that may facilitate or impede performance of the behavior [78])

![Figure 4: Visual Representation of Theory of Planned Behavior][77]

The TPB put great emphasis on social support systems to facilitate changes in behavior or to maintain existing behaviors [79]. The Shorer et.al, 2011[80] study used the TPB to assess the role of a parenting style in achieving metabolic control in adolescents with type 1 diabetes. In a study of 100 adolescents and their parents, an authoritative nonhelpfulness parenting style was
found to be associated with better adherence to treatment and glycemic control. Omondi, et.al, 2009 [81] also applied the TPB model to understand physical activity behavior among a group of type 2 diabetes patients in Kenya, therefore predicting diabetes management behavior much like the other behavior change models.

3.3.4 Diffusion of Innovation Theory

The concept of Diffusion of Innovations was popularized in 1962 by Everett Rogers in his book *Diffusion of Innovations* which examines how innovations are adopted by groups. The theory states that there are four main elements that influence the spread of a new innovation: the innovation itself, communication between individuals or groups to spread the message, time, and finally a social system (units with the same problem trying to accomplish the same goal).

Adoption of a new technology, again according to Rogers, 1995 [82] takes place in five stages:

1. Knowledge: individual is exposed to innovation
2. Persuasion: individual is interested in innovation and seeks information
3. Decision: individual weights advantages/disadvantages of using the innovation and decided whether to adopt or reject the innovation
4. Implementation: individual uses the innovation and determines whether it is useful or not
5. Confirmation: individual decides to either continue or discontinue using the innovation

Like those mentioned above, this model also examines subjective perceptions of the potential user [79]. The DIT was using in the Bachman, et.al, 2008 [83] study that evaluated online education geared towards diabetes management in school settings. The DIT guided the development, implementation and evaluation of an online continuing education program with the objective of being perceived as better than the existing method in terms of convenience, and satisfaction. To our knowledge, the DIT has not been used in any study evaluating the use of insulin pumps or CGM.

The studies that utilize belief models for identification of barriers to adoption rarely consider objective benefits of the medical devices, while studies only looking at objective benefits for example rarely depend on subjective perceptions to make design recommendations. Therefore, we propose a study that examines both objective and subjective criteria that influence adoption of the insulin pump and CGM. Objective criteria will be gathered through usability testing.
through examination of use errors. To our knowledge, no research has been conducted comparing the usability of these five insulin pumps.

3.4 Human Factors and Usability Testing

The FDA describes human factors (HF) as the “science and methods used to make devices easier and safer to use”[84]. HF is used to fulfill goals of health and safety and is concerned with how users fit with the equipment/design or environment. HF specialists do not generally advocate training as a method of improving safety and ease of use. Instead, HF focuses on redesign in order to create a system better suited to the user (i.e. design out the usability issues and make the usage more intuitive). Redesigns, in theory, are expected to eliminate errors. However, it is impossible to eliminate all potential for errors in a design and therefore, training can be used as a tool to prevent usability issues.

Training has the benefit of being culturally acceptable in the healthcare field [85] and is faster than HF analyses (testing, redesign, validation, etc.) since vendor training materials already exist. Through training based on HF, users become more aware of issues that may cause confusion that the vendor is unlikely to focus on. Though redesign is preferable when it comes to reducing the likelihood of errors, training is an alternative when this is not possible. However, by focusing training on problematic issues in addition to providing standardized vendor recommended training, clinicians (nurses in diabetes clinics, in this case) would likely need to commit more time to training which could be problematic.

3.4.1 Previous Insulin Pump Usability Evaluations

In order to inform training and identify best practices in insulin pump design, this research group decided to include a usability study evaluating the five insulin pumps currently available in North America. Three manufacturers (Insulet, Roche and Tandem) have previously published comparative user evaluations of their insulin pumps. The findings of these studies will be briefly described below.

3.4.1.1 Insulet Pump Evaluation

In 2005, the manufacturer undertook a clinical evaluation of the Insulet OmniPod insulin pump with 20 subjects with type 1 diabetes. The purpose was to study a 30-day period and to assess
the comfort, function, and use of the system compared to traditional insulin pumps. The authors (the manufacturers), found that 18 of 20 participants preferred the OmniPod over traditional insulin pumps (with tubing) and noticed a significant drop in A1c over the month-long period [86]. This was attributed to the fact that users never had to disconnect the “Pod” (insulin reservoir). Traditional pumps are usually removed when showering, changing clothes or exercising [87]. Another difference between the traditional pumps and the Omnipod was that a traditional pump is tethered to the body and therefore moves around in relation to the insulin infusion site. The authors hypothesized and presented in [88] there is a hydrostatic effect on traditional pumps during basal and bolus insulin delivery which means there is variability in insulin delivery. The authors concluded the Omnipod did not have this same problem. These results focused on behavioural perceptions and adoption as indicated by the drop in A1c.

3.4.1.2 Roche Pump Evaluation

Published in 2013 was a paper by Ziegler et.al. [89] aimed at investigated the impact of patients switching from older pumps (including previous versions of Roche AccuChek, Medtronic, Animas and Cozmo) to the AccuChek Combo System [89]. 299 patients were enrolled in this study at 61 Europeans sites. Glycemic control, safety and diabetes management parameters were measured at baseline, after 3 months and after 6 months. The study investigators found that the transitions from older pumps to the new pump (the AccuChek) led to more stable glycemic control with significant improvements in A1c in patients that had previously has unsatisfactory HbA1cs. There was a decrease in bolus frequency and an increase in self-monitoring in patients using the AccuChek, which suggests increased confidence in diabetes management and a decreased need for correction boluses [89]. Another similar study was performed by Kerr et.al.[90], where HbA1c levels decreased continuously and treatment satisfaction significantly improved. The authors attributed some of this to the added features related to bolus advice and correction insulin dosing, but also to the discrete nature of the insulin pump [90]. These results focused on both behavioural perceptions and adoption.

3.4.1.3 Tandem Pump Evaluation

When the Tandem t:slim went on the market, the manufacturer performed an evaluation study to better understand users’ perceptions of the t:slim pump versus the existing pumps on the market
The authors had participants complete the Insulin Delivery System Rating Questionnaire [92] along with a Participant Training Satisfaction Questionnaire and a t:slim Pump Satisfaction Questionnaire [91]. In the study, participants were provided with a t:slim for 30 days for everyday use. The study was conducted at 4 institutions across the United States; a total of 74 participants took part. The inclusion criteria included participant be over 18 years of age, willing to be compliant and able to read, speak and understand English. [91]. The exclusion criteria included a participant having any medical, social or psychosocial medical condition that might prevent them from participating fully, potential for lack of compliance as well as currently using the Insulet Omnipod for their insulin management [91]. The authors excluded Omnipod users as they felt the system was too different in the way it was worn and used compared to the t:slim.

The authors found lower levels of embarrassment with the t:slim versus a previous pump system and concluded that participants’ scores were favourable because they were more free to dress as they wanted. Overall, participants felt that they achieved better blood glucose control using the t:slim. These results focused on both behavioural perceptions and adoption. However, this study was not without limitations. There was no control group included and only one validated questionnaire was included for data collection. Furthermore, Insulet Omnipod users were excluded from the study, which may have skewed results.

3.4.2 The Case for Simulation as a Tool to Identify Training Needs and Best Practices in Insulin Pump Design

A typical usability testing procedure was proposed for this study by the investigator in order to inform recommendations for improved training protocols. Usability testing is defined as a “process of having users interact with the system to identify human factors design flaws overlooked by designers” [93]. Design flaws in each instrument will be addressed specifically. The usability study will also elicit problematic features worth emphasizing more explicitly in training.

As is typical of a usability test, the protocol utilized exploratory questions and encouraged a “think aloud” approach in order to gain insight into a participant’s expectations, opinions and mental model. Because the usability study was evaluating the technology and not the participant themselves, hints were provided after the participant seemed to have exhausted all other avenues,
expressed frustration or asked for help after making several attempts to complete a task on their own.

3.5 Conclusion

Though researchers have attempted to better understand patient perceptions of diabetes technologies through quality of life and interview studies, a lack of understanding remains regarding patient perceptions when considering adoption. Theoretical models such as the Technology Acceptance Model have been used to better identify patient perceptions of technology but there remain a number of unknowns such as how perception of severity of disease links to perceived usefulness of a technology. The goal of the first two phases of this study is to link the Health Belief Model and Technology Acceptance Model to better understand a patient’s experience during the period of adoption.

As mentioned above, few evaluations of the usability of insulin pumps have been conducted by independent reviewers. There is a need for a usability study that includes all five insulin pumps available in North America in order to identify best practices in insulin pump design. Since human factors methods have been shown to be highly applicable in healthcare and have been used in aviation and other fields to inspire training protocols aimed at lessening the occurrence and severity of human error, this type of study also holds the potential to generate better training protocols delivered at diabetes centres.
4 Methods

The following section described the study schedule and design. The bracketing exercise conducted by the study investigator is also described in detail.

4.1 Experiment Design

The study, divided into three phases is described below. Chapters 5, 6 and 7 will outline each phase separately and in detail.

4.1.1 Testing schedule

The three phases of this research study did not occur simultaneously, though they did not necessarily depend on one another. The timeline was dictated first by the research ethics board at the University Health Network and the office of research ethics at the University of Toronto (see Appendix C and D, respectively for the approval letters) and second by third parties who made their instruments available to the investigator for the usability study.

The first phase conducted was the insulin pump semi-structured interview phase. The continuous glucose monitor semi-structured interview phase followed the first phase by two months. The insulin pump usability study followed the CGM interview phase – approximately one month later.

4.1.2 Study Phase Design

As mentioned above, this study was comprised of two interview phases and one usability study focused specifically on the usability of insulin pumps. The usability study would allow the study investigator to identify best practices in insulin pump design and to tailor education to better fit patient needs. A CGM usability study was not included for a number of reasons. First, the technology does not lend itself to task-based scenario design easily as it is primarily used for gathering and interpreting blood glucose data. Secondly, the analysis of data through another application, CareLink, was necessary for optimizing CGM use. Testing the whole user experience of the CGM which would include CareLink would not necessarily yield a depth of knowledge that would add significantly to the research. Therefore, analysis of CGM usability was excluded.
4.1.3 Bracketing

Before beginning the first phase, the researcher conducted a bracketing reflection. Bracketing refers to an investigator’s identification of bias, vested interests, personal experience, hunches as well as any presumption that might influence the study’s data - especially important in qualitative research [94]. Any “involvement” is put into “brackets” and “shelved” while the research is being conducted [94,95]. The purpose of this reflection is to ensure that once the study is complete, the researcher’s understanding of results would be shared by others looking at the same data. This is termed a reflection and not an exercise as it is intended to be repeated constantly throughout the research project as perceptions and stances can shift over time. The reflection allows the researcher to become aware and mindful during the research process [96].

The first step in a bracketing engagement is a disclosure of sorts. This means allowing readers to see “where the author is coming from” [94, 97]. Presumptions from the author’s background may influence data analysis and findings and they are “put aside”. Following this disclosure, a number of methods are suggested for identifying further bias. The study investigator completed a “mind map” based on the approach presented by Tattersall et.al. [98]. A central question related to the research topic is written at the centre of the map and from their thoughts, comments and questions are divulged and linked to one another. This process can continue interminably; however, at some point, certain themes can evolve [99, 100]. The study investigator’s bias lay in the fact that she was trained as an engineer and therefore is likely to presume that technology, when used properly, helps more than it hurts. By identifying this bias, she was able to reflect upon the research findings, conscious to ignore her previous pre-conceived notions [94].

4.2 Summary

This chapter focused on the rationale for the study design. The study was comprised of three phases, two of which were structured as interviews, while the third was a usability study. The final section of the chapter described the study investigator’s “bracketing” exercise which allowed for the identification and “shelving” of her engineer’s bias before the study began.
5 Insulin Pump Perceptions Study

The following chapter will describe insulin pump perceptions study in detail including the objectives, methodology, data collection, analysis and discussion. The study limitations are also described at the end of the section.

5.1 Objectives

The goal of this phase was to conduct semi-structured interviews with adult T1DM patients in order to identify barriers to the adoption and use of insulin pumps. These interviews investigated barriers to adoption and use of the insulin pump. A qualitative analysis of these interviews identified themes that drove the development of recommendations for training module design.

5.2 Setting

All interviews for this phase were conducted over the phone. Prior to the interview date, a consent form was sent to each participant via email. Participants were asked to give consent over the phone before the beginning of the interview. Once consent was received, two audio recording methods were used: via laptop computer and a handheld audio recorder.

5.3 Methodology

In order to capture a wide scope of perceived barriers and benefits of insulin pump technology, two types of patients were recruited: the first group included patients currently using the technology; while the second was composed of individuals who had considered adopting the technology previously, but ultimately rejected it. This semi-structured interview phase’s design and results will be described below.

5.3.1 Use of Theoretical Frameworks to Generate Open-Ended Interview Questions

The Health Belief Model and Technology Acceptance Model were used to better categorize patient understanding of these technologies. The Health Belief Model (HBM) predicts that a patient will adopt a course of treatment or will act in some way related to their health if they perceived the benefits of this action to outweigh the barriers. The Technology Acceptance Model (TAM) provides a general explanation of the intention to use a specific system, based on
perceived usefulness and perceived ease of use. Neither framework alone could provide the depth of knowledge that was necessary to understand the “user experience”. The open-ended questions were posed in a manner that suited adoption chronology i.e. identification of need for change in diabetes management, consideration of the device, adoption of the device. The frameworks were mixed based on the question chronology.

5.3.2 Participants

Potential participants for the study were identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants were sent a personal invitation. After initial contact was made by the TGHDC, participants were contacted by the study coordinator via telephone. At this time, participants were provided with a detailed description of the study that included the information necessary for the participant to give informed consent.

Potential participants had to be adults (over 18 years of age) with T1DM in order to be included in the study. They also had to be able to read, write and speak English and be willing to participate.

The total number of participants was twelve. Participants were recruited continuously until response saturation was achieved: six individuals in each group, half currently using an insulin pump and the other six contemplating adopting (or who had previously contemplated and rejected) an insulin pump. This allowed the research team to catalogue a wide range of barriers and benefits to the adoption of insulin pumps.

Participants varied in age and duration on the insulin pump which allowed for broad perspectives on the topic of barriers to adoption and use of the medical technologies. The participants on insulin pump technology were also recruited based on which pump they were currently using since all pump manufacturers needed to be represented so as to avoid any bias.

There are currently 4 insulin pumps on the Canadian market. The four companies manufacturing these pumps are: Medtronic, Animas, Roche and Insulet. As mentioned above, 6 participants were insulin pump users while 6 participants were non-insulin pump users i.e. multiple daily injection users.
5.3.2.1 Insulin Pump User Participants

Full demographic information collected from participants in the pre-test questionnaire can be found in Appendix H.

- Of the six insulin pump users, 2 were Medtronic insulin pump users, 2 were Animas users, 1 was an Insulet user and the last a Roche user
- The users varied in age from 18 to 59
- Two participants were male, while four were female
- The median years since diagnosis of type 1 diabetes was 5.5 years
- The median years since adoption of an insulin pump was 4.5 years. This is consistent with ADP regulations (Assistive Device Program) which state that a patient must wait at least one year from diagnosis before adopting an insulin pump [101].

5.3.2.2 Multiple Daily Injection User Participants

Full demographic information collected from participants in the pre-test questionnaire can be found in Appendix H.

- Of the six multiple daily injection users (non-insulin pump users), four were female while two were male
- Their ages ranged from 18 to 59 years old
- The median years since diagnosis of type 1 diabetes was 11.5 years

5.3.3 Procedure

The study consisted of three stages, described below. The complete testing protocol and script can be found in Appendix E and F respectively.

1. Introduction to study

Participants were oriented to the study and its purpose. Verbal consent was obtained (See Appendix G for consent form).

2. Pre-test questionnaire
A pre-interview questionnaire was posed to each participant in order to gauge their experience with insulin pumps, as well as to amass demographic information to ensure all inclusion criteria was being respected (Appendix H).

3. Interview

Participants were asked the semi-structured interview questions. The study investigator took notes and employed two methods for recording the audio. Any participant questions were answered by the study investigator and the details of their compensation were finalized. Each participant was paid $30 for their involvement.

5.3.4 Data Collection

The two audio recordings allowed the investigator to send an audio file to a transcriptionist for future data analysis purposes.

As mentioned above, a pre-test questionnaire was posed to participants to collect basic demographic information.

Following the conclusion of the study, the study investigator felt further demographic information could shed more light on the study results. Five additional questions were sent to participants via an electronic survey regarding educational level, comfort with technology and diabetes health (most recent HbA1c).

5.3.5 Data Analysis

Audio recordings of interviews were transcribed and analyzed. The method employed was a general inductive method where interview transcripts and notes were reviewed repeatedly and text segments were coded for potential themes. As the coding framework was developed, recorded notes were be reanalyzed in light of new themes that may have emerged.

5.3.5.1 Reliability

The use of more than one analyst in qualitative research is often appropriate since one analyst’s research bias may be perceived as affecting consistency and reliability of data [2]. A second master’s student conducted data analysis on the transcripts. The investigator proposed that if the
majority of the transcripts were reviewed and agreement was found, the assumption could be made that the analysis of the rest of the transcripts would yield similar results. The two reviewers were in general agreement regarding themes emerging from the transcripts. The reviewers worked separately, and then came together to discuss the findings (Figure 5). Any discrepancies were discussed and resolved until consensus was reached.

Figure 5: Example of iterative coding process with second reviewer

5.4 Results and Discussion

Four themes were identified from the interview transcripts, in agreement between the two reviewers. The nomenclature for the following sections is as follows:

- IP-#: insulin pump user, participant #
- MDI-#: multiple daily injection user (non-IP user), participant #

5.4.1 Lack of “Value-add”: IP adoption may not add value to diabetes therapy

A perhaps novel perspective shared by MDI users was the concept of “value-add”. Value-add, in the realm of business terminology, refers to the addition of benefits or functionality to a product in order to increase its value to potential customers. In the realm of diabetes technology, to the majority of MDI users (4 of 6 participants interviewed), the insulin pump did not add value to their diabetes management. Participants referred to both software and hardware when discussing
what they perceived to be a lack of sophistication when it came to the design of the insulin pump.

Participant MDI-4: “from what I understand the technology is still a little bit flaky when I've been in discussion groups [...] it's not quite robust at this point”

Two participants commented on the lack of feedback coming from the pump. They were concerned that there wasn’t enough information reassuring them neither that the pump had been setup correctly nor that it was working correctly. This was especially worrisome in the context of cannula insertion as participants were unsure how they would immediately know they were performing the task correctly. They didn’t want to wait until hours later to know the insertion had failed.

When participants were asked why they had considered the technology and then rejected it, most answered that it did not fit their needs or did not meet their expectations. For example:

Participant MDI-4: “One of the reasons I haven’t gone for a pump at this point is...I guess I'm just waiting for the technology to get better.”

Participant MDI-3: “I still feel like I’m probably not going to adopt pump unless there is some information that I’ve never heard before.”

Furthermore, a number of participants commented on their surprise that CGM was not by default, incorporating into all insulin pumps. Their expectation was that the two technologies were synonymous, so alone, the insulin pump itself was not worth the “extra work”.

Participant MDI-4: “...all these things that go with the pump that it was probably a lot work and then without, you know, things like continuous glucose monitoring there was...I guess, in my case, I felt that the benefits were a bit more limited.”

Of note, this participant contemplated insulin pump adoption greater than five years ago and had not been introduced to sensor augmented Medtronic pumps. Please see below Section 5.5 “Limitations of the study”.
From a hardware perspective, the size of the pump itself, as well as the physical burden perceived by both users and non-users was a barrier to adoption. These factors were described by most participants including participant MDI-1 who perceived the attachment of the pump and the physical burden to out-way any benefits the pump might have had on her diabetes management.

*Participant MDI-1: “And I have thought about the pump but I have reasons against that. I really do think the pancreas is an amazing little thing and until it's perfected, or a replacement, um we are doing the best we can with the MDI throughout the course of the day.”*

5.4.2 Psychosocial Impact: Perception of self and others can affect adoption

Psychosocial impact is likely one of the most reported and consistent barriers to adoption of insulin pumps. This theme was reflected in each of the 12 interviews conducted. There were variations on the theme, whether it was perception of self and/or others that was alluded to.

In terms of self-perception, a number of participants reflected on the attachment to the machine itself and perceived themselves as “robots”. One participant mentioned that living on the insulin pump was more of a psychological adjustment than a physical one.

*Participant IP-2: “I would say it's staying in good mental health and just good overall psychological wellbeing […] that is a really good foundation for also having good diabetes control.”*

But perhaps more poignant was perception of others. Participants did not want to draw attention to themselves and their diabetes and felt that the insulin pump would do that.

*Participant MDI-6: “More the worry that it really makes you stand out as a diabetic […] having this thing attached to me at all times.”*

Both users and non-users discussed how the pump had/would change their style of dress which was deemed a significant disadvantage. The perception was that the pump would not allow the patient to be discrete about their disease. The following are comments regarding their appearance:
Participant MDI-3: “I don’t like telling people I have diabetes but I wouldn’t want them to know because of the way I dress. Like if I have to wear looser shirts. I don’t want to worry about whether it was showing.”

Participant IP-2: “man, I...it like looks really unattractive. I don’t want to be the kind of person that just looks like they’re always wearing a pager all the time. I want to be discrete about my insulin pump.”

Beyond style of dress, for non-users, was the fear that wearing the pump might force a change in lifestyle itself. This was a deemed a significant disadvantage for adoption of the pump.

Participant MDI-3: “I like going out and I’ve never seen a pump on anyone before. I don’t know if that’s because people can have it discreetly on them or because people who have them don’t actually go out.”

Under the umbrella of psychosocial impact was also the perception that the pump would be a negative reminder of diabetes. Because it would be attached to the patient at all times, there was no way to “ignore” their disease if they so desired.

Participant IP-1: “It was nice with injections, you can kind of throw it in your purse and not think about it whereas the pump is always on you [...] so, it's kind of a little more of a reminder that, you know, you've got diabetes.”

Participant MDI-1: “The way I am managing it at the moment, I feel like I can ignore it [my diabetes], but I’m not constantly reminded of it because I’m attached to something.”

Two of the six IP users brought up a “mental burden” associated with being on the pump. Though they discussed increased control in their diabetes they thought of the pump as overwhelming, resulting in a “love/hate” relationship as one participant referred to it.

Participant IP-2: “It's a lot of information. It's very...it's really useful for me. And then sometimes it's not. [...] Sometimes I have a hate relationship with my iPhone because it's really unhealthy, like it's too much information and it's kind of the same with the pump.”
5.4.3 Lack of Support Structure

All the participants, both IP users and non-users, mentioned support structure whether it was in a negative or positive context. Support structures were different in every case, whether it was family/friends, physician/diabetes nurse or other type 1 diabetics met through online forums, support groups or in person at the “Smart Pumpers” events held at the TGH Diabetes Clinic. A number of participants also discussed camps aimed at T1DM adolescents. This theme was often identified as the prompt for decision-making (e.g. to go on an insulin pump or not) or the reason the participants themselves felt comfortable or uncomfortable making a decision. For example, one participant (IP-1) discussed the role her mother played in her decision to adopt a pump. Another participant (MD-3) discussed the role support groups played in having him consider the insulin pump.

Participant IP-1: “I had told my mom about it a little bit and she [...] had no idea what diabetes was when I was diagnosed. [...] She was kind of backing me up while I did all my research and everything.”

Participant MDI-3: “I’ve been to support groups with JDRF; I’ve been to one session and everyone had a pump, basically. Basically I just went, and people talk about managing diabetes and they talk about different pumps coming out and I saw two brands of pumps. That was the first time I saw it.”

However, another participant discussed how, without the support of her partner, she had difficulty prioritizing her insulin pump therapy and eventually gave the pump up for a few months.

Participant IP-2: “My partner was also really busy and going through a lot of stress in his work so that [was] putting a strain on our relationship, both of us being really burned out. [...] I found that it just became harder to prioritize my diabetes. Like, I could feel myself becoming defeated.”

The investigator would also identify “self”, the participants themselves, as part of the support structure. A number of participants mentioned that learning about insulin pumps and gathering
the information to make an informed decision led to a feeling of empowerment. That confidence had an impact on decision making.

Participant IP-5: “reading all the studies that generally people’s hemoglobin A1Cs come down, weight was better managed...those are some key ones, you know. The kind of confidence […] of knowing that I was on the machine that was having great results with other people.[…]. Having the confidence that I was on the best course of action, that was seeing the best results, you know…”

The role of the support structure was vital in both groups, emphasizing the importance of an available support network at the early stages of adoption. This particular discovery cannot be controlled beyond the care team. However, the care team appears to be vital in instilling confidence when a patient first takes the pump home. IP-4 discussed how useful her diabetes nurse had been her first few days on the pump:

Participant IP-4: “Yeah, the first night…I needed a lot of support. Not technical support but just like talking about it […] I needed support. Maybe if I had been left with the device I think I would have figured it out but I'm sure glad I wasn't. It was a big deal. It was a big deal to do that”

Emphasizing and strengthening this structure may lower burden of care at early stages of adoption. Though participant IP-3, mentioned that he was able to figure out the pump on his own, there is the possibility that having a care team supporter might have had a more positive impact early on.

Participant IP-3: “I had to do it on my own. I mean, I was teaching the nurse how to use the pump when I did that training so I knew it wouldn’t be too hard to do on my own. But, I would still have to work.”

5.4.4 Behavioural Readjustment: A substantial readjustment is necessary for success early on

Every participant in both the user and non-user groups described or predicted behavioural changes, respectively, associated with adopting the insulin pump. A number of changes mentioned were expected and have been described in the literature: the increase in flexibility in
daily life due to the convenience of the technology, the perceived increase in “control” and feeling of independence. What participants alluded to the most (in both patient groups) was the notion that the pump could be adjusted to fit their lifestyle, rather than the reverse.

Two of the six participants from the IP user group discussed the behavioural shift they underwent when started on the pump. They had predicted the device to be a “miracle cure”. These participants described changing their attitudes from more passive to proactive when they realized the pump alone would not allow them to achieve better “control”. They described the initial disappointment they faced when they didn’t see immediate improvement on the pump.

Participant IP-5: “It took…it did take an emotional toll. I was a bit disappointed when those things didn’t happen for me [weight loss and improved A1c]. I struggled to get my A1cs down, they were kind of hovering in the 8s. It’s only my last hemoglobin A1c do I feel a level of success that it’s down to 7.6.”

(This participant had been on the pump for 7 years by the time this interview was conducted).

A “forced” behavioural change, preparedness and a greater sense of accountability, was mentioned by a number of insulin pump users and the majority of MDI patients. Participants chronicled expectations of how their lives would change if on the insulin pump because of this forced behavioural change. These included getting dressed, to organizing their day, to picking activities on the weekend like going to theme parks. This need to develop foresight was most described as “hindersome”.

Participant IP-1: “You kind of have to be mentally prepared for different situations that can arise […]. If you're on injections you're not going to have that problem. So, I think the preparedness…it's not really a disadvantage but it's kind of hindersome [sic i.e. a hindrance] to have to carry a little more, have to think a little bit more depending on what you're doing. […] I didn't think about that beforehand.”

Two IP users mentioned negative habits associated with adopting the insulin pump. One participant discussed what he referred to as too great a reliance on the insulin pump. He had come to rely on the pump for alarms, safety checks and warning and no longer brought extra
supplies or batteries when he left home. This perception of negative habit forming was shared by another participant (IP-3) who has become less active on the pump as described below:

Participant IP-3: “Sometimes, I can be lazy on the pump. I know that sounds bad! But, if I was on injections I might not be as lazy. When I would eat something or do something, I would get up and get my insulin but now on the pump, I don’t really have to do that so I’m a bit lazier I guess.”

5.4.5 Examination of Demographics

A number of studies have attempted to make connections between perceptions and level of education. As mentioned above, a post-test questionnaire was distributed to gather information such as level of education, annual household income, profession, perceived comfort with technology and most recent A1c. This questionnaire was distributed months after the study was conducted and therefore fewer responses were collected than the number of participants (See Appendix H). However, some conclusions can be made.

There was no concrete evidence that level of education impacted the decision to adopt an insulin pump since both groups of patients interviewed (insulin pump users and non-users) were both highly educated.

Participants who responded that they were “very comfortable with technology” were insulin pump users. Non-users were split between “comfortable with technology” and “somewhat comfortable”. Comfortable meant the participant used a computer at home and had a smart phone for example. Being somewhat comfortable meant the participant used a computer at work only for example. This is consistent with the literature which shows that more tech-savvy people are likely to adopt new technologies related to diabetes management [32].

Household income was varied within each participant group (users and non-users). However, the highest incomes reported were IP users.

There was no real consensus regarding profession. There was no indication that one profession might influence IP adoption over another.
The HbA1c levels were varied in each group. The highest levels were reported predominantly by non-users though there was one IP user with a high HbA1c level. In the literature, studies have shown that patients who are less controlled are less likely to adopt the pump [53]. Though the results are not decisive in this case, this trend was observed among participants interviewed.

5.5 Study Limitations

One-on-one interviews were conducted over the phone so that insulin pumps were described and not visualized which may have also led to different perceptions.

Of note in the demographics collected was the “median years since diagnosis”. Though the two patient populations interviewed had very similar distribution in age groups, the years since diagnosis in the MDI group was greater than those of the IP group. We hypothesize that it’s likely a patient who does not adopt diabetes technologies early into their diagnosis is less likely to adopt later.

5.6 Summary

As described above, twelve semi-structured interviews were conducted with both users and non-users of insulin pump technology. The purpose of this phase was to identify patient perceptions of insulin pumps. The open-ended interview questions were based on two theoretical models: the Health Belief Model and the Technology Acceptance Model. Four themes that transcended both patient populations (users and non-users of pump) were identified. These themes reflected perceived usefulness in terms of quality and relevance and perceived ease of use related to self-efficacy and anxiety in agreement with the Technology Acceptance Model. Each modifying factor associated with individual perceptions of the seriousness of diabetes was identified (including perceived threat of the disease, symptoms, personality, and knowledge) and encouraged or discouraged likelihood of action (perceived benefits vs. barriers) in agreement with the Health Belief Model. These themes included:

1. Lack of “Value – Add”: insulin pump adoption may not add value to diabetes therapy

2. Psychosocial impact: perception of self and others may affect adoption

3. Lack of Support structure: without one, initial stages of adoption can be challenging
4. Behavioural readjustment: a substantial readjustment is necessary for success early on

The most prominent study limitation was that interviews were conducted over the phone, rather than in person, which meant that references to the pump itself were described as best as possible, rather than pointed out directly on the device.
6 CGM Perceptions Study

The following chapter will describe the CGM perceptions study in detail including the objectives, methodology, data collection, analysis and discussion. The study limitations are also described at the end of the section.

6.1 Objectives

The goal of this phase was to examine patient perceptions of utility and usability of CGM. These could be examined based on the voiced experience of CGM users and the knowledge of non-CGM users. This phase was structured similarly to the insulin pump semi-structured interview phase described in Chapter 5 above. This phase involved conducting semi-structured interviews with adult T1DM patients in order to identify barriers to the adoption and use of CGM.

6.2 Setting

Interviews for this phase were conducted either over the phone or in person at the participant’s request. Prior to the interview date, a consent form was sent to each participant via email. Participants were asked to give consent over the phone or in person before the beginning of the interview. Once consent was received, two audio recording methods were used.

6.3 Methodology

In order to amass a large scope of perceived barriers and benefits of continuous glucose monitoring technology, two types of patients were recruited: the first group included patients currently using the technology; while the second group had considered adopting the technology previously, but ultimately rejected it. This semi-structured interview phase’s design and results will be described below.

6.3.1 Use of Theoretical Frameworks to Generate Open-Ended Interview Questions

In the interview, questions were based on the Health Belief Model and the Technology Acceptance Model and were exploratory in nature (open-ended questions). The interview guide was a variation on that used in the first phase of this study (Please see Appendix I).
6.3.2 Participants

Potential participants for the study were identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants were sent a personal invitation. After initial contact was made by the TGHDC, participants were contacted by the study coordinator via telephone. At this time, participants were provided with a detailed description of the study that included the information necessary for the participant to give informed consent.

Potential participants had to be adults (over 18 years of age) with T1DM in order to be included in the study. They also had to be able to read, write and speak English and be willing to participate. Potential participants were asked to participate on a voluntary basis only.

The total number of participants was twelve. Participants were recruited continuously until response saturation was achieved: six individuals in each group, half currently using an insulin pump and the other six contemplating adopting (or who had previously contemplated and rejected) an insulin pump. This allowed the research team to catalogue a wide range of barriers and benefits to the adoption of insulin pumps.

Participants varied in age and duration on the CGM which allowed for broad perspectives on the topic of barriers to adoption and use of the medical technologies

6.3.2.1 CGM User Participants

Full demographic information collected from participants in the pre-test questionnaire can be found in Appendix L.

- The CGM users ranged from ages 18-64 years.
- There were four male participants and two females.
- Four participants were using the CGM full time, consistently, while two were using it part-time.
- Four of the six participants at the time of their interviews, were using the Medtronic CGM, though 2 of these participants mentioned they were transitioning to the Dexcom CGM. At the time of the interview, two participants were using the Dexcom CGM. The Dexcom CGM was released in Canada in September of 2013.
- The median years since diagnosis of type 1 diabetes was 16.5 years.
• The median years since insulin pump adoption was 5.5 years.
• Median years since adoption of the CGM was 4 years.

6.3.2.2 Non-CGM User Participants

Full demographic information collected from participants in the pre-test questionnaire can be found in Appendix L.

• The non-CGM users ranged from ages 18-59 years.
• There were three male participants and three females.
• Two of the participants were on multiple daily injection therapy (non-pump users), while 4 participants were insulin pump users.
• Their median years since diagnosis of diabetes was 15 years.
• Of the insulin pump users, their median years since adoption of the insulin pump was 7.75 years.

6.3.3 Procedure

The study consisted of three stages, described below. The complete testing script and protocol can be found in Appendix I and J, respectively.

1. Introduction to study

Participants were oriented to the study and its purpose. Verbal consent was obtained (see Appendix K for consent form).

2. Pre-test questionnaire

A pre-interview questionnaire was posed to each participant in order to gauge their experience with CGM, as well as to amass demographic information to ensure all inclusion criteria was being respected (Appendix L).

3. Interview
Participants were asked the semi-structured interview questions. The study investigator took notes and employed two methods for recording the audio. Any participant questions were answered by the study investigator and the details of their compensation were finalized.

6.3.4 Data Collection

The two audio recordings allowed the investigator to send an audio file to a transcriptionist for future data analysis purposes. As mentioned above, a pre-test questionnaire was posed to participants to collect basic demographic information.

Following the conclusion of the study, the study investigator felt further demographic information could shed more light on the study results. Five additional questions were sent to participants via an electronic survey regarding educational level, comfort with technology and diabetes health (most recent HbA1c).

6.3.5 Data Analysis

Audio recordings of interviews were transcribed and analyzed in the same way as the previous insulin pump semi-structured interview phase. The method employed was a general inductive method where interview transcripts and notes were reviewed repeatedly and text segments were coded for potential themes. As the coding framework was developed, recorded notes were be reanalyzed in light of new themes that may have emerged.

6.3.5.1 Reliability

The use of more than one analyst was necessary since one analyst’s research bias may be perceived as affecting consistency and reliability of data. A second master’s student conducted data analysis on of the interview transcripts. The two reviewers were in good agreement regarding themes emerging from the transcripts. The reviewers worked separately, and then came together to discuss the findings. Any discrepancies were discussed and resolved until consensus was reached. An example of this iterative process is shown in Figure 6.
6.4 Results and Discussion

Based on the analysis performed with the two reviewers, three themes were identified. The nomenclature used is as follows:

- NCGM -#: non-CGM user participant#
- CGM-#: CGM user participant#

6.4.1 “Use” Frustrations

When all twelve participants were asked about their experience with CGM, advantages/disadvantages and what they were least confident about (or expected to be least confident about) when taking the CGM home for the first time, their responses were overwhelmingly consistent and pointed to the theme “use frustration”. Frustration was related to accuracy and reliability of the CGM. Along that vein, alarm fatigue was eluded to several times (both in CGM users’ and non-users’ interviews), tied to frustration with the technology. An example follows:

Participant CGM-5: “Like if you have alarms going off and you are used to shutting them off because they aren’t meaningful what happens when an alarm goes off and it is meaningful
they aren’t differentiating between the important ones and the ones that are “oh gee wiz isn’t that great technology”. And the important stuff gets caught up in the “oh gee wiz” stuff. So all of these alarm capabilities these things have, to a great extent, conditions people to ignore alarms.”

Most CGM users discussed the improvements associated with Medtronic’s change to soft sensors and the increased accuracy that accompanied that change. However, participants still experienced significant frustration especially related to accuracy. The calibration process as well as the need for calibration was noted as a hindrance and when often inaccurate, decreased the participant’s trust in the technology. This challenged the perceived reliability of the device. The calibration and task of interpreting when the data was accurate was deemed complicated, with considerable room for improvement. Participants said the following:

Participant CGM-1: “It was nuts. It was mainly the mechanics. And the calibration: don’t calibrate if it’s going up or down. But I don’t remember anybody ever telling me to look for the points that don’t make sense.”

Participant CGM-2 referred to the calibration process and inaccuracies that accompanied it as the most frustrating element to CGM technology.

Participant CGM-2: “And I didn’t think it was quite working properly. Sometimes my glucose meter would be way different from the CGM so that kind of thing. The calibration. [...] I hated it.”

Participant CGM-4: “When you calibrate more often it’s much more inaccurate and it starts like getting confused and it gives you wrong readings and I didn’t really know... what to get for an accurate number. [...] it’s frustrating... I was a little confused with it.”

Participant CGM-5 discussed the impact that “inaccurate alarms” have had on his daily life. This participant was currently making the switch from the Medtronic to the Dexcom CGM at the time of the interview. The Dexcom CGM does not allow for all alarms to be suspended (a “master alarm override”) over a period of time, however this functionality exists on the Medtronic. For this user, the “master override” was vital at nighttime since alarms disturb his wife. However, this missing feature was not enough to deter him from adopting the new CGM, he said:
Participant CGM-5: “I don’t know, I mean I’m going to be sleeping on the couch a lot. […] That’s a pretty serious lifestyle thing that doesn’t look to me like they dealt with very well. I think they need to pay a lot more attention to how the users use this, and the effect it has on their lives. Not from a diabetes point of view, but from a dealing-with-everything else point of view. Like a human behavior kind of view.”

6.4.2 CGM data promotes “power”

Despite the challenges mentioned above, the CGM was considered very useful in better understanding a patient’s physiology and allowed the users to better manage their diabetes. This perception of the technology was shared by non-users who expected to see improved “control” and A1c levels if they were to adopt the CGM. The notion of reducing variability was vocalized by all 12 participants.

Participant CGM-1: “The metaphor I always use is if you want me to control the temperature of a room, and you are going to tell me 4 times per day every day, that’s not a lot of information. At least give me a thermometer, and that’s what CGM is. It tells you where it’s heading and gives you context to figure out what it’s doing and what to do now or later on how to set up your pump or your life differently.”

The CGM users discussed the emotional and psychological effect that the CGM has had on them. The data, the ability to interpret the data and to make changes to their management on a daily basis has allowed the participants the freedom to live as if they don’t have diabetes, which was described as “life changing”.

Participant CGM-3: I mean I’m not as controlled and someone who doesn’t have type 1 diabetes so…CGM helps me get there for sure.

Participant CGM-1: My new mantra is live your life as if you didn’t have diabetes. […] It was the ability to live as I don’t have diabetes. It means freedom and keeping A1c below 7, a healthy A1C really, and minimizing fear of long term complications.

Participant CGM-6: “And so these are things you can’t see without it. It’s just more information is more power. And that’s the other thing: I thought I was always high but when I put on the
CGM I was seeing low, then high for a long time, then low and then high for a long time. I would have never known that was happening if I didn’t have a CGM.”

The ability to be proactive and the CGM’s ability to facilitate action were described as other advantages of using a CGM as said by participant NGM-1:

Participant NGM-1: “No, I mean any extra information you can see and that’s accessible will lead to tighter control. Like, I used to hate filling out log books, hated it – so much work. I mean, I didn’t really see. When I looked at it, it was just a bunch of numbers. […] Being able to upload the information and being able to see if things are trending up or down, your highs, lows, how many values above or below targets put together on one page. It’s so much easier to understand and if it’s easier to understand, you can react better.”

Participant NGM-1: I’ve noticed a change from checking [my blood sugar] 4 times a day to 12 so obviously if it was being checked continuously…that would probably increase your control even more.”

Increased confidence that the user was managing their diabetes as best they could was also mentioned. Peace of mind was another way participants described what the CGM offered. These perceptions were shared by both users and non-users of CGM.

Data overload was reported by Ritholz, et.al [32] where patients interviewed had reported that the large amount of retrospective data available was overwhelming. This was not a notion shared by the patients interviewed in this phase. Though patients did mention there was a large amount of data, it was described in a positive context rather than described as a burden. The necessity of all the information to a patient was called into question, though there was seemingly no doubt that the amount of information was appropriate for their physician.

6.4.3 Cost/Benefit ratio: Cost benefit analysis substantial barrier to adoption

The cost of the device seemed to outweigh any other disadvantages of the technology mentioned, such as the device’s unreliability, and the physical burden that came with a second insertion site. Some private insurance plans cover the cost of the pump, while others don’t. Half the CGM
users interviewed were paying out-of-pocket for the CGM. Those participants discussed the “horrendous” cost of CGM, but considered it a priority, such as participant CGM-1.

*Participant CGM-1:* “I was excited about it but really bothered by the cost. My wife and I have both chosen to work for ourselves so we have no insurance and we’ve had to fund our medical expenses and our retirement. But since then my attitude just changed. This is what we’re saving our money for after all. The way I think of money is that everything’s a priority. You spend your money where you want to.”

However, though this perspective was shared by all CGM participants who paid out of pocket for CGM, the participant demographics have to be considered. This study was presented to all patients at the Toronto General Hospital (now Samuel Lunenfeld Research Institute) diabetes clinic, who met the inclusion criteria, and who were interested in participating in this research study, during the period of January 2014-February 2014. During recruitment, as mentioned above, education level or occupation information was not collected. Those interested were engineers, financiers working in the technology sector or researchers at hospitals in Toronto (this information was shared during the interviews). This particular group has completed post-secondary education and is perhaps more likely to be able to afford the technology. Therefore, we can hypothesize that a certain demographic of people are more likely to adopt this technology than others (“tech-savvy” patients working in the diabetes/technology sector) and therefore offer different perspectives than those who do not. Education level and occupation and their effect on perceptions of CGM was beyond the original scope of this research project. However, the study investigator believed it warranted mention.

For the non-CGM users, the greatest concern was that if the CGM did not function as intended, money would be wasted. This was perhaps best vocalized by participant NCGM-4:

_Q: “What did you think would be difficult for you if you were to start using CGM?”_

*Participant NCGM-4:* “Making sure that I did it without screwing it up. Like I say, it’s so expensive, over 50 dollars apiece and if you screw it up, you throw out money. That would probably be the one thing, the biggest. They told me how much it was, oh my god I said.”
This reaction was shared among non-CGM users who had contemplated adopting the technology, with all participants saying what participant NCGM-3 vocalized:

*Participant NCGM-3*: “I’ve asked questions about it [...] I was thinking about it, but it’s just too expensive. It’s just out of my budget.”

One participant’s story stood out when discussing the cost/benefit analysis that she had to undertake and realized she needed a CGM. This participant was able to pay for the device by lobbying friends and colleagues for help through gofundme.com, a website where donations can be made for causes such as this.

*Participant CGM-6*: “I absolutely hate, hate that no one is willing to cover this. Like why are you willing to cover my amputations, and my hospitalization, which is $5000 every time I end up in the ER but you are not willing to pay for the thing that will prevent that. Like it makes no sense. [...]”

### 6.4.4 Examination of Demographics

As mentioned above, a post-test questionnaire was distributed to gather information such as level of education, annual household income, profession, perceived comfort with technology and most recent HbA1c (a measure of diabetes health). This questionnaire was distributed months after the study was conducted and therefore fewer responses were collected than the number of participants (See Appendix L). However, some conclusions can be made.

There was no concrete evidence that level of education impacted the decision to adopt an insulin pump since both groups of patients interviewed (insulin pump users and non-users) were both highly educated. In fact, the lowest level of education that was reported by a participant was a CGM user.

All participants who completed this particular survey reported being either “very comfortable with technology” or “comfortable with technology” The CGM users’ answers did not reflect a greater comfort with technology than non users. This is perhaps not surprising as most the non-CGM users who participants in the survey were insulin pump users.
Household income was varied within each participant group (users and non-users). However, the highest incomes reported were CGM users.

There was no real consensus regarding profession. Of the CGM users who completed the survey, one was an engineer, another a statistician working in a hospital, another a nursing student. Of the non-CGM users, there was a project manager, a tech assistant and someone who worked in logistics. There was no obvious distinction between the two groups’ professions.

The HbA1c levels were varied in each group. The highest HbA1c level was reported by a non-user.

6.5 Study Limitations

A limitation of this study was that some of the interviews were conducted in person while others were conducted over the phone, at the request of the participant scheduling around working hours. The interviews that were conducted in person were mostly CGM users (though there was one non-user who interviewed in person). The inconsistency in medium in which the interview was conducted could have altered the interpretation of perceptions as per the way they were conveyed since participants may have been more or less comfortable conducting the interview in a certain fashion (phone vs. in person).

6.6 Summary

As described above, twelve semi-structured interviews were conducted with both users and non-users of continuous glucose monitor technology. The open-ended interview questions were based on two theoretical models: the Health Belief Model (HBM) and the Technology Acceptance Model (TAM). Three themes that transcended both patient populations (users and non-users of pump) were identified. These themes were consistent with the theoretical models as issues of self-efficacy (TAM), intrinsic motivation (TAM) and perception of severity/susceptibility were identified (HBM). In addition, through the identification of “use” frustrations, users alluded to issues of trust in the technology, specifically associated with the calibration process, consistent with the Technology Acceptance Model. The specific themes identified included:
1. “Use” frustrations

2. CGM data promoted “power”

3. Cost/Benefit: Cost benefit analysis substantial barrier to adoption.

There were limitations in this study, one of which was the inconsistent media over which the interviewers were conducted (in person vs. phone interview).
7 Insulin Pump Usability Study

Four of the five insulin pumps included in this study are available to Canadians consumers. They include: the Omnipod by Insulet Corporation (GlaxoSmithKline), Accu-check by Roche, OneTouch Ping by Animas (Johnson & Johnson) and the MiniMed Paradigm Veo by Medtronic. Another pump by Tandem will be entering the market soon; it is currently only available in the USA. Its inclusion in this research study stemmed from the fact that its design is quite different from the four mentioned above which share similar design features. Therefore, the inclusion of the Tandem pump would provide a different perspective for analysis. A description of each pump is included in Appendix M.

7.1 Objectives

The goal of this phase was to test the usability, usefulness and ease of use of five insulin pumps in the Human Factors lab within the Centre for Global eHealth Innovation at UHN. The results from this phase allowed the research group to identify best practices in pump design and contribute to alternations in how training is delivered.

7.2 Methodology

In order to gather unbiased perceptions of insulin pump technology, non-pump users were recruited for this phase of the study. This phase’s design will be described below.

7.2.1 Experiment Design

Each participant included in the study interacted with three of the five insulin pumps due to time restrictions. Training on five pumps and testing multiple task-based scenarios on five pumps would require too much time from participants and was expected to decrease participant interest. Furthermore, participant fatigue would be likely following an extended session, which would likely affect any subsequent results. Training and testing on three pumps took approximately 2 hours.

7.2.1.1 Counterbalance

A counterbalanced pump testing order was created for a number of reasons. First, the counterbalanced order was created to ensure that each pump would be tested between 5 and 7
times. This is considered the point of theoretical saturation in a qualitative study. In this study, each pump was tested 6 times. Second, in order to ensure that no bias would lie in the order in which the pumps were testing. A degree of “learnability” is expected once a participant completes testing on one or two pumps and therefore the third pump could not always been the same one. Thirdly, the counterbalance would ensure the choice and order of pumps in each session was controlled. The importance of counterbalancing for validity in qualitative research has been widely published [102-104]. A sample size of 10 participants was determined to be appropriate (Appendix N).

7.2.1.2 Choice of Scenarios

The scenarios or tasks for the study were written by the study investigator and edited by a diabetes nurse educator over multiple iterations. This was to ensure their accuracy and appropriateness for the simulation. The tasks chosen were specific for the participant population being tested. The participants recruited were non-pump users and therefore asked to perform tasks on concepts (and their corresponding features) that were familiar to them such as “carb counting” and bolusing. Concepts such as setting up basal rates for example were not included since it was believed that educating participants on basal rates was deemed too large a task to undertake in 2 hours.

7.2.1.3 Training

The training script was developed based on the training that is conducted by nurses at the Toronto General Hospital Diabetes Clinic (TGHDC). A nurse from the TGHDC and also a member of the study team trained the investigator on the insulin pumps the way patients are trained one-on-one at the TGHDC. The curriculum was noted as well as specific verbal phrases that complemented explanations. The training script followed a chronology representative of what a user would encounter had they just received the pump for the first time. Pump setup was the first objective which included time and date settings, followed by bolus setup. More specialized or advanced features were introduced near the end of the training once the basics of pump technology had been covered.

The TGHDC training curriculum was utilized for the usability testing sessions of this study, though adapted due to time constraints. Questions were indirectly discouraged for experimental
control by asking the participants to hold their questions until the end of the session. The training script can be found in Appendix O. The training script for each of the five pumps was designed to be of equal length. This was to discourage any bias as a result of longer training: the longer the training, the more familiar a participant might become with a pump, making them less likely to err compared to another who participated in a shorter training session.

However, because of inherent pump design, certain models took more time to explain to new users. For example, explaining the Roche pump menus took more time than any other pump as each menu is displayed on a separate screen rather than listed on one screen.

7.2.2 Location

The experiment was conducted at the human factors lab within the Centre for Global eHealth Innovation, Toronto General Hospital, which was mocked up to recreate a typical office or home setting where a patient might be using their pump (for complete participant immersion in the scenario). Patients were observed through one-way glass and overhead cameras.

The facilitator was present in the room with the participant in order to conduct training on each of the three insulin pumps with which the participant was interacting. The facilitator took notes during the study. The participant was left alone when completing surveys.

Study location photos can be seen in Appendix P.

7.2.3 Participants

Potential participants had to be adults (over 18 years of age) with T1DM and currently using multiple daily insulin injections to manage their diabetes (i.e. no insulin pump), in order to be included in the study. Participants on MDI were recruited in order to better observe first impressions and interactions with the devices during usability testing. They were required to be able to read, write and speak English and willing to participate. Potential participants were asked to participate on a voluntary basis only.

The total number of participants was 10 based on the necessary counterbalance. The participant demographic information is as follows:

- The participants ranged from ages 18-59 years
• There were four male participants and six females
• The median years since diagnosis of type 1 diabetes was 9 years
• The majority of participants were “somewhat familiar” with the insulin pump for reasons such as: attendance at diabetes camp, attendance at pump information sessions, sibling owns an insulin pump. The rest of the participants were unfamiliar with the insulin pump.

7.2.4 Procedure

The study procedure consisted of four stages, described below. The training scripts, protocol and complete testing script can be found in Appendix O, Q and R, respectively.

1. Introduction to the study and the lab

Participants were oriented to the simulated office/home environment and written consent was obtained (Appendix Q). The participant then completed a background questionnaire to gauge their experience with insulin pumps (Appendix S).

2. Training

Each participant received training on each pump before they were asked to complete the task-based scenarios. Training scripts can be found in Appendix O.

3. Completion of Scenarios

Participants were asked to complete the scenarios. Participants were informed that if they had questions, they should feel free to ask them, though the investigator may not answer. Any questions related to the use of the pump would be answered once the scenarios were complete.

Stages 2 and 3 were repeated three times during each session with each participant. As mentioned above, each participant tested three of the five pumps being evaluated in the study.

The study investigator remained, unobtrusively in the room taking notes. A second note-taker sat behind a one-way mirror.

4. Post experimental questionnaire
Participants completed a final questionnaire (Appendix T), and any remaining questions were answered and the details of their compensation were finalized.

7.2.5 Data Collection

In addition to the two sets of notes being taken, both by the investigator and a second master’s student, usability sessions were also fully audio-and video-recorded for further analysis. The second master’s study helped facilitate the video recording throughout the experiment. If any proceeding was unclear, the investigator was able to consult the video recording or the notes that were taken during the session.

As mentioned above, a pre-test questionnaire was posed to participants to collect basic demographic information.

A post-test questionnaire was also distributed to participants in order to gather their subjective feedback.

Following the conclusion of the study, the study investigator felt further demographic information could shed more light on the study results. Five additional questions were sent to participants via an electronic survey regarding educational level, comfort with technology and diabetes health (most recent HbA1c). Results can be found in Appendix T.

7.2.5.1 Error Rating

The data emerging from usability testing was used for qualitative analysis and not quantitative. Errors that are committed during testing were categorized based on severity: high, moderate or low. High severity errors refer to high priority issues that would likely impact patient safety. A moderate error refers to an issue that would have little or no impact on patient safety and a low priority issue would result in user frustration or inefficiencies but would not impact patient safety.

7.2.5.2 Deviations

In order to assess the efficiency and the ease of use, the investigators looked for “deviations”. Deviations are defined as situations where the participant takes actions that do not lead to the goal of correctly completing the task on the insulin pump. This could mean pressing the wrong
button or entering the wrong parameters. Deviations serve as indicators of inefficiency because it is possible that the participant does not understand the programming process and is therefore deviating from the prescribed task. It is important to note that it is possible that the participant can deviate numerous times and spend time on irrelevant actions but completes the task with 100% accuracy.

However, if the pump is incorrectly programmed, deviations may have occurred. Incorrect actions such as putting in the wrong parameters are considered a deviation.

### 7.2.5.3 Post-test Questionnaire

The NASA-TLX was considered for use at the conclusion of usability testing tasks. This scale, which stands for the NASA Task Load Index, is a subjective assessment tool that allows study investigators to better understand participant perceived workload when performing tasks [105]. It is divided into two parts: 1) the scales and 2) the analysis.

The workload is divided into six subscales: mental demand, physical demand, temporal demand, performance, effort and frustration. Participants are expected to read descriptions of each subscale before completing the rating of each task performed. Each rating has a 100-point range, with 5 point steps.

The analysis, or second portion of the TLX involves participants adding weight to the subscales. Participants would be asked to choose which measurement is most relevant to their perception of workload. Based on those weights, and the scales, the overall task index load could be determined. The weighting process is often eliminated and the subscales analyzed on their own. This has become increasingly popular, as the index is easier to apply, easier to average and creates a sufficient estimate of overall workload [106-108].

The concepts of the index influenced in the development of the post-test questionnaire for the usability study. A number of questions reflect the six subscales described in the tool. The tool was not explicitly utilized, as it has been in at least 550 studies because it would require feedback after each pump [105]. Due to time constraints (participants recruited for 2 hours at the Human Factors Labs), such a questionnaire could not be distributed multiple times during the study.
period. The post-test questionnaire that was distributed was done so at the conclusion of the study session to gauge overall perception of usefulness, ease of use and workload.

7.2.5.4 Inter-rater reliability

To determine inter-rater reliability, a second rater reviewed recordings of each of the five insulin pumps being tested by one participant each, and collected data on use errors and deviations. The second rater also ranked the errors based on severity: high, moderate or low depending on the error’s likelihood to cause a patient safety risk, as described above.

7.2.6 Data Analysis

Notes and video footage were consulted in order to identify the usability issues in each session with each pump. Deviations in each task were also noted in each session. Finally, the severity of each issue was ranked. The details of how the usability data was analyzed are described in detail below.

7.2.6.1 Inter-rater Reliability

In usability testing, a second reviewer was used. The two evaluators independently assessed the errors, rated the severity according to the definitions mentioned above and tabulated the number of deviations once for each pump being evaluated. Agreement (inter-reliability) between the investigator and the second rater (two evaluators) will be measured.

An important distinction must be made regarding interrater agreement and interrater reliability. Interrater agreement represents consistent decisions and findings being made between the two raters or reviewers. Interrater reliability differs in that it is used to assess the degree to which different raters make consistent estimates of the same theme or phenomena. In the case of reliability, it is not necessary for reviewers to share the same interpretation as long as each reviewer is consistent in classifying their own findings.

There are a number of ways in which interrater reliability can be crudely measured [109]. However, the best estimate of reliability between the same two reviewers can be found through calculation of Cohen’s kappa which ranges from 0 to 1. The use of Cohen’s kappa involves the derivation of quantitative grading and statistical analysis from qualitative data. This scale (from
0 to 1) represents proportion of agreement corrected for chance [109, 110]. For Cohen’s kappa, 0 .5 on the scale is considered acceptable [109]. If reliability measures are low, additional training of raters can lead to better attenuation of results.

However, in this study, Fleiss’ kappa was also used; a statistical measure very similar to Cohen’s kappa. Fleiss’ kappa measures reliability of agreement between a fixed number of raters when assigning categorical ratings or for classifying items. Since reviewers will be assigning severity ratings to categories, this measure was also used.

Training raters to come to an exact consensus requires considerable time that may or may not be necessary for a particular study. The raters can also participate in an iterative process of revision and clarification if agreement is low. There is evidence that changing the coding procedure can increase initial intercoder reliability [111]. It is expected that initial review by multiple reviewers will generate low levels of agreement [112 -114]. The conclusion of these findings is that studies should not stop at the first round of review, instead undergoing multiple iterations to generate acceptable agreement between reviewers.

There is considerable disagreement in the literature regarding whether qualitative research should be rejected on the basis of low reliability between reviewers since “different researches would be expected to offer different accounts of reality itself” [115-117]. Interrater reliability in qualitative research remains contested [116,118]. In a study performed by Armstrong et.al, [115], six analysts were asked to identify themes from a focus group interview transcript. The study team’s goal was to determine whether researchers should be expected to identify the same themes in a transcript or whether they should be expected to produce different accounts. This study was performed to “clarify the nature of the debate” [115]. The study results showed that each reviewer identified similar themes that were described and “packaged” differently. The analysts labeled each theme differently. Each theme was contextualized to make it coherent by each analyst and the study team attempted to make links between their respective conclusions. Armstrong et.al [115] found that there was consensus in identification of the themes despite the fact that they were labelled different. Therefore, it is expected in this research study that reviewers will lend unique accounts and interpretations to the findings. However, the study
investigator will look for concordance at a basic level since results that are extracted have already been “contaminated by the researchers” [115].

In this study, the reviewers did not require an iterative process of revision as there was substantial agreement after the first revision. This will be described further below.

7.3 Results

The results of the usability study will be described below, including both the deficiencies in safety and efficiency that exists in all five pumps from a human factor’s perspective.

7.3.1 Length of Training

Each training session for each pump was based on the protocols of training delivered at the Toronto General Hospital Diabetes Clinic to new users. The training session was shortened to fit the usability test session time limitations. Variations existed in duration of training often due to participants attempting to ask questions. The investigator encouraged the participants to hold their questions until after the session. Variation in training duration was also based on pump design since certain concepts required more time to explain. The training specifics are described below:

- The average length of Medtronic pump training was 6:43 (min:sec) with a maximum training time of 8:55 and a minimum of 5:02.
- The average length of Animas pump training was 7:12 (min:sec) with a maximum of 8:19 and a minimum 6:02
- The average length of Insulet pump training was 7 (min) with a maximum of 8:21 and a minimum of 5:29
- The average length of Roche pump training was 9:06 (min:sec) with a maximum of 11:06 and a minimum of 6:37
- The average length of Tandem pump training was 6:10 (min:sec) with a maximum of 7:13 and a minimum of 5:27
7.3.2 Usability Test Results: Severity Rankings

The list of usability problems and their hypothesized root causes were combined by the investigator. The two evaluations (the investigator and a second reviewer) independently assessed the validity of each usability issue and rated its severity according to the definitions listed in Table 3.

Table 3: Severity rating definitions for usability study data analysis

<table>
<thead>
<tr>
<th>Severity</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Indicates a high priority issue that will likely have a major impact on patient safety if left unaddressed</td>
</tr>
<tr>
<td>Medium</td>
<td>Indicates a medium priority issue that may contribute to use errors that may have little or no impact on patient safety if left unaddressed</td>
</tr>
<tr>
<td>Low</td>
<td>Indicates a low priority issue that could result in user frustrations or inefficiencies if not addressed</td>
</tr>
</tbody>
</table>

7.3.2.1 Medtronic Pump: Classification of usability issues by severity rating

Figure 7 summarizes the severity of the issues found in the Medtronic insulin pump system. During the evaluation process, the two human factors experts had disagreements on one of the severity ratings. The reviewers deliberated until there was a complete agreement. Most of the usability issues were classified as low severity issues and thus have no impact on patient safety. However, six usability issues were found to be of high severity, indicated the potential to have a major impact on patient safety. As such, recommendations to the manufacturer and for training were developed for each of the high severity issues in order to mitigate the risks of potential consequences. The complete list of high severity issues, their frequency, their potential consequences as well as the recommendations that were developed, can be found in Appendix U.
The list of moderate and low severity errors can also be found in Appendix U. The next section will highlight some of the high severity issues and briefly summarize the moderate and low severity issues identified.

**Figure 7: Severity ratings for Medtronic pump portion of usability study**

### 7.3.2.1.1 Examples of High Severity Issues

**Example #1**

**Usability Issue:** In scenario 4, participants were asked to suspend a bolus dose that they had been previously instructed to program. When faced with the “suspend” option on the main menu, it is not immediately apparent what is being suspended i.e. the basal dosage or the bolus.
dosage. Five out of 6 participants suspended the basal dosage as the bolus dose had already been delivered in its entirety. When participants were asked to confirm what they had suspended, all answered that it was the bolus. When prompted to resume the basal dosage, participants were confused and realized the error. Suspending a basal dose rather than a bolus can pose significant patient safety risk, as it would result in completely halting all insulin delivery. Suspending bolus delivery leaves the underlying basal delivery intact.

**Recommendations for manufacturer:** Participants had no trouble locating the suspend option. However, when the option was chosen, a confirmation message was displayed, asking participants to confirm suspension. It is likely that participants did not read the entirety of the message, instead focusing on completing the task. Therefore, the confirmation message could be redesigned, with the typeface emphasizing what is being suspended. Ideally, there would be two suspend options: one to suspend the bolus and one for the basal. If clearly marked, this would likely eliminate the risk associated with the current design.

**Recommendations for training:** In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. However, trainers can emphasize the distinction between basal and bolus rate suspension. Trainers should also highlight the importance of the error messages and ensure participants understand what is being conveyed. A number of participants were unsure of the meaning of the “Resume” message and told the study investigator that they would call the manufacturer for an explanation in a case such as this.

**Example #2**
Usability Issue: Participants were asked in scenario 5 to program a square wave bolus of 6 units of insulin over 5 hours. Two of the six participants programmed the extended bolus but were not confident they had done it correctly. They had both expected to see a confirmation message, but saw none. They expressed an interest in rechecking their work but were unable to do so because the device does not allow for it. Both participants said they were uncomfortable with being unable to recheck. They said in a real situation, they would stop their pump completely or call the manufacturer as they didn’t want to receive what could have been an incorrect dosage. One of the two participants had programmed it incorrectly since she had left the default time parameter of 30 minutes rather than changing it to 5 hours.

Recommendations for manufacturer: An additional confirmation screen should be presented once all parameters have been individually entered; before delivery. A list of all relevant information (i.e. insulin of units, time) on the same display screen provides context and may prompt users to recheck their work and correct any possible errors. On this confirmation display, an option to deliver and an option to edit should be present. Once users choose to edit, they should be returned to the individual parameter screens.

Recommendations for training: As mentioned above, in the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. However, trainers should emphasize
care in programmed a square wave bolus, especially surrounding the time parameter as this was where the participants struggled.

Example #3

![Figure 10: Bolus menu on Medtronic pump](image)

**Usability Issue:** When participants were asked to setup “insulin carb” rations (I:C), two participants selected the bolus menu from the main menu and proceeded to enter the I:C parameters into the bolus delivery option. This could result in an unexpected delivery of insulin that was not requested. One participant confirmed the bolus she had established/programmed but when she saw the bolus delivery screen, she immediately cancelled delivery, realizing the error.

**Recommendations for manufacturer:** Participants gravitated towards “settings” or “options” menus when prompted to setup I:C ratios, rather than the bolus menu. This is likely because I:C ratios are programmed less frequently than a bolus. Therefore, it follows that a parameter not often employed would be embedded in a menu not as frequently employed (the bolus menu is frequently employed). Therefore, “bolus setup” (the name of the I:C ratio set up menu) might be more fitting elsewhere, rather than in the bolus menu. Furthermore, having the I:C ratio setup in a settings menu would perhaps decrease the likelihood of participants accidently delivering a bolus immediately when their intention is to set up a ratio. The name of the parameter could also be made more intuitive since “bolus setup” in a settings menu could cause further confusion.
Recommendations for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. However, trainers should draw attention and explain the many menus stemming from the bolus menu. Since I:C ratios are a setting for future use, they would be programmed in bolus setup rather than in Bolus Wizard or Manual Bolus. The latter menus are for bolus setup immediately or in the near future.

7.3.2.1.2 Summary of Moderate and Low Severity Issues

In terms of moderate severity usability issues for the Medtronic pump, they can be separated into two categories. The first has to do with the general display of the pump, and the second having to do with the bolus calculator.

The remaining high, moderate and low severity issues can be found in Appendix U.

1. Pump Display

Participants had a number of concerns regarding the pump display. For example, the battery information made 4 out of the 6 participants nervous as they felt little can be gathered from the imprecise icon. Participants expected an associated percentage or time corresponding to the battery icon segments. The nomenclature of the pump was also a source of confusion. Short forms such as “N” and “S” were unclear to 3 of the 6 participants. Participants also expressed concern regarding programmable parameters. For example, when programmed a bolus, users are prompted to enter their blood glucose. Though this is recommended, it is not required. It was not clear to participants that filling this parameter was optional and they expressed a desire for optional parameters to be noted as such. Three participants were unsure how to deliver a bolus because they did not have the information. This could become a patient safety risk.

Recommendations: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. However, trainers should focus on nomenclature of the pump so that users are able to troubleshoot and better understand the pump functionalities. This is not necessarily a feature for redesign by manufacturers. In terms of the battery icon, trainers should warn patients to carry backup batteries in case of premature failure. Having the percentage of battery life
remaining is not necessarily possible with AA batteries; this was something desired by most if not all participants. However, what participants desired was for the pumps to be rechargeable using an outlet like most other forms of consumer electronics.

2. Use of bolus calculator

In scenario 3, participants were asked to program a bolus, knowing that they had just ingested 30g of carbohydrate. Users were expected to use the bolus calculator in order for the pump to recommend an appropriate insulin dosage. However, 4 of the 6 participants chose not to use the calculator and instead manually programmed the insulin dosage they deemed appropriate based on their own experience. Though this won’t necessarily lead to an immediate safety risk if done correctly, studies have shown that bypassed bolus calculators can be detrimental as manual delivery can often be inaccurate [64].

The complete list of low severity issues can be found in Appendix U.

7.3.2.2 Animas Pump: Classification of usability issues by severity rating

Figure 11 summarizes the severity of the issues found in the Animas insulin pump system. During the evaluation process, the two human factors experts had no disagreements regarding severity ratings. Most of the usability issues were classified as low severity issues and thus have no impact on patient safety. However, ten usability issues were found to be of high severity and had a high likelihood to have a major impact on patient safety. Recommendations to the manufacturer and for training were developed for each of the high severity issues in order to mitigate the risks of potential consequences. The complete list of high severity issues, their frequency, their potential consequences as well as the recommendations that were developed, can be found in Appendix V. The list of moderate and low severity errors can also be found in Appendix V. The next section will highlight some of the high severity issues and briefly summarize the moderate and low severity issues identified.
7.3.2.2.1 Examples of High Severity Issues

Example #1

*Usability Issue:* As mentioned above, in scenario 4, participants were asked to suspend the bolus they had previously programmed. Participants navigated to the suspend option in the main menu and suspended what they thought was the bolus (when asked). All of them had in fact suspended the basal (delivery) as well since the pump is stopped completely upon suspension. Many had all allowed the bolus to delivery in its entirety before finding the suspend option. Others suspending the bolus as expected but did not understand the “resume” message or did not read it. The alert warned users to resume the basal delivery.
Recommendations for manufacturer: When the suspend option was chosen, a confirmation message was displayed, asking participants to confirm suspension. As mentioned above, it is likely that participants did not read the entirety of the message, instead focusing on completing the task. Therefore, the confirmation message could be redesigned, with the typeface emphasizing what is being suspended. Ideally, there would be two suspend options: one to suspend the bolus and one for the basal. If clearly marked, this would likely eliminate the risk associated with the current design.

Recommendation for training: Again, in the interest of immediate action, training recommendations can be made. Trainers should emphasize the difference between suspending the basal and bolus dosages. They should also explain that “resume” means to restart the basal dose and not the bolus that had previously been programmed and stopped. This will be discussed further below.

Example #2

Usability Issue: Participants in scenario 5 were asked to program a combo bolus of 6 units of insulin over 5 hours. Three participants had expected to be able to confirm the values programmed before delivering but were not given this option. They expressed nervousness and fear and when asked how they would proceed in “real life” they said they would likely disconnect the pump or call the manufacturer for help to ensure they weren’t delivering an incorrect dosage.

Recommendations for manufacturer: An additional confirmation screen should be presented once all parameters have been individually entered; before delivery. A list of all relevant information (i.e. insulin of units, time) on the same display screen provides context and may prompt users to recheck their work and correct any possible errors. On this confirmation display, an option to deliver and an option to edit should be present. Once users choose to edit, they should be returned to the individual parameter screens.

Recommendation for training: Again, in the interest of immediate action, training recommendations can be made. As mentioned above regarding the Medtronic pump, trainers should advise care in programming a combo bolus and should also ensure participants are made...
aware of how to cancel the delivery so as to avoid disconnecting and then reconnecting the pump.

Example #3

*Usability Issue:* Alarm or alert messages were a source of confusion for two of the six participants who tested the pump. At the bottom of each message was a prompt to press “OK” to confirm. The participants were unsure whether pressing “OK” would confirm the message or confirm the action the message was suggesting.

*Recommendations for manufacturer:* The error messages should be reworded so that the consequences of confirming the message by pressing “OK” are clear. For example, the message could end with a statement such as: “OK to confirm the message” which clearly demonstrates that the action confirms the message alone. The reverse could also be applied.

*Recommendation for training:* Again, in the interest of immediate action, training recommendations can be made. Trainers should add a section into their training curriculums specifically for understanding error/alert/alarm messages. The distinction between confirming a message and confirming an action must be emphasized since a lack of understanding could result in a severe patient safety risk.

Example #4

*Figure 13: Pump status display on Animas pump*

*Usability Issue:* Four of the six participants had considerable trouble locating the battery icon or any indication of battery life on the pump. The participants remained on the main menu and

Most users did not navigate back to the status menu when completing a task but rather, remained on the main menu. This made the battery icon location less obvious.
attempted to look through settings menus. It was not their expectation to move outside the main menu to the “status screen”. All four participants expected an icon at the top of each screen for simplicity and ease. Once the icon was found, like in the case of the Medtronic pump, participants were uncomfortable not having a more detailed icon. Participants expected percentage of power left or remaining battery lifetime in hours to be displayed.

**Recommendations for manufacturer:** As mentioned above, finding the battery icon was a source of confusion for a number of participants. The battery icon should be obvious on all screens in the top left or right hand corner, instead of simply being displayed on the status screen. However, if this was not possible, its location on the status screen could be altered to make it more visible. As of now, the icon is below the time of day on the right side of the screen. Many users said the icon was not obvious. Putting it at the top of the display in the corner may make it more visible simply because it follows a standard employed in a number of electronics.

**Recommendations for training:** Instructions of where to find the battery icon are already in place in training modules at diabetes clinics and were included in training during this study. Trainers should emphasize the location of the icon and the purpose of the status screen (versus the main menu). They should also emphasize the importance of carrying additional batteries in case of premature failure.

### 7.3.2.2.2 Summary of Moderate and Low Severity Issues

The moderate severity usability issues for the Animas pump can be separated into two categories. The first has to do with the general display of the pump, and the second having to do with the bolus calculator.

#### 1. Pump Display

Participants faced a few challenges in terms of task completion and those were attributed to difficulties in interpreting pump displays. In scenario 9, users were asked to program insulin carb ratios into the pump for future use. Three of the six participants felt that the display was unclear once it was found; hesitating over the time parameter and how to add a second ratio once the first was inputted. For example, a number of participants felt it was not intuitive to only enter the start time for the ratio: would that mean the end time of one ratio was the start time of
the next ratio? Another participant asked the facilitator for guidance in saving the first ratio and moving on to program a second. She associated the left and right pointing arrows with the done and home options displayed and could not see an alternate workflow that would allow for programming a second ratio.

The battery icon was also a concern for 5 of 6 participants who tested the pump. A number of participants were not able to locate the icon without some guidance with the facilitator. When asked, participants explained that they believed the details of battery life to be somewhere within the main menu architecture rather than the status screen. The majority of the participants had forgotten about the status screen completely. When the icon was found, participants felt uncomfortable with the lack of detail: particularly where there was no estimated battery lifetime.

2. Use of Bolus Calculator

The other moderate severity issue of interest was the bypassing of the bolus calculator. As mentioned above in the Medtronic pump section, bypassing the calculator and programming a bolus dosage manually is not necessarily incorrect, but leaves more room for error which in turn will lead to poorer control over time [64]. Two of the six participants skipped the bolus calculator menu.

The moderate severity issues are described in more detail along with low severity issues in Appendix V.

7.3.2.3 Insulet Pump: Classification of usability issues by severity rating

Figure 14 summarizes the severity of the issues found in the Insulet insulin pump system. During the evaluation process, the two human factors experts had no disagreements regarding severity ratings. Most of the usability issues were classified as low severity issues and thus have no impact on patient safety. However, 9 usability issues were found to be of high severity, indicated the potential to have a major impact on patient safety. Recommendations to the manufacturer and for training were developed for each of the high severity issues in order to mitigate the risks of potential consequences. The complete list of high severity issues, their frequency, their potential consequences as well as the recommendations that were developed, can be found in Appendix W. The list of moderate and low severity errors can also be found in
Appendix W. The next section will highlight some of the high severity issues and briefly summarize the moderate and low severity issues identified.

![Insulet Pump Bar Chart](image)

**Figure 14: Severity ratings for Insulet pump portion of usability study**

7.3.2.3.1 Examples of High Severity Issues

Example #1
Usability Issue: As mentioned above in both the Medtronic and Animas sections, there was also confusion among Insulet users regarded what was being suspended when the suspend option was selected. For this particular pump, the Omnipod, a “delivery screen” remains on the pump until the entire bolus has been delivered. Four out of the six participants waited for the bolus to be delivered in its entirety (the lifetime of the delivery screen) before proceeding to the main menu to then suspend what they thought was the bolus, when asked.

Recommendations for manufacturer: As mentioned above, the distinction between suspending a bolus and basal could be made clearer. See Example #3 below for a more descriptive recommendation.

Recommendation for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. For this particular pump, trainers should ensure patients are able
to distinguish between the two suspend features (for the basal and bolus rates). An unclear understanding of the two features could lead to severe patient safety risk.

Example #2

![Image](image.png)

**Figure 16: I:C ratio setup menu**

*Usability Issue:* In scenario 9, participants were asked to program insulin carb ratios. The format in which the ratios must be programmed was not intuitive to five of the six users and each asked the study investigator for assistance. On this pump, the system auto-populates the start time of the next ratio with the end time of the previous ratio. When asked, the participants said the format did not meet their expectations. In fact, the majority of them did not realize how the system worked at all. This was likely the root cause of the difficulty.

*Recommendations for manufacturer:* Though forcing users to set up ratios with a definitive start and end time would appear to be the safest option, most users had difficulty understanding the format and often left incorrect ones in play. Based on the rest of the usability study, participants appreciated only having to enter a start time for each ratio so that intuitively, the start time of the second ratio would be the same as the end time of the first ratio. This format would likely alleviate the use errors committed on this pump. Also, an option to delete a ratio should also be
added to this menu setup as most users left incorrect ratios in place when they were programmed incorrectly since no delete option was apparent.

Recommendation for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. Trainers should emphasize the purpose of insulin carb ratios: the concept that a ratio must always “exist” on the pump; a ratio has to be set for any given time. The investigator hypothesizes that this concept was not understood. This is an important training feature as incorrectly programmed ratios can have significant patient safety risk.

Example #3

Figure 17: Bolus delivery display on Insulet pump

Usability Issue: As mentioned above in Example #1, when a bolus is being delivered, a “delivery screen” is displayed until it is completed. At the bottom of the screen, a cancel option is displayed. Two of the six participants noticed this option but were unsure whether the “cancel” referred to the action of simply cancelling the display of the current screen or cancelling the bolus delivery all together.

Recommendations for manufacturer: The “cancel” should be worded to convey to users that if pressed, the bolus delivery itself will be canceled, rather than the display of the current screen.
Having the display show the bolus delivery status in its entirety was unexpected to all users. Most expected to be automatically returned to the main menu while the bolus was being delivered. Having the delivery status displayed on the main menu would likely fit user needs.

**Recommendation for training:** As mentioned above, the distinction between how to cancel a basal and a bolus must be emphasized in training in order to dissuade the likelihood of severe patient safety risk.

**Example #4**

*Usability Issue:* Similar to the Animas pump discussed above, there was some confused particularly with one participant about confirmation messages. Specifically, does the action of pressing “OK” confirm the message or the action described in the message?

*Recommendations for manufacturer:* The error messages should be reworded so that the consequences of confirming the message by pressing “OK” are clear. For example, the message could end with a statement such as: “OK to confirm the message” which clearly demonstrates that the action confirms the message alone. The reverse could also be applied.

*Recommendation for training:* In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. Training curriculum should focus on raising awareness of alert messages. As the participant mentioned, in cases where the basal has been suspended for some reason and the patient is panicking, having to absorb a long complicated message is not helpful. Ideally, the message would be short and clear in order to mitigate the likelihood of patient safety risk.

7.3.2.3.2 **Summary of Moderate and Low Severity Issues**

The moderate severity usability issues for the Omnipod can be summarized into two categories. The first has to do with the general display of the pump, and the second having to do with the bolus calculator.
1. Pump Display

The display of the Omnipod was often not what participants expected as they completed the task-based scenarios in the study. For example, when a bolus was delivered and the bolus running display was visible, 2 of the 6 participants expected it to remain on screen for a few moments before being forced back to the main menu. When the “running display” remained on screen, participants attempted on their own to return to the main menu but were unsure of how to proceed. Another concern regarding the display stemmed from the extended bolus programming. One participant didn’t notice the “extend” option at the bottom of the screen and felt it should be more prominent. The battery life details were also not satisfactory for participants as they felt they weren’t being conveyed enough information. These issues, though not likely to be causes of significant patient safety risks, could still pose a threat. For example, missing the extended button might have led to the unintentional delivery of a bolus upfront instead of over time. This could affect a patient’s blood glucose significantly. Cancelling the bolus running display would cancel the bolus all together which might also affect blood glucose significantly.

2. Use of Bolus calculator

Much like the Medtronic and Animas pump users in the study, one Insulet user also bypassed the bolus calculator. Though this will not necessarily lead to an immediate safety risk if done correctly, studies have shown that bypassed bolus calculators can be detrimental as manual delivery can often be inaccurate [64].

Please refer to Appendix W for the complete list of moderate and low severity issues.

7.3.2.4 Roche Pump: Classification of usability issues by severity rating

Figure 18 summarizes the severity of the issues found in the Roche insulin pump system. During the evaluation process, the two human factors experts had disagreements on two of the severity ratings. Please see Appendix Z for more inter-rater reliability details.

The reviewers deliberated until there was a complete agreement. Most of the usability issues were classified as low severity issues and thus have no impact on patient safety. However, 18
usability issues were found to be of high severity, indicated the potential to have a major impact on patient safety. As such, root cause analysis and recommendations for training were developed for each of the high severity issues in order to mitigate the risks of potential consequences. The complete list of high severity issues, their frequency, their potential consequences as well as the recommendations that were developed, can be found in Appendix X. The list of moderate and low severity errors can also be found in Appendix X. The next section will highlight some of the high severity issues and briefly summarize the moderate and low severity issues identified.

![Table showing severity ratings of Roche pump issues]

**Figure 18: Severity ratings for Roche pump portion of usability study**

### 7.3.2.4.1 Examples of High Severity Issues

**Example #1**

![Image of Roche pump status display]

*Figure 19: Status display on Roche pump*

Distinction between function of two buttons not immediately clear; root cause of multiple errors and source of user frustration
**Usability Issue:** There was considerable confusion among all six participants who tested this pump regarding the distinction between the “menu” button and the “enter/checkmark” button. For example, when programming an extended bolus, participants are expected to enter parameters such as the number of units over a time. In order to toggle between the two parameters (units of insulin and time), the “menu” button must be pressed rather than the checkmark. Most participants, once inputting the number of units, pressed the checkmark. This confirmed the bolus delivery setup. In cases such as this, the default time setting is left as is. This poses a considerable safety risk as the incorrect dosage of insulin would be delivered. Half the participants realized their error, stopped the pump and reprogrammed the extended bolus correctly.

**Recommendations for manufacturer:** The checkmark symbol was interpreted by all users to mean confirmation that a parameter had been entered correctly, which was a false assumption; the other “menu” button should have been employed for this function. The manufacturer should reconsider the symbols on the buttons so that they are more representative of their function. The function could be displayed on the screen adjacent to the button to remind users of its purpose. The same applies to the file or “menu” button above the checkmark.

**Recommendation for training:** In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. Trainers must make the distinction between the two buttons’ functionalities clear in order to limit the likelihood of severe patient safety risk. The “checkmark” button should only be pressed when the user has confirmed all values and is ready to deliver the dosage or go back to the menu listing.

**Example #2**
Usability Issue: Three of the six participants had considerable trouble setting up the insulin carb ratios on the remote meter. As in the case of the Insulet Omnipod, the pump auto-populates the start time of a new ratio with the end time of the previous ratio. When asked, participants expressed the desire to set up the ratios independently, without the help of the pump. None of these three participants were able to complete the task correctly.

Recommendations for manufacturer: Though forcing users to set up ratios with a definitive start and end time would appear to be the safest option, most users had difficulty understanding the format and often left incorrect ones in play. Based on the rest of the usability study, participants appreciated only having to enter a start time for each ratio so that intuitively, the start time of the second ratio would be the same as the end time of the first ratio. This format would likely alleviate the use errors committed on this pump. Also, an option to delete a ratio should also be added to this menu setup as most users left incorrect ratios in place when they were programmed incorrectly since no delete option was apparent.

Figure 20: I:C ratio setup menu on Roche remote
**Recommendation for training:** In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. As mentioned above in the Insulet section, trainers should emphasize the purpose of insulin carb ratios: the concept that a ratio must always “exist” on the pump; a ratio has to be set for any given time. The investigator hypothesizes that this concept was not understood. This is an important training feature as incorrectly programmed ratios can pose significant patient safety risk.

**Example #3**

![Figure 21: "Stop the pump" menu on Roche pump](image)

**Usability Issue:** Similar to the previous pumps, five of the six participants had difficulty differentiating between the concepts of suspending a basal dose versus a bolus dose. In order to stop a bolus on this pump, the pump has to be completed stopped which was not necessarily what was expected. The five participants stopped the pump and when asked, believed that only the bolus had been stopped.

**Recommendations for manufacturer:** Though this menu name is descriptive and conveys its purpose, most users felt uncomfortable “stopping” the pump, though they had no issue with “suspending” it. Therefore, the notation of the pump could be altered to better communicate to users that this is the correct function necessary for suspending a bolus. Ideally, there would be two suspend options: one to suspend the bolus and one for the basal. If clearly marked, this would likely eliminate the risk associated with the current design.
**Recommendation for training:** In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. As mentioned above, the distinction between how to cancel a basal and a bolus must be emphasized in training in order to dissuade the likelihood of severe patient safety risk.

**Example #4**

**Usability Issue:** One participant of the six who used the pump programmed a bolus unintentionally when attempting to setup an insulin carb ratio.

**Recommendations for manufacturer:** Though the location of I:C ratio setup is not necessarily clear to all users, it is distinct from bolus setup. Therefore, no design recommendation can be made regarding this issue.

**Recommendation for training:** Trainers should emphasize the distinction between bolus delivery now and the setup of a ratio for use later. The purpose of the settings menu for I:C ratios setup should be distinguished from the bolus setup menu in order to dissuade this error from occurring again as it can have significant patient safety risk.

**Example #5**

![Image of an insulin pump displaying an error message](image-url)
Usability Issue: The meaning of the “snooze” message, alerting the user that the pump was still not running was unclear to two of the six participants. The participants asked the investigator what “snooze” meant in this particular context, unsure of what would happen if they confirmed the message.

Recommendations for manufacturer: The error messages displayed above are visually complex, making each line less visible and less prominent. The users were unsure how to follow the message and take action. Therefore, the messages should be simplified and if symbols are to be displayed, their purpose must be clear. Furthermore, jargon should not be utilized in error messages or any confirmation messages as the user should not be trying to interpret messages. “Power interrupt” was not an intuitive error type to users, nor was “E8” and neither was the action of “snoozing”. These should be reworded to better fit patient expectations.

Recommendation for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. Trainers should add a section into their training curriculums specifically for understanding error/alert/alarm messages. The distinction between confirming a message and confirming an action must be emphasized since a lack of understanding could result in a severe patient safety risk.
7.3.2.4.2 Summary of Moderate and Low Severity Issues

The moderate and low severity usability issues for the Roche pump can be summarized into two categories. The first has to do with the general display of the pump, and the second having to do with the bolus calculator.

1. Pump Display

Participants were very vocal regarding concerns they had with the Roche pump display. For example, one source of difficulty was unlocking the pump. When the pump is locked and a button is pushed, “instructions” appear on the screen, indicating how the pump can be unlocked. However, all 6 participants who used the pump felt the instructions were unclear and were unable to unlock the device without prompting from the facilitator. Along that same vein, the “Pump menu” on the remote was also a source of frustration for the participants who accessed it. The pump menus are displayed in their original format in the Pump menu of the remote so that users are able to access the pump directly in order to perform actions. The way to cycle through the menus was not intuitive to participants. Some attempted to use it, but even with prompting, the facilitator, gave up on this function and used the pump directly. Furthermore, the nomenclature on the pump was not intuitive to participants who had trouble understanding not only the format of menus, but the symbols and short forms as well.

Additionally, the pump vibrates and rings whenever a parameter is changed. However, five of the six participants felt the cause or reason for the vibration was not clear. Whenever they heard it, they felt they were programming something incorrectly. Finally, the battery “details” were a source of concern for all six participants. All participants searched for icons, battery life percentages or “hours remaining” on the pump for some time before the facilitator prompted a recall of what was taught in training: the only indication of battery life is the alarm that goes off alerting participants that the pump battery is almost empty. None of the 6 participants felt comfortable with this method of conveying battery information.

2. Use of Bolus calculator

Much like the Medtronic, Animas and Insulet pump users in the study, three Roche user also bypassed the bolus calculator. Though this won’t necessarily lead to an immediate safety risk if
done correctly, studies have shown that bypassed bolus calculators can be detrimental as manual delivery can often be inaccurate [64].

7.3.2.5 **Tandem Pump: Classification of usability issues by severity rating**

Figure 23 summarizes the severity of the issues found in the Tandem insulin pump system. During the evaluation process, the two human factors experts had no disagreements regarding the severity ratings. Most of the usability issues were classified as low severity issues and thus have no impact on patient safety. However, 6 usability issues were found to be of high severity, indicated the potential to have a major impact on patient safety. As such, root cause analysis and recommendations for training were developed for each of the high severity issues in order to mitigate the risks of potential consequences. The complete list of high severity issues, their frequency, their potential consequences as well as the recommendations that were developed, can be found in Appendix Y. The list of moderate and low severity errors can also be found in Appendix Y. The next section will highlight some of the high severity issues and briefly summarize the moderate and low severity issues identified.

![Figure 23: Severity ratings for Tandem pump portion of usability study](image)

**7.3.2.5.1 Examples of High Severity Issues**

**Example#1**
Usability Issue: Four of the six participants who tested the Tandem pump had considerable trouble understanding the format necessary for programming the insulin carb ratios correctly.

Recommendations for manufacturer: The notation and the nomenclature for the setup of insulin carb ratios were the sources of confusion for the four users. The title “timed settings” did not convey the purpose of the menu to these users and could be changed to a more descriptive title. Furthermore, users did not expect insulin carb ratios to be set up in the same entry as the target blood glucose for example. Therefore, these should be separated and put in a menu under a title that better describes its purpose rather than the existing “Personal Profiles” menu name.

Recommendation for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. Trainers should emphasize the purpose of insulin carb ratios: the concept that a ratio must always “exist” on the pump; a ratio has to be set for any given time. The investigator hypothesizes that this concept was not understood. This is an important training feature as incorrectly programmed ratios can have significant patient safety risk.

Example#2

Usability Issue: One participant expected an additional confirmation of the extended bolus before delivery and when she saw the bolus was running, stopped it and reprogrammed it because she couldn’t remember whether she had changed the time parameter. The expectation
that there is another checkpoint to verify a programmed bolus, when there isn’t one, could pose a patient safety risk as the user was uncomfortable and had to stop or disconnect the pump.

**Recommendations for manufacturer:** Multiple confirmations exist when programming an extended bolus as designed. These were said to be sufficient by the other users who employed this pump. Therefore, no design of additional confirmation messages are recommended. However, the “delivery” action button could be more descriptive, alerting the user that the next step is in fact insulin delivery.

**Recommendation for training:** In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. As mentioned above regarding the Medtronic and Animas pumps, trainers should advise care in programming an extended bolus and should also ensure participants are made aware of how to cancel the delivery so as to avoid disconnecting and then reconnecting the pump.

**Example#3**

![Figure 25: Examples of possibilities for suspending (left) insulin and (right) bolus on Tandem pump](image)

**Usability Issue:** One participant had trouble distinguishing between stopping the pump altogether and stopping the bolus dosage. When a bolus is delivered a “delivery screen” flashes for a few seconds before the screen times-out. If a user wants to consult the pump for another reason or wants to suspend the bolus, they must unlock the pump and press the red “x” next to the bolus menu. The one participant in this case went to the options menu and stopped the pump.

**Distinction between “X” and “stop insulin” unclear to one user**
altogether. When asked as to why she stopped the pump completely, she said she had intended to stop the bolus. She had expected the “delivery screen” to remain in place for the duration of the bolus delivery and was confused as a result about whether the bolus had been delivered or not.

Recommendations for manufacturer: Most participants felt that this format was clear. The red “x” shows which insulin dose is being canceled: the bolus.

The delivery screen was only visible for a few seconds before the user was returned to the main menu. The alternating circles flashing which denoted bolus delivery (on the bolus menu) could be larger or the contrast could be made greater to ensure that users see that the bolus is still being delivered (see Figure 25, right).

Recommendation for training: In the interest of immediate action, training recommendations can be made. It is worth emphasizing that training on a feature will not necessarily alleviate the risk associated with this problem. As mentioned above, the distinction between how to cancel a basal and a bolus must be emphasized in training in order to dissuade the likelihood of severe patient safety risk.

7.3.2.5.2 Summary of Moderate and Low Severity Issues

The moderate severity usability issues for the Tandem can be summarized into one category having to do with intuitiveness of menu displays/options and menu names.

Participants commented on the intuitiveness of the menu functions and menu titles/names. For examples, the menu title “personal profiles” was a source of confusion for 5 of the 6 participants who tested the pump. This menu title was mistaken for the location of pump information like the serial number, or mistaken for the location of bolus/BG history. Only one participant immediately made the connection between personal profiles and I:C ratio setup. The format of this menu was also a source of confusion as participants felt that the purpose of the menu was not conveyed well.

Another example was regarding the BG input into the pump. In order to save a BG reading, users are expected to go to the bolus menu and input the value there. Three of the six
participants could not recall this step in the training and felt that it was not an intuitive action: to input BG in a bolus menu when they had no intention of delivering a bolus.

Please refer to Appendix Y for the complete list of moderate and low severity issues.

7.3.3 Deviations

Below, in Table 4, is a summary of the number of participants (out of 6 who tested each pump), who deviated in completion of a task. For example, in the case of the Medtronic pump, 2 of the 6 participants deviated when attempting to setup a bolus.

**Table 4: Number of participants who deviated per task (out of 6 users), per pump**

<table>
<thead>
<tr>
<th>Task</th>
<th>Medtronic</th>
<th>Animas</th>
<th>Insulet</th>
<th>Roche</th>
<th>Tandem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time/Date Setup</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Bolus History Search</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Bolus Setup</td>
<td>4</td>
<td>6</td>
<td>-</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Extended Bolus Setup</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Use of Bolus Calculator</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Low reservoir alarm setup</td>
<td>4</td>
<td>2</td>
<td>-</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Battery Check</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I:C setup</td>
<td>4</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>BG History</td>
<td>4</td>
<td>-</td>
<td>4</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>BG input</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Locking</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Suspend /Resume</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

The highlighted cells indicated the most problematic tasks on each pump in terms of deviations, where more than half of the participants had difficulty completing the scenario and deviated from the logical workflow. Each of the highlighted cells suggests a usability issue. A review of the video footage allowed for the description of these trouble spots for each respective pump, which are presented below in Table 5.

**Table 5: Deviations described per pump**
<table>
<thead>
<tr>
<th>Highlighted Scenario/Section</th>
<th>Reason for concern</th>
<th>Possible reasons for deviations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use of bolus calculator</strong></td>
<td>Affected 67% of participants who tested the Medtronic pump (4 out of 6 participants)</td>
<td>Participants may have felt the bolus calculator was unnecessary for delivering a bolus based on their experience doing “mental math” when injecting insulin multiple times per day. Also possible that participants forgot about the bolus calculator.</td>
</tr>
<tr>
<td><strong>Low reservoir alarm setup</strong></td>
<td>Affected 83.3 % of participants who tested the Medtronic pump (5 out of 6 participants)</td>
<td>Participants struggled trying to find where the low reservoir alarm setup should take place. Participants searched the bolus menu, the Utilities menu, reservoir and set menus. Participants didn’t make the connection that they were being asked to setup an alarm threshold.</td>
</tr>
<tr>
<td><strong>I:C ratio setup</strong></td>
<td>Affected 67% of participants who tested the Medtronic pump (4 out of 6 participants)</td>
<td>Participants had difficulty determining in which menu the I:C ratio setup would belong. Participants looked in the bolus menu, the Utilities menu, among others before completing the task.</td>
</tr>
<tr>
<td><strong>BG history check</strong></td>
<td>Affected 67% of participants who tested the Medtronic pump (4 out of 6 participants)</td>
<td>Participants had difficulty understand the meaning of “capture event” and what might be found in that menu. The bolus menu and the utilities menu were searched</td>
</tr>
<tr>
<td>Battery Check</td>
<td>Affected 67% of participants who tested the Animas pump (4 out of 6 participants)</td>
<td>Participants searched the setup menus, specifically the advanced setup menus searching for battery-life information. These participants expected to find this information in the main menu rather than the status display.</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Use of bolus calculator</td>
<td>Affected 100% of participants who tested the Insulet pump (6 out of 6 participants)</td>
<td>Participants bypassed the bolus calculator, feeling it was unnecessary as they were able to judge the necessary insulin bolus dose based on experience. Also possible participants forgot about bolus calculator.</td>
</tr>
<tr>
<td>I:C ratio setup</td>
<td>Affected 83.3% of participants who tested the Insulet pump (5 out of 6 participants)</td>
<td>Participants had difficulty determining in which menu the I:C ration setup belonged. Participants looked in the bolus menu, the settings menu, more actions menu, etc. unable to find a menu option that fit their expectations.</td>
</tr>
<tr>
<td>Bolus setup</td>
<td>Affected 100% of participants who tested the Roche pump (6 out of 6 participants)</td>
<td>Participants felt uncertain regarding which device (pump or remote) they should use for multiple tasks including bolus</td>
</tr>
</tbody>
</table>
setup up. Participants toggled between the two before settling on one and delivering the desired bolus. The decision of whether to use the bolus calculator (only available on remote) added to the number of deviations.

<table>
<thead>
<tr>
<th>Extended bolus setup</th>
<th>Affected 83.3 % of participants who tested the Roche pump (5 out of 6 participants)</th>
<th>Participants felt uncertain regarding which device (pump or remote) they should use when programming an extended bolus. Participants also struggled with programming the desired bolus in one step. Many started the programming, left the menu and then returned to complete programming.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Check</td>
<td>Affected 100% of participants who tested the Roche pump (6 out of 6 participants)</td>
<td>Participants searched the alert settings menu, therapy settings, my data, etc. in order to see battery life information. All participants asked the facilitator for help.</td>
</tr>
<tr>
<td>I:C ratio setup</td>
<td>Affected 67% of participants who tested the Roche pump (4 out of participants)</td>
<td>Participants had difficulty determining on which device (pump or remote) they should use when programming the I:C ratios. When participants determined the remote was the necessary device, they toggled between the two “Bolus Advice” menus. Participants did not make the connection between “time blocks” and I:C ratio setup.</td>
</tr>
<tr>
<td>Function</td>
<td>Affected Percentage</td>
<td>Participant Experience</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>Locking</strong></td>
<td>100%</td>
<td>Participants were unsure of whether both the remote and pump had to be locked separately. Participants cycled through menu options multiple times before settling on the correct one. Once on the correct menu, participants had difficulty with actually locking, forcing them to cycle through the menus again.</td>
</tr>
<tr>
<td><strong>Suspend/Resume</strong></td>
<td>83.3%</td>
<td>Participants struggled with the “stop the pump” option, unsure of whether they should suspend the bolus this way. Participants also struggled choosing between which (pump or remote) they should suspend the bolus.</td>
</tr>
<tr>
<td>TANDEM</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bolus history check</strong></td>
<td>67%</td>
<td>Participants had difficulty locating the bolus history menu, expecting to see it in the bolus menu rather than in the options menu. When participants chose the options menu, they did not immediately see the history option, as it required participants to “scroll” to the next Options menu page.</td>
</tr>
<tr>
<td><strong>I:C ratio setup</strong></td>
<td>67%</td>
<td>The menu title “personal profiles” was not where participants expected to find I:C ratio setup. Participants toggled between the bolus and</td>
</tr>
</tbody>
</table>
Once in the options menu, participants went through all menu options. Only when prompted did participants make the connection with “personal profiles”.

7.3.4 Inter-rater Reliability

The investigator and the second rater were in 100% agreement regarding the occurrence of errors as well as the number of deviations committed by the users. Therefore, a Cohen’s kappa of 1 is applicable as there was agreement between the two reviewers.

The ranking of error severity by the two raters was identical in the cases of the Animas, Insulet and Tandem pumps. The two reviewers disagreed about one severity ranking for an issue on the Medtronic pump and two severity rankings for issues on the Roche pump. This corresponds to a Fleiss kappa of 0.71 and 0.77, respectively. These two kappa values can be interpreted as substantial agreement between the two reviewers.

The establishment of a low rate of disagreement between the two reviewers was deemed sufficient to avoid the need for further verification of the study session videos. Therefore, the data collected by the investigator was determined to be reliable. The methodology and details are outlined in Appendix Z.

7.3.5 Post-test Questionnaire

The following is a brief summary of the post-test questionnaire findings:

- Of the 6 users who tested the Tandem pump, all 6 considered it to be the easiest to use of the three they each tested.
  
  One participant noted commented regarding the Tandem: “I would definitely pay extra for it. Smart phone interfaces are now available on almost all phone models, why should it be different for something as important as an insulin pump”
• Of the 6 users who tested the Tandem, 5 considered it to be the best at showing them the information they needed of the three pumps each participant tested
• Of the 6 users who tested the Tandem, 5 considered it to be the best at drawing their attention to important information
• Six of the 6 users who tested the Tandem also ranked it as their preferred pump of the three they each tested
• Medtronic and Animas had similar results; chosen as the most efficient pump for completing the study tasks by 2 or 3 of the 6 participants who used them. However, Animas was chosen as the preferred pump by 2 of 6 participants while Medtronic was preferred by 1 of 6
• Insulet was chosen by two of 6 users as their preference in two categories: bolus setup and I:C ratio setup
• Insulet was not chosen by any participant in 3 main categories: easiest to use, better at drawing attention to important messages and preference
• Roche was considered the easiest to use by 1 of 6 participants who tested it, while 2 of 6 participants chose it as the best at drawing their attention to important information (in the group of 3 pumps each participant tested)

The complete questionnaire results can be found in Appendix T.

7.4 Discussion

What often allowed a user to complete a task effectively on a particular pump instead of another was a pump’s design and its attention to the hierarchy of effectiveness (Appendix AA) [119]. The hierarchy of effectiveness is a risk management tool or theory that rates interventions related to human behavior toward the bottom of the scale, favoring instead technological interventions, which are viewed as more reliable or more effective.

7.4.1 Bolus Calculator Design

At the top of the scale is the concept of “forcing functions”. What was perhaps unique about the Tandem (compared to every other pump tested), specifically in the case of the bolus calculator, was that it forced the user to utilize the bolus calculator functions; no option to deliver a bolus
manually was present. This eliminated the moderate risk that accompanies manual bolusing since it is possible that users err when programming a bolus based on “mental math”. Furthermore, other pumps allow the user to turn off the bolus calculator altogether, leaving only the manually bolusing option available. The Tandem pump does not include this feature.

This was likely the best practice in terms of bolus delivery design. Though some participants felt uneasy with the pump forcing calculations, they did realize the benefits associated with automatic delivery of a bolus based on measured blood glucose, target blood glucose, carbohydrate content of meal ingested.

7.4.2 Menu Design

Perhaps another reason why the Tandem pump allowed for the fewest high severity errors was its tendency towards simplification in the design. There were only two menu options available on the home screen. The first was strictly reserved for programming a bolus or capturing a BG measurement. This eliminated the bolus menu as an option for any other task. This was different from the other pumps where the main menu was home to at least 5 menus that further branched into additional menu options. Multiple starting points on the main menu may have left room for confusion and may have accounted for the number of deviations committed by users as described in Section 7.3.3.

7.4.3 Bolus Setup Automation

Tandem also likely considered automation from the perspective of a hierarchy of effectiveness. When programming a bolus, the calculator takes the information provided and makes a recommendation, auto-populating the bolus “dosage” field. The next action would be for the user to proceed. This differs from the Animas pump, for example, where a recommendation is made and users are expected to then program the bolus manually, choosing to either respect the recommendation or ignore it. Though this adds user liberty to the process, it does leave room for error. For example, one user did not read the display and did not see the recommendation made by the bolus calculator on the Animas pump. She then tried to recall what she thought had been the recommendation displayed on the previous screen. She ended up manually delivering an incorrect dosage. Therefore, though Tandem may eliminate some freedom in bolus programming, it can be argued that the reduced freedom also reduces the likelihood of error.
Animas did utilize the concept of automation, specifically in the Combo Bolus menu. This was in certain cases, to the detriment of the user. When a combo bolus is programmed, the user is first expected to enter the number of units of insulin to be delivered. Once that value has been confirmed, the pump automatically selects the “Go” option (at the bottom of the screen) to deliver the bolus. The pump cursor bypasses the time parameter and the distribution percentage, leaving the default values (30 minutes and a distribution of 0%: 100%). If a user wants to change the time over which the bolus is delivered, they must manually move the cursor up to that parameter. This may have indirectly encouraged errors in the delivery of the bolus. Several participants did not know, or realized later, that the time parameter had been left at its default value.

Though other pumps do utilize default times in order to facilitate programming, none encourage the user to bypass the parameter altogether like the Animas pump.

Another example of automation on the Tandem, though not directly related to bolus setup, was noticed and mentioned by one participant. If in using the pump, the screen times-out or is locked, the next time the pump is unlocked, the user is returned to their last-used page. This is in contrast to every other pump where the user is returned to the status screen or the home screen (example of automation). One participant considered this favorably and expressed a desire that every other pump follow Tandem’s lead with this design decision.

7.4.4 Location of I:C Ratio menu

The search for the I:C ratio setup menu led to task deviations on each of the five pumps tested (see Section 7.3.3 for deviations). The location of the setup menu differed on each pump. For example, on the Medtronic pump, the ratios were to be setup in the Bolus setup menu, found in the Bolus menu.

On the Animas pump, the ratios were to be setup in the “Advanced” menu of the “Settings” menu, though buried 7 pages deep in “Adv Settings 7”.

On the Insulet pump, the I:C ratio menu could also be programmed from the “Settings” menu, though a number of menus had to be chosen correctly before the I:C ratios were reached:
“System Setup” then “Bolus/Basal/Calcs”, followed by “Ratios/factors/targets” and then finally “I:C ratio”.

On the Roche pump, I:C ratios could only be setup on the remote via the “Settings” menu, followed by “Bolus Advice” and then “Time blocks”.

For the Tandem pump, the settings could be programmed in the “Options” menu’s “My Pump” menu, followed by “Personal Profiles”.

The settings menu was most often chosen by pump manufacturers to house the I:C ratio setup menu (Animas, Insulet and Roche). Tandem chose the “Option” menu. Medtronic likely chose to put I:C ratios in the Bolus menu as they relate to the bolus calculator directly and this would seem an intuitive location. But as mentioned above, no pump was immune to deviations completing this task. The fewest deviations were committed using the Animas pump. This can likely be attributed to Animas’ “built-in” distinction between menus on the home page: simplification of menu titles. Each menu title appeared to relay their purpose. Other than the bolus menu, the Settings menu likely seemed the only alternative for programmed the ratios. This is in contract to the Insulet pump for example which had other menus such as “More Actions” that could likely be confused with the “Settings” menu. The Medtronic pump also had the “Capture Event” menu option whose title was unintuitive to many users. The Insulet and Roche pump menu titles also caused confusion among users.

This leaves the Tandem pump which would seem the best design as only two menus exist on the home page. What Tandem was able to do was encourage the “safest” deviations. As mentioned above, in the case of Animas, users confused the Bolus menu and the settings menu. Some users attempted to program the ratios as a bolus which could lead to severe patient safety risks. The Tandem pump eliminated this risk by limiting the Bolus menu to two functions: bolusing and BG measurement capture. However, despite this simplistic menu design, 4 of 6 participants were unable to find the I:C ratio setup with ease. This can be attributed mostly to the menu title “Personal Profiles”. Users were unable to decipher the meaning of that title without prompting. Users passed over it multiple times in search of the I:C ratio setup, believing it to be personal information either about the pump (model #, etc. ) or information about the owner themselves.
Therefore, based on these results, recommendations can be made regarding how to design I:C ratio menus in order to discourage deviations and lessen patient safety risk. As was the case in a number of pumps, the I:C ratio setup menu should be in a “settings” or “options” menu rather than being placed in the same menu as bolus setup and delivery. Though it may seem intuitive to keep all features related to bolusing in the same menu, it can often lead to more confusion (see section 7.3.3). Since I:C ratios are not set up as often as a standard bolus, it follows that the ratio setup menu should be located with other features not utilized regularly such as in a settings menu. That being said, the ratio setup should not be buried so deep in menu architecture that the menu becomes inaccessible. Though not used often, it is more likely used than other features such as “language settings” (often in the same menu).

An example of this misleading design is in the Animas pump. As mentioned above, the I:C ratios are found seven pages deep in the advanced settings menu. A number of participants read through the first three or four display pages and then left the menu, believing that a feature as important as I:C ratios would not be found further in the menu. This was the cause of a number of deviations and eventual errors. However, it is important to note that participants’ inclination was to look at this specific advanced settings menu. Had the ratios been displayed at the front end, participants may have completed the task more efficiently.

As mentioned above, the naming of I:C ratio menus was also a source of confusion. The Roche pump referred to the menu as “bolus advice”, the Tandem “personal profiles”, the Insulet pump “ratios/factors/targets”, the Medtronic “bolus setup” and Animas “adv settings 7”. None of these menu titles was interpreted correctly by all users. When asked, participants often attributed difficulties in task completion to their confusion in interpreting menu titles. This was especially true in the case of the Tandem pump, where “personal profiles” was misinterpreted by almost every participant. Therefore, pump manufacturers should consider renaming and reconsidering the menu placement of the I:C ratio setup to better fit patient expectations.

7.4.5 I:C Ratio Setup

As mentioned above, forcing functions can most likely mitigate high risk errors. In terms of I:C ratio setup, two pumps forced “intentional” setup: Insulet, Roche. For these pumps, the end time of a previous ratio was defaulted as the start time to the next ratio. Though there were errors
committed during setup on these pumps, users were not confused about what the setup meant since there was a clearly marked start and end time. Though this was a source of confusion for users initially, this eliminated the uncertainty of the ratio timeline.

For the Medtronic, Animas and Tandem pumps, only a start-time parameter was available. During the sessions, users often wondered whether that meant that the ratio was applicable starting at the programmed time and remained so until the next ratio start time. Though this is the correct assumption, users did express their uncertainty.

Therefore, it follows that forcing ratio timelines reinforces the concept and the purpose of the ratios (a ratio must always exist for any given time) more so than allowing users to program a start–time only. The forcing function also likely reinforces confidence in setup which is of extreme importance in insulin pump use as seen in the literature [27]. However, as mentioned above in a number of cases, this forcing function structure led to considerable confusion as participants were unsure how to delete ratios (e.g. Insulet, Roche, Tandem). If the forcing function structure is to be utilized, there should be a simple way for users to delete ratios no longer applicable rather than having them change each ratio one by one to achieve the desired outcome. This was the only way that ratios could be deleted as each ratio was based on “end time” rather than “start time”. Therefore, manufacturers should base their ratio setup on start times. Participants should be able to input a start time for each segment and based on those start times, end times can be automatically generated. When the user then looks at the complete picture of the ratios, their timelines are decipherable. From that display, each timeline should be available for edit or easily deleted.

7.4.6 Battery Details

As mentioned above in Section 7.3.2, the battery “display” was unsatisfactory for all pumps; least satisfactory in the case of the Roche pump (6 of 6 users unsatisfied) and most satisfactory in the case of the Tandem pump (1 of 6 users unsatisfied). The Roche pump alerts the user of low battery in real time with an error message only, while the Tandem pump has an icon constantly on display with the percentage of battery life remaining displayed. The pump icon also provided visual cues (green, orange, red) to alert the user of battery life.
Standardization is also considered an effective system-focused tool for mitigation of safety issues according to the Hierarchy of Effectiveness. Battery life in percentage is a standard for electronics whether it be a smart phone or a computer. Though a message alerting to “low battery” is also customary, it is usually in addition to a constant display of battery life (icon with percentage). This standardized method of conveying battery life with an icon and percentage was likely the reason for the Tandem’s warmer reception.

The other pumps (Animas, Insulet and Medtronic) also displayed a battery icon similar to a standard electronic. However, no percentage or indication of what the icon signified left some users uneasy. Participants in the study felt that interpreting the icon could be problematic, especially as a low battery can lead to significant patient safety risk if batteries are not on hand.

7.4.7 Confirimation of Actions

Reminders, checklists and double checks are people-focused methods of ensuring safe actions on medical devices. In a number of scenarios on a variety of pumps, users often felt that a confirmation message was missing that would allow users to see a summary of results before taking action. For example, 2 of 6 Medtronic users, 3 of 6 Animas users, and 1 of 6 Tandem users expected a final confirmation before delivery of a bolus in order to facilitate a re-check of programmed parameters.

The Medtronic pump has no confirmation messages for any bolus delivery action. The Animas pump, when using the bolus calculator, forces a user to “confirm” or ignore the recommendation by manually inputting the number of insulin units to be delivered. Therefore, the need for additional confirmation messages may instill confidence in the action. As mentioned above, confidence is imperative in insulin pump use [27].

The Tandem, however, differs in that it displays two confirmation messages during bolus setup: one to confirm the dosage and the other to confirm delivery. The user who commented on a lack of confirmation messages was programming an extended bolus. In doing so, the same two confirmation messages are displayed as when a regular bolus is setup. It is likely that the user came to expect confirmation messages and because of the nature of the extended bolus, expected further confirmation that what is normally displayed.
7.4.8 Suspension

As mentioned above, the suspension of a bolus was often confused with a basal. On two of the five pumps, Tandem and Insulet (though not immediately clear on the Insulet), the distinction was clearer as to which dose was being suspended. However, errors were made on each one of the five pumps by at least one user.

As mentioned above, distinction between cancelling a bolus and basal is necessary in design to avoid user confusion regarding insulin suspension. Fewest use errors were committed on the Tandem pump as a clear distinction was made between suspending a bolus and stopping the pump. Firstly, the two features were available in different menus. Furthermore, a red “x” was visible on the bolus menu so that users could associate the suspension with the bolus dose directly, rather than the basal. The “stop the pump” feature, which was in the options menu, was less easily accessible as it is likely used less frequently. This is in contrast to the Roche pump which had only a “stop the pump” and also in contrast to the other pumps who simply displayed a “suspend” menu option on the main menu, not indicating readily which dosage would be suspended: basal or bolus.

The pumps eventually would remind users that insulin delivery had been suspended via an alarm or alert message. Furthermore, training emphasized the difference between suspending a bolus versus a basal. However, it is important to note that basal dosages were not explained in great detail as it was beyond the scope of the study. These two interventions (alerts and training) are not often the most effective as displayed on the hierarchy of effectiveness. (Appendix AA). Therefore, it follows that no single strategy will completely eliminate use errors that lead to patient safety risks or adverse events. Instead a combination of strategies is necessary for a user to be successful. No pump completely eliminated this use error of suspending the wrong dose.

Further strategies are necessary in order to mitigate this risk.

7.5 Study Limitations

The study and its results were affected by a number of factors. Each factor is discussed below.
7.5.1 Realism of the study

The study’s realism as perceived by the patient participants plays a significant role in the validity of the study results. In large part, the participants were responsive to the study’s objective and attempted to perform the tasks as they would expect to in their home/office environment. In fact, participants were anxious about their performance in the study which will be described further in Section 7.5.2 below.

7.5.1.1 Omission of physical actions modifying patient behavior

Participants inconsistently paid attention or considered safety risks. For example, participants would explore or “experiment” with starting a bolus when they were unsure of programming parameters. Participants also “gave up” in completing tasks, expressing frustration with a scenario and the pump they were testing. This would not likely occur had the user been wearing the pump in a real situation as “giving up” could pose a safety risk if the task directly affected insulin dosage.

It is possible that the lack of “physical actions” or what would be required in normal administration of insulin furthered assumptions that the actions they were performing were not important or would not likely impact patient safety. Furthermore, the presence of the facilitator in the room, though attempting to be as unobtrusive as possible, may have lessened the importance of completing a task independently.

The implication here is that users would have perhaps made fewer errors had insulin administration been simulated more realistically.

7.5.2 Performance Anxiety

In some cases, a user would be unaware of a significant error but would find it later when they performed a similar task. The realization of this error may have added to the anxiety of some users. It is possible that the stress and anxiety had the potential to affect behaviour as seen in the literature [120].
However, because the conditions were controlled and there were no distractions and minimal noise, it’s also possible that users were more vigilant, making them less likely to commit errors and more apt to catch errors.

### 7.5.3 Length of Training

Best efforts were made to ensure each time a participant was being trained on a particular pump, training sessions were equal in length. Furthermore, protocols for training on all 5 pumps were designed to be as close in length to one another. A longer training is assumed to provide more information and thus may skew results.

The average training length for each pump is as follows:

- The average training session length for the Medtronic pump: 6:43 (min:sec)
- The average training session length for the Animas pump: 7:12
- The average training session length for the Insulet pump: 7:00
- The average training session length for the Roche pump: 9:06
- The average training session length for the Tandem pump: 6:10

As described above, the average training session was between 6 and 7 minutes excluding the Roche pump. This raises the question of whether a shorter training session might have led to different results. However, this question is misleading as the training protocol was based on training delivered at the Toronto General Hospital Diabetes Clinic. Therefore, shortening the training time would have required a protocol structural change which was beyond the scope of this project.

One concern to mention in this section is the variability of training times within each training protocol. As described in Section 7.3.1, training was delivered over a range of time. This was predominantly as a result of the pace at which each user worked, and also as a result of participants attempting to ask questions. Participants were asked to hold their questions until the end of the training session or alternatively told that they would not need to know the answer to that question or that more details would be provided at the end of the study. Ultimately, the ranges between each pump’s training sessions were similar and therefore should not have affected the results of the study in any significant way.
8 Significance

This section will highlight the priorities for insulin pump training redesign. It will also describe the implications of the present work and how the three phases of the study together can impact design focus. Finally, implications of this work on future research will be explored.

8.1 Performance vs. Preference

As described above, the Tandem pump was preferred by all those who used it, over the other 4 pumps included in the usability study. However, the study results showed that fewer high, medium and low severity errors were committed on the Medtronic pump. Here the objective and subjective metrics seem to conflict. Though on average users performed more poorly on the Tandem pump, they preferred the Tandem pump more often than the pump in which they performed better (Medtronic). Nielsen, et.al [121] conducted a metaanalysis of 57 studies to better understand subjective user preference and objective performance. He found that there was a strong positive association between users’ average task performance and their average subjective satisfaction. Therefore it follows that one would have reasonable success if one chooses between systems based solely on users’ opinions. The practical take-away from this study was that both user opinions and preferences are valuable data that should be taken into account when choosing an interface design for example. The data gathered to come to this conclusion, however, was based on complete systems where design changes could not be implemented. The Tandem and Medtronic pumps’ results reflect this performance vs. preference paradox.

The Tandem pump had a preferred physical design that appealed to users. It included a touch, coloured screen as well as transition and animations. The Medtronic pump conveyed features and concepts more clearly such as the I:C ratio format for example which encouraged better performance. In the cases of Tandem and Medtronic, both would benefit from further design and further usability testing to assess more closely user performance.

8.2 Significance of Phases 1 and 2

Two theoretical models were employed in phases 1 and 2 to better uncover patient perceptions of insulin pumps and continuous glucose monitors. These two models, the Health Belief Model
(HBM) and Technology Acceptance Model (TAM) were chosen, because they examine the patient, how they perceive their chronic disease (type 1 diabetes) and how they perceive diabetes technologies. In both phases, perceived barriers and benefits were explained regarding both technologies, in agreement with the health belief model. Perceived barriers included perception of others and self, while benefits included better A1c control and fewer hypoglycemic episodes. Those who had previously considered adoption of these diabetes technologies did not perceive the disease to be enough of a threat to warrant adoption of an insulin pump or CGM which is often a modifying factor for chronic disease management according to the HBM.

Through the interviews, perceived ease of use and usefulness were explained by patients in accordance with the TAM. For example, in the case of the CGM interviews, patients discussed self-efficacy and anxiety as the technology promoted proactivity despite its inconsistency and unreliability, respectively. This discussion of inconsistency and unreliability brokered the topic of trust in the machine which is the most recent addition to the TAM; trust and its relationship to intention of use of the technology.

These findings were consistent in the two phases. Therefore, through interviews guided by both the HBM and the TAM, patient perceptions of the two diabetes technologies and their effectiveness were gathered and can be added to the existing body of literature.

8.3 Significance of Phase 3

From the third phase of this research project, two significant lessons can be learned: best practices in design and priorities for training redesign. These two will be described in detail below.

8.3.1 Best practices in insulin pump design

Based upon the usability study, which included evaluation of the five insulin pumps available in North American, certain best practices in insulin pump design were identified. The first relates to main menu design and was alluded to above. The main menu should display information at a glance, specifically battery life. There should also be a way in which to convey whether a bolus is running. On the main menu should also be a list of all menu options: bolus, settings, suspend/resume, etc. so that a user can see what features are available and make decisions
accordingly from one central location. Without a main menu from which all options are available, users can have difficulties understanding the information architecture of the pump (e.g. Roche).

The menu titles should be descriptive but intuitive. Jargon and special brand terms such as “capture event” for example, do not necessarily convey what is contained in a menu and can lead to confusion, possibly delaying treatment or simply causing user frustration. As was the case for most pumps, features used most frequently should be visible at the top of the menus rather than the bottom. It follows that features more frequently used in a specific menu should be easily accessible at the top of said menu rather than buried with many other features (refer to section 7.4.4).

The same is applicable to icons and buttons for example. In the case of the Roche pump, as mentioned above, the purpose of the two buttons for pump navigation were often confused as their purpose was unclear, leading to unintentional actions which could cause patient safety risks. Buttons should also consistently force the same action. In the case of the Medtronic pump, the ACT and ESC buttons did not consistently result in the same actions in all the menus and this did frustrate users.

Two features specifically should be designed with forcing functions so as to prevent user error readily: the bolus calculator and insulin carb ratio setup. As was the case in the Tandem pump, the bolus calculator should be the only avenue for delivering a bolus: either the user has to input their blood glucose reading or the number of carbohydrates being ingested. Not only does this promote better diabetes management (regular checking of blood glucose readings), but it eliminates risk associated with patients quickly conducting “mental math”. The insulin carb ratio setup should also include forcing functions to promote deliberate programming. As mentioned previously, when users only input start times for the ratios, they were unsure as to what the stop time was. Therefore, the time settings should be generated based on start times: start time of second ratio should be the end time of the first ratio. Furthermore, though forcing functions should exist, the format should be one that promotes the ability to edit readily, as was the case in the Tandem pump.
8.3.2 Priorities for training redesign

The conclusions of this usability study are twofold. First, based on observations during the usability study and the interviews conducted with both users and non-users of diabetes technologies, training can be influenced in two ways. The first way is by emphasizing and clarifying certain aspects of pump use where patients are likely to face the greatest challenges. This emphasis and clarification would take place during a session where a diabetes educator would be training the patient directly, one-on-one.

The second way in which training can be influenced is by creating a type of 6 months to 1 year post-adoption, “checkpoint” such as the one described by Meade et.al [64]. During the insulin pump semi-structured interview phase, two users of the diabetes technology mentioned that they do not use the combo/extended/square wave bolus function. Therefore, a checkpoint survey or interview between the diabetes educator and the patient would likely highlight where the patient may be inappropriately using the pump, or perhaps not maximizing its use (e.g. not using combo/extended/square wave bolus function).

The insulin pump training protocols were adapted from the Toronto General Hospital Diabetes Clinic and at this time, there is not post-adoption training or interview/meeting in place to re-evaluate a patient’s skills in utilizing the pump. However, based on the points of confusion identified in this study, a post-adoption survey could be developed to help patients maximize pump use and optimize diabetes management.

Based on all three phases of this study, especially on observations during the usability study, Table 6 summarizes the priorities to be addressed in training delivered at diabetes clinics. Changes or points of emphasis for each priority are discussed.

Table 6: Priorities for emphasis in future training protocol

<table>
<thead>
<tr>
<th>Issues that are a priority for training redesign</th>
<th>Rationale for Inclusion</th>
<th>Suggested Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarify rationale for use of bolus calculator</td>
<td>It was observed during the usability study that users using all pumps except the Tandem</td>
<td>Users adopting the pump should be discouraged from turning off the bolus calculator</td>
</tr>
</tbody>
</table>
pump, were bypassing the bolus calculator in favor of manually programming a bolus dose. In some cases the dose was incorrect. As mentioned previously, studies have shown that bypassing the bolus calculator regularly can lead to poorer control and diabetes management function and in turn encouraged to make use of the calculator in order to improve accuracy.

Users should also be encouraged to check their blood glucose prior to a bolus and to enter that information so that the calculator can make use of this information for more accurate dosage.

If users are concerned about over-reliance on the machine for diabetes management (mentioned by participants in all 3 phases of this study), they can be reminded that the combo/extended/square wave bolus requires the use of “mental math” in programming a dose.

| Clarify the purpose and format of I:C ratios | When asked to program I:C ratio, depending on the pump manufacturer, users were unsure of the format. Some wanted to program start and end times for the ratio while others could not illicit the end time if only a start time parameter was displayed. When the pump auto-programmed a subsequent start time with the previous ratio’s end time, users were | The purpose of the I:C ratio should be described and explained in greater detail, not only in terms of the pump format but also in terms of diabetes management and the bolus calculator. The connection between the bolus calculator and I:C ratios should also be emphasized by the trainer. Without a |

Clarify the purpose and format of I:C ratios

When asked to program I:C ratio, depending on the pump manufacturer, users were unsure of the format. Some wanted to program start and end times for the ratio while others could not illicit the end time if only a start time parameter was displayed. When the pump auto-programmed a subsequent start time with the previous ratio’s end time, users were

The purpose of the I:C ratio should be described and explained in greater detail, not only in terms of the pump format but also in terms of diabetes management and the bolus calculator.

The connection between the bolus calculator and I:C ratios should also be emphasized by the trainer. Without a
also unable to input the ratios as expected.

The purpose of the ratio also appeared to be unclear to users. Users chose start times and assumed end times that were inappropriate as it would leave hours with no associated I:C ratio. This meant the concept of a ratio was unclear to participants.

| Reducing incidences of default time being left for an extended bolus program | Each pump model had the time parameter for the extended bolus in a different “location”; whether it was underneath the delivery ratio (%) or above. In some cases it was on a different screen altogether. On multiple pumps, users did not change the default time setting to the time asked in the scenario because they either did not see the time parameter (Roche, Tandem pumps), the pump facilitated a bypass over the parameter (Animas pump) or the user was not able to reach the parameter as they pressed a wrong button (Roche pump). | Each pump is programmed with a default time value to encourage the delivery of a combo/extended/square wave bolus, whether the time frame itself is correct or incorrect. The location of the time parameter should be pointed out and emphasized.

The wrong time frame for delivery of an extended bolus can have significant patient safety risks. |
<table>
<thead>
<tr>
<th>Ensure that the status menu/display is being utilized as effectively as possible</th>
</tr>
</thead>
</table>
| As mentioned above in Chapter 7, the battery details were often a source of frustration and in the case of the Animas pump, could not be located. Users did not think to navigate back to the status menu; instead they searched from the main menu for pertinent battery details.  

Furthermore, users were often unsure if a bolus was running or whether the insulin delivery had been suspended.  

There was a lack of attention and time spent on the status menu or status toolbar available on each pump. A lot of information could be elucidated from the status of the pump but this was not clear to participants in the usability study.  

By highlighting the “functions”/icons/information displayed on the status menu or status toolbar on each pump model, trainers would be able to show users a number of ways they can gather information quickly regarding the status of their pump and insulin delivery. For example, on the Medtronic pump, an icon of a circle or a blocked circle is always present on the status toolbar, indicating delivery of insulin or suspension of insulin, respectively.  

On the Insulet pump, the suspension status of the pump is also displayed.  

The battery icon exists on the status display of the Animas pump. Most users were unable to find this information easily without prompting.  

Bolus delivery status is also present on the status toolbar of the Tandem pump.  

Emphasis on how to read and
| Improve response to alert/alarm messages | Users sometimes did not understand the meaning of an error or alert message. For example, on the Insulet, Animas and Roche pumps, users were unsure how to interpret messages that ended in “OK confirm” (press OK to confirm). Users were unsure whether pressing OK would confirm the message or confirm the action to which the message was referring. This left users uneasy and unsure of how to proceed. Reducing uncertainty with these error messages has great potential to improve confidence in pump programming. | Trainers should simulate all error messages on the pumps, in case based scenarios, during training one-on-one. In the demonstration, the trainer could show the user how to identify the message and how to decipher it. The trainer would then be able to solve the issue or confirm the message so that the user would be able to replicate the solution on their own in the future. Through the case based learning, the user would be able to understand how to react to these messages quickly and safely. |
| Ensure users understand the meaning of “suspend/resume” | As seen extensively in the usability study, users had difficulty distinguishing between suspension of a bolus versus a basal dose which could lead to a safety risk since basal suspension would mean the patient was not receiving their insulin at all. This was common among all pump models. | By emphasizing the distinction between a basal and bolus dose and what “suspend/resume” means on each pump, incorrect suspension would be limited. This would further reduce the likelihood of significant safety risks associated with prolonged insulin suspension. |
When the pump alerted the user that no insulin was being administered and that it should be resumed, a few users were unsure what dose would resume: basal or bolus. An emphasis on the meaning of “resume” would also like encourage correct use of the feature.

8.4 Implications of Present Work

The three phases of this study were aimed at gaining a better understanding of patient perceptions of diabetes technologies. The first two phases focused on adoption of these technologies while the last phase had non-insulin pump users interact with the pumps for the first time. This last phase allowed the investigator to gain insight into a patient’s first impression of the pump, possible sources of confusion and possible safety risks associated with pump use.

Where the three studies converged was around the need for ease of interpretation of information. In the first phase (IP perception study), some participants discussed expectations that the pump would be a “miracle cure” and were disappointed when it was not. These participants did not meet success early into their pump adoption and it wasn’t until years later that they were able to interpret what behavioural changes were needed.

In the second phase (CGM perception study), participants mentioned that interpretation of data allowed them to be more proactive in terms of their diabetes management (data=power). On the opposite side of the spectrum, difficulty interpreting data led to calibration errors, often resulting in incorrect insulin dosage.

These findings in the first two phases related to one major finding in the last phase. As mentioned above, Tandem was chosen by 5 of its 6 users for being the best at displaying necessary information, and drawing attention to important messages. Therefore, it is likely that Tandem was perceived as superior because of its ability to illustrate data over the other pumps included in the study. It follows that the ease at which information can be conveyed and
interpreted is vital in diabetes technology design. Looking forward to the artificial pancreas, this is important to note as researchers create a corresponding patient user interface.

8.5 Possible Avenues for Future Work

As mentioned in Chapter 6, there are a number of opportunities where further research can be pursued to discover patient perceptions of diabetes technologies. For example, in the context of technology use; do patient’s perceptions differ if they use the technology intermittently versus all the time?

Also, further research into insulin pump versus multiple daily injections users on CGM would also likely yield new insights regarding perceptions and expectations of CGM technology.

Applying the training recommendations described above in a comparative study would also be a fruitful avenue to explore.

Finally, an area not explored regards the way in which training was delivered in the usability study. The training was modeled after the protocol created at the Toronto General Hospital Diabetes Clinic. However, a case could be made for attempting new training approaches such as a case-based learning approach.
9 Conclusion

The first two semi-structured interview phases identified themes consistent with the Health Belief Model and Technology Acceptance Model. Participants described their perceptions of both insulin pumps and continuous glucose monitors as related to perceived usefulness, perceived ease of use, and trust. Participants also described how diabetes technology adoption was dependent upon perceived seriousness of disease. These interviews focused on the period of adoption and therefore add to the existing body of literature that had been lacking in this area.

The insulin pump usability study yielded a number of recommendations, not only to manufacturers in terms of design, but also for how training can be refocused at diabetes clinics. Best practices in insulin pump design were also highlighted. This lays a few cardinal rules for how diabetes technology—not only insulin pumps but continuous glucose monitors and the artificial pancreas alike—should be designed in the future.
10 References


[23] Linkeschova, R., Raoul, M., Bott, U., Berger, M., et.al, “Less severe hypoglycemia, better metabolic control, and improved quality of life in Type 1 diabetes mellitus with continuous subcutaneous insulin infusion (CSII) therapy; an observational study of 100 consecutive patients followed for a mean of 2 years,” Diabetes Medicine, vol.19, pp.746-751, 2002


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[98] Tattersall, C., Watts, A., Vernon, S., “Mind mapping as a tool in qualitative research.” *Nursing Times*, vol.103, no.26, pp.32-33


Appendix A - CGM Systems Compared

Below in Figure 26 is a table of CGM device specifications from the literature [39].

Figure 26: Features of the Real-Time Continuous Glucose Monitoring Systems [39]
Appendix B – Pump Training Questionnaire and Results from Literature

Below in Figure 27 is the pump questionnaire described above in addition to the study results in Figure 28 [64].

Figure 27: Pump questionnaire [64]
<table>
<thead>
<tr>
<th>Area of Training Deficiency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expired or no basal insulin prescription</td>
<td>83</td>
</tr>
<tr>
<td>No prescription for mupirocin</td>
<td>72</td>
</tr>
<tr>
<td>Lack of insulin syringe</td>
<td>68</td>
</tr>
<tr>
<td>Failure to check ketones</td>
<td>56</td>
</tr>
<tr>
<td>No antiemetic prescription</td>
<td>52</td>
</tr>
<tr>
<td>Using manual bolus</td>
<td>51</td>
</tr>
<tr>
<td>Lack of in-date glucagon kit</td>
<td>44</td>
</tr>
<tr>
<td>No temporary pump removal guidelines</td>
<td>42</td>
</tr>
<tr>
<td>Lack of toiled wrapped ketone strips</td>
<td>39</td>
</tr>
<tr>
<td>Not carrying extra pump supplies</td>
<td>38</td>
</tr>
<tr>
<td>Skips meals when blood glucose is high</td>
<td>35</td>
</tr>
<tr>
<td>Max bolus exceeded</td>
<td>33</td>
</tr>
<tr>
<td>Not changing site if 2 blood glucose values over 250 mg/dL</td>
<td>33</td>
</tr>
<tr>
<td>Uses a syringe to lower blood glucose</td>
<td>33</td>
</tr>
<tr>
<td>No glucagon kit</td>
<td>28</td>
</tr>
<tr>
<td>Care partners do not know how to use glucagon kit</td>
<td>22</td>
</tr>
<tr>
<td>Not giving recommended boluses</td>
<td>18</td>
</tr>
<tr>
<td>Needs to review carbohydrate counting</td>
<td>16</td>
</tr>
<tr>
<td>Not blousing before meals</td>
<td>15</td>
</tr>
<tr>
<td>Not using bolus calculator</td>
<td>15</td>
</tr>
<tr>
<td>Unsure how many carbohydrates to treat</td>
<td>13</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>13</td>
</tr>
<tr>
<td>Unaware of fixed prime amount</td>
<td>12</td>
</tr>
<tr>
<td>Not changing site every 3 days</td>
<td>11</td>
</tr>
<tr>
<td>No thermometer at home</td>
<td>9</td>
</tr>
<tr>
<td>Not carrying treatment for hypoglycemia</td>
<td>6</td>
</tr>
<tr>
<td>Not entering carbohydrates before blousing</td>
<td>6</td>
</tr>
<tr>
<td>Not completing fixed prime with every site change</td>
<td>4</td>
</tr>
</tbody>
</table>

Figure 28: Areas of training deficiency, % [64]
Appendix C – UHN REB Approval Letters

Notification of REB Initial Approval

Date: August 29th, 2013
To: Dr. Joseph Cafazzo
    Rm 5, 4th Floor, R. Fraser Elliott, Toronto General Hospital, 190 Elizabeth St.
    Toronto, Ontario
    Canada
    M5G 2C4

Re: 13-6592-AE
    Adoption of Insulin Pumps: Patient Perceptions of Utility and Usability - Phase 2

REB Review Type: Expedited
REB Initial Approval Date: August 29th, 2013
REB Expiry Date: August 29th, 2014

Documents Approved:
- Protocol  Version date: July 17th, 2013
- Consent Form  Version date: August 27th, 2013
- Recruitment Letter  Version date: August 27th, 2013
- Phone Script  Version date: August 27th, 2013
- Participant Email Recruitment Script  Version date: August 27th, 2013
- Questionnaire  Version date: July 4th, 2013

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing.

Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Best wishes on the successful completion of your project.

Sincerely,

Alan Bartlet, MD PhD FRCPC
Co-Chair, University Health Network Research Ethics Board
Notification of REB Initial Approval

Date: October 11th, 2013
To: Dr. Joseph Cafazzo
    Rm 5, 4th Floor, R. Fraser Elliott, Toronto General Hospital, 190 Elizabeth St.
    Toronto, Ontario
    Canada
    M5G 2C4

Re: 13-6495-AE
    Adoption of Insulin Pumps: Patient Perceptions of Utility and Usability

REB Review Type: Expedited
REB Initial Approval Date: October 11th, 2013
REB Expiry Date: October 11th, 2014

Documents Approved:
- Protocol Version date: September 30th, 2013
- Consent Form Version date: October 10th, 2013
- Recruitment Letter Version date: September 30th, 2013
- Email Recruitment Script Version date: September 30th, 2013
- Interview Script Version date: September 30th, 2013
- Phone Script Version date: September 30th, 2013

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing.

Furthermore, members of the Research Ethics Board who are named as investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Best wishes on the successful completion of your project.

Sincerely,

Alan Bardet, MD PhD FRCPC
Co-Chair, University Health Network Research Ethics Board
University Health Network
Research Ethics Board
10th Floor, Room 1056
700 University Ave
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7649

Notification of REB Initial Approval

To: Mr. Joseph Calazzo
Rm 5, 4th Floor, R. Fraser Elliott, Toronto General Hospital
190 Elizabeth St.
Toronto, Ontario, Canada
M5G 2C4

Re: 13-6932-AE
Adoption of Continuous Glucose Monitors (CGM): Patient Perceptions of Utility and Usability

REB Review Type: Expedited
REB Initial Approval Date: February 10th, 2014
REB Expiry Date: February 10th, 2015

Documents Approved:
- Protocol
- Consent Form
- Recruitment Email
- Recruitment Letter
- Recruitment Telephone Script
- Interview Script
- Pre-test Questionnaire

Version date: January 5th, 2014
Version date: February 2nd, 2014
Version date: February 2nd, 2014
Version date: January 5th, 2014
Version date: January 5th, 2014
Version date: November 6th, 2013

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing.

Furthermore, members of the Research Ethics Board who are named as investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Best wishes on the successful completion of your project.

Sincerely,

[Signature]

Alien Ber Sloot, MD PhD FRCPC
Co-Chair, University Health Network Research Ethics Board
Appendix D – U of T Ethics Approval Letters

Please note the two insulin pump study protocols (interviews and usability study) were submitted for ethics approval from the University of Toronto together.

UNIVERSITY OF
TORONTO

OFFICE OF THE VICE PRESIDENT, RESEARCH

PROTOCOL REFERENCE # 29547

November 6, 2013

Dr. Joseph Catazzo
DEPT OF HEALTH POLICY, MANAGEMENT &
EVALUATION
FACULTY OF MEDICINE

Ms. Isabelle Dutill
DEPT OF HEALTH POLICY, MANAGEMENT &
EVALUATION
FACULTY OF MEDICINE

Dear Dr. Catazzo and Ms. Isabelle Dutill,

Re: Administrative Approval of your research protocol entitled, “Adoption of insulin pumps: Patient perceptions of utility and usability”

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative approval to the above-named research protocol. The level of approval is based on the following role(s) of the University of Toronto (University), as you have identified with your submission and administered under the terms and conditions of the affiliation agreement between the University and the associated TAHSN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-Identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University’s involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

Daniel Gyewu
REB Manager
PROTOCOL REFERENCE # 30048

March 11, 2014

Dr. Joseph Cafazzo  Ms. Isabelle Dutil
DEPT OF HEALTH POLICY, MANAGEMENT & DEPT OF HEALTH POLICY, MANAGEMENT &
evaluation evaluation
FACULTY OF MEDICINE FACULTY OF MEDICINE

Dear Dr. Cafazzo and Ms. Isabelle Dutil,

Re:  Administrative Approval of your research protocol entitled, "Adoption of Continuous Glucose
Monitors (CGM): Patient perceptions of utility and usability"

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative
approval to the above named research protocol. The level of approval is based on the following role(s)
of the University of Toronto (University), as you have identified with your submission and administered
under the terms and conditions of the affiliation agreement between the University and the associated
TAHSHN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-Identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital
Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study
Completion Reports or Amendments to the ORE unless the involvement of the University changes so
that ethics review is required. Please contact the ORE to determine whether a particular change to the
University's involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

Daniel Gyewu
REB Manager
Appendix E – IP Interview Study Protocol

Title Adoption of Insulin Pumps: patient perceptions of utility and usability

Investigator Dr. Joseph Cafazzo, Senior Director
Healthcare Human Factors
Centre for Global eHealth Innovation
(416) 340 4800 x 3634

Study Coordinator Isabelle Dutil, Research Student
Centre for Global eHealth Innovation
416.340.4800 x5514
idutil@ehealthinnovation.org

1. Abstract

Insulin pumps are designed for continuous subcutaneous insulin infusion (CSII) in the treatment of type 1 diabetes mellitus. Four insulin pumps are currently on the market in Canada (Medtronic, Insulet, Animas and Roche), with another entering the market soon (Tandem).

Despite their widespread use in the type 1 diabetes community, there have been few research studies regarding patient barriers to the adoption and use of insulin pumps. Furthermore, little attention has been paid to comparing the usability of these tools.

This study is intended to explore and better understand the burden of care associated with the adoption of CSII. Thus, the goal of the present research is to determine patient
perceptions of CSII and how they perceive benefits and barriers of using this technology. The usability of three insulin pumps will also be evaluated to understand ease of use and the usefulness of the technology. Results will likely inform the design of new insulin pumps able to better meet the needs of its users, improving self-efficacy and enhancing the overall patient experience.

2. Background

Since 2000, up to 700,000 type 1 diabetes patients have adopted a CSII device, the majority of who live in the United States. Reported advantages to the use of CSII include tighter glycemic control, a reduction in hypoglycemic episodes and greater precision with insulin dosing. However, despite these published clinical advantages, several studies examining glycemic control of CSII users have shown that some patients improve on insulin pumps while others do not. Furthermore, other research has also shown that some patients experience anxiety when adopting insulin pumps while others do not. Therefore, the purpose of this research is to examine these relationships: why certain patients choose to adopt the technology and why some improve on the CSII while others do not. This study will differ from previous qualitative studies since it will include a comparative usability testing of the medical devices.

3. Rationale

Results of the proposed project will contribute to the understanding of patient perceived barriers of adoption of insulin pumps and the role the device itself plays in either helping or hindering adoption. Addressing these barriers and understanding why patients may or may not consider these medical devices to be useful, easy to use and trustworthy, can inform the design of new insulin pump technology.

4. Significance

The identified barriers to adoption and themes that emerge from this project will be easily applicable to various research groups developing new insulin pumps and other medical technologies such as the artificial pancreas for the type 1 diabetes mellitus community.
5. Research Overview

The proposed study research is separated into two phases: the first phase involving a semi-structured interview and the second, usability tests. An overview of the study is provided below; we are seeking approval for the entire study.

5.1 Phase 1

The first phase of this project will involve conducting semi-structured interviews with adult T1DM patients in order to identify barriers to the adoption and use of insulin pumps. This work will be conducted by Human Factors Specialists who are trained observers and will take place at the Centre for Global eHealth Innovation.

5.2 Phase 2

In this second phase, three insulin pumps (Omnipod by Insulet, Minimed Paradigm Veo by Medtronic and T-slim by Tandem) will be evaluated in order to assess their usability, effectiveness and ease of use in the simulation lab at Healthcare Human Factors at UHN. These three insulin pumps have been chosen because they differ in approach and design.

6. Procedure

6.1 Phase 1

Participants (adults with type 1 diabetes mellitus) will be asked to spend 1 hour in an in-person semi-structured interview with the test facilitator. The investigators will explain the purpose and methods of the study to the participants and answer any questions they may have.

Prior to being interviewed, participants will be walked through the written consent form (submitted; called Written Consent Form for Phase 1), encouraged to ask any questions, and provided with as much time as needed before signing the form. The consent form will also be signed and dated by the witness (interviewer) in person. Participants will be free to refuse to answer any question that they may find offensive, objectionable or otherwise makes them uncomfortable. All information obtained during
the study will be held in strict confidence. Neither participants’ name nor identifying information will be used in any publication or presentation; they will only be identified through a coded identification number.

Interviews will last approximately one hour and participants will receive a $30 honorarium for their time. From experience with past studies, it is believed that a small honorarium is necessary to generate interest. In the interview, questions (based on the Health Belief Model and the Technology Acceptance Model) will be exploratory in nature (open-ended questions). An outline of the questions that will serve as a guide for the interviews has been included for reference in the table below:

<table>
<thead>
<tr>
<th>Theme</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived severity and threats</td>
<td>1. Please tell me about your diabetes and how you are managing it currently. [Prompt: Which insulin pump are you currently using?] Do you consider your diabetes to be under control? Do you consider your current treatment therapy to be more effective than your previous therapy in controlling your diabetes? Do you want to change your treatment therapy now?</td>
</tr>
<tr>
<td></td>
<td>2. What prompted you to change treatment therapies? [Prompts: Did your doctor/family members suggest it?]</td>
</tr>
<tr>
<td>Perceived anxiety</td>
<td>3. Can you describe the period before you switched from your original treatment therapy to the one you</td>
</tr>
<tr>
<td>Perceived benefits and barriers</td>
<td>4. What was your impression of the new therapy when you started using it? What benefits to you did you see? What did you find difficult when you adopted the therapy?</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Perceived usefulness</td>
<td>5. Did you find that you were managing your diabetes differently when you changed your regime? [Prompts: Please describe any advantages and disadvantages that you saw when you changed treatment therapies]</td>
</tr>
<tr>
<td>Perceptions of external control</td>
<td>6. Please describe the training you received before starting the new therapy</td>
</tr>
<tr>
<td>Perceived self-efficacy and ease of use</td>
<td>7. Can you describe how you felt using your insulin pump on your own after you completed training? [Prompts: Did you have any help (call nurse)? Was there any task in particular that you found easy or difficult to perform? Was there something that could have been done to make it easier for you?]</td>
</tr>
<tr>
<td>Overall perception</td>
<td>8. A continuous glucose monitor is a device that determines glucose</td>
</tr>
</tbody>
</table>
levels every few minutes via a disposable sensor placed under the skin. The sensor is linked to a non-implanted transmitter that communicates glucose levels to another device, worn like a pager. Had you heard of CGM prior to receiving this information? [Prompts: If so, from whom?]

9. What is your impression of this therapy? What do you think the benefits to you could be? What do you think would be difficult for you if you were to adopt this therapy? Would you consider using this therapy?

6.2 Phase 2

The objective of this second part of the research study is to conduct formal usability testing on three insulin pumps. Adults with type 1 diabetes mellitus will be asked to spend roughly two hours interacting with three insulin pumps. Interaction scenarios have been developed for usability testing. The investigators will explain the purpose and methods of the study to the participants and answer any questions they may have. Prior to beginning the usability testing, participants will be walked through the written consent form (submitted; called Written Consent Form for Phase 2), encouraged to ask any questions, and provided with as much time as needed before signing the form. The consent form will also be signed and dated by the witness (interviewer) in person. Participants will be free to refuse to answer any question that they may find offensive,
objectionable or otherwise makes them uncomfortable. All information obtained during the study will be held in strict confidence. Neither participants’ name nor identifying information will be used in any publication or presentation; they will only be identified through a coded identification number.

Usability testing will last approximately two hours and participants will receive a $50 honorarium for their time. From experience with past studies, it is believed that a small honorarium is necessary to generate interest. The tasks that will be used to assess the usability of the insulin pumps are summarized below:

<table>
<thead>
<tr>
<th>Task</th>
<th>Completing Task</th>
</tr>
</thead>
</table>
| Time and Date    | Main menu  
|                  | Navigate to “settings” menu  
|                  | (different name in different pump)  
|                  | Choose correct menu from “settings”  
|                  | Select date/time  
|                  | Put in specific information  
|                  | Return to main menu |
| Navigate History | Navigate to bolus history menu from main menu |
| Bolus Delivery   | Enter carbohydrate content to be consumed  
|                  | Confirm bolus  
<p>|                  | Start bolus |</p>
<table>
<thead>
<tr>
<th>Feature</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolus Delivery over Time</td>
<td>Go to bolus menu and select an advanced bolus menu</td>
</tr>
<tr>
<td></td>
<td>Begin new bolus</td>
</tr>
<tr>
<td>Check last BG value</td>
<td>Navigate to status screen</td>
</tr>
<tr>
<td></td>
<td>Check time/value of last BG taken</td>
</tr>
<tr>
<td>Battery check</td>
<td>Icon on screen or via menus</td>
</tr>
<tr>
<td>Reservoir threshold setup</td>
<td>Navigate to menu</td>
</tr>
<tr>
<td></td>
<td>Set warning to 20 units</td>
</tr>
<tr>
<td></td>
<td>Return to main menu</td>
</tr>
<tr>
<td>Bolus Suspension</td>
<td>Suspend the bolus being delivered</td>
</tr>
<tr>
<td>Carb Ratio Setup</td>
<td>Setup specific ratios/times</td>
</tr>
<tr>
<td></td>
<td>(will be provided)</td>
</tr>
<tr>
<td>Enter BG</td>
<td>Navigate to correct menu for entering blood glucose measurement</td>
</tr>
<tr>
<td></td>
<td>Input correct number</td>
</tr>
<tr>
<td>Lock keypad</td>
<td>Navigate to correct menu</td>
</tr>
<tr>
<td></td>
<td>Lock pump</td>
</tr>
</tbody>
</table>
A pre-testing survey (submitted; called Testing Surveys) will be given to each participant immediately prior to starting the scenarios in order to gauge experience level with insulin pumps and to provide context for data analysis. A post-testing survey (submitted; called Testing Surveys) will also be given after the completion of testing in order to gather qualitative participant insights on any usability issues they found particularly troublesome and the overall perceived ease of use of the insulin pumps.

The semi-structured interviews and usability tests will be conducted in the labs at Healthcare Human Factors based at UHN. The labs themselves are equipped with multiple cameras mounted on the ceiling in addition to microphones. The labs are adjacent to observational rooms with one-way glass where audio and video recording as well as editing takes place. Audio recordings of the interviews and audio/video recordings usability tests will be taken for record keeping purposes after written consent from the participant is obtained. Video recordings are necessary during usability testing in order to capture gestures or any kind of interaction with the technology in order to evaluate usability. The investigators will endeavor to videotape only non-identifying features of the participant by focusing the camera on the participant’s hands and the insulin pump. In the unlikely event that identifying features are captured, the investigators will blur the features. All recordings will be kept confidential and shared only among the study team.

Records of these interviews and usability tests will be kept for a minimum of two years to a maximum of seven years after the completion of the study and then destroyed by shredding of paper or erasing digital information as per previous studies conducted at the Centre for Global eHealth Innovation. Any personal identifiable information will be stored and protected on servers with adequate security measures.

All information that allows correlation between unique identifiers with participant’s personal data and all data collected during the study will be kept secure in a locked filing cabinet. Participant identifying information will not be audio-recorded and participants will only be identified by study number. Audio recordings will be transcribed after the interview and then deleted. Furthermore, participants will be asked to refrain from using any personal identifying information. However, in the event of personal
identifying information being accidentally released, it will be removed from the study data. Though unlikely, if personal health information is disclosed to an unauthorized party, the following actions will be taken: any further release of information will be stopped, as much information as possible will be retrieved, UHN REB and UHN Privacy Offices will be contacted and notified, and then further actions will be taken based on their recommendations.

7. Analysis

7.1 Phase 1

Once a sufficient level of saturation from the interviews is achieved, a general inductive method will be used to analyze the interview transcripts. Notes will be reviewed repeatedly and text segments will be coded for potential themes. As the coding framework is developed, recorded notes will be reanalyzed in light of new themes that may have emerged. Coding will be free of presumptions.

7.1.1 Participant recruitment

Potential participants for this study will be identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants will be given a personal invitation (submitted; called Recruitment Form for Phase 1). After initial contact is made by the TGHDC, participants will be contacted by the study coordinator via the phone (submitted; called Phone Script for Phase 1). At this time, participants will be provided with a details description of the study which will include any information necessary for the participant to give informed voluntary consent.

Potential participants must be an adult (over 18 years of age) with T1DM in order to be included in the study. They must also be able to read, write and speak English and must be willing to participate. Potential participants will be asked to participate on a voluntary basis only.

The total number of participants is to be determined. Participants will be recruited continuously until response saturation is achieved. It is hoped that saturation will be
achieved with 10 individuals. Roughly five individuals currently using an insulin pump and five individuals contemplating adopting (or previously contemplated and rejected) an insulin pump will be recruited. This will allow the research team to amass a larger scope of barriers and benefits to the adoption of insulin pumps.

7.2 Phase 2

Errors include incorrect completion, deviations in completing the task or unintentional slips when completing the task. In addition, qualitative feedback from participants collected in the surveys will also be reported by frequency to allow for contextualization of the quantitative data.

7.2.1 Participant recruitment

Potential participants for this study will be identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants will be given a personal invitation (submitted; called Personal Invitation for Phase 2). After initial contact is made by the TGHDC, participants will be contacted by the study coordinator via the phone (submitted; called Phone Script for Phase 2). At this time, participants will be provided with a details description of the study which will include any information necessary for the participant to give informed voluntary consent.

Potential participants must be an adult (over 18 years of age) with T1DM using an insulin pump, in order to be included in the study. Participants on a pump are being recruited in order to limit training time prior to usability testing. They must also be able to read, write and speak English and must be willing to participate. Potential participants will be asked to participate on a voluntary basis only.

The total number of participants is to be determined. Participants will be recruited continuously until response saturation is achieved. It is hoped that saturation will be achieved with 10 individuals.

7.4 Timeline This research has been projected to be completed in July and August of 2014.
7.5 Risks and Benefits

The participants are put at minimal risk in this study. Possible risks include participant discomfort with sharing their opinions with the study coordinator. Participants will be reminded at the start of the interview and usability testing process that they can withdraw from the study or take breaks at any time should they feel uncomfortable. They will also be reminded that their diabetes care will remain the same since their participation is not directly related to their care.

Participants will not receive direct benefits from participating in this study. Participants are taking part in study where their feedback will enable the development of recommendations for the future design of insulin pumps. In the future, it is possible that these recommendations will be adopted by insulin pumps or other medical device manufacturers (e.g. artificial pancreas manufacturers) and would be available to participants to assist with their daily diabetes management should they be eligible for a new insulin pump or artificial pancreas.

However, it is the human factors specialists and insulin pump researchers that will benefit from a better understand of the needs and perceptions of the participants with regards to the use of these technologies.

8. Dissemination Strategy

We plan to publish our findings in appropriate scientific journals and through presentations at appropriate scientific conferences.

9. Budget

Funding is provided by The Centre for Global eHealth Innovation.
Appendix F – IP Interview Script

Green: both groups of patients

Red: non IP users

Blue: current IP users

[Identifying perceived severity, perceived threats]

Please tell me a little about your diabetes and the insulin therapy (e.g. a pump or injections) that you are currently using or are considering. [Prompt: Do you believe your insulin regimen is effectively controlling your diabetes? Do you feel a change in your insulin therapy is necessary for you to achieve optimal control?]

[Identifying perceived barriers and benefits]

What was your impression of insulin pumps? What did you think the benefits of using a pump are/could be? What did you think would be difficult for you if you were to start using a pump?

[Perceived anxiety]

Please describe your feelings during the period when you contemplated switching your insulin therapy. [Prompts: Did you have any concerns or worries about changing your regime? What concerns affected your decision not to use the pump?]

[Perceived anxiety]

Please describe your feelings during the period before you switched to an insulin pump. [Prompts: Did you have any concerns or worries about changing your regime? Was using the pump what you expected? If not, how was it different?]

Can you describe the process you went through that eventually led you to deciding to use an insulin pump? [Prompts: Was it what you expected? Was there anything that would have made it easier for you to make this decision?]

[Perceived usefulness]
Do you think that with an insulin pump, you would manage your diabetes differently than the way you do currently? [Prompts: Why?] Do you think that using a pump would help you control your diabetes better?

[Perceived usefulness]

Did you find that you managed your diabetes differently when you changed to an insulin pump? [Prompts: What changes were there in how you managed your diabetes? Has using an insulin pump helped you control your diabetes better? Please describe the advantages or disadvantages for you of changing to an insulin pump.]

[Perceived ease of use]

How difficult was it/do you think it would be to use the insulin pump? What kind of features would have/would make it easier to use your pump? What is most difficult?

[Identifying self-efficacy]

How confident were you that you would be able to use your pump effectively once you were trained? What were you most confident/least confident about?

Did you think you would be able to perform this therapy on your own or did you think you would need some help from a nurse or physician? [Prompts: Why?]

Do you think you underwent an adjustment period (or more than one) after starting on the insulin pump? How long do you think it/they lasted? [Prompts: If you identified an adjustment period (s), what do you think happened during that time? Can you identify what it was?]

[Perceptions of external control and identifying self-efficacy]

What kind of training do you think you would need before starting to use a pump? How much training? [Prompts: Why?]

[Perceptions of external control]
Please describe the training you received before starting the new therapy. (What was the most important part of training? Were there pump features that you did not get enough training on?)

Can you suggest anything else that manufacturers or healthcare providers could do to make using an insulin pump easier to accept?
Appendix G – IP Interview Study Consent Form

Consent to Participate in a Research Study

Principal Investigator  Dr. Joseph Cafazzo, Senior Director
Personal Health and Information Technology
Centre for Global eHealth Innovation
(416) 340 4800 x 3634

Study Sponsor  Centre for Global eHealth Innovation

Study Coordinator  Isabelle Dutil, Research Student,
Centre for Global eHealth Innovation
isabelle.dutil@mail.utoronto.ca
idutil@ehealthinnovation.org

Title  Adoption of Insulin Pumps: patient perceptions of utility and usability

Introduction
You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take
part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

**Background and Purpose**

Despite the prominent use of insulin pumps as a diabetes therapeutic tool, to our knowledge, little research has been conducted, examining barriers to adoption of insulin pumps. Thus, the goal of the present research is to understand patient perceptions of insulin pumps and how they perceive benefits and barriers of using this technology.

An estimated ten participants, all adults living with Type 1 Diabetes, will be asked to participate in these interview sessions. You have been asked to take part in this research study because you are an adult with Type 1 Diabetes, who can read, speak and understand English.

**Procedures**

If you agree to participate in the study, you will be asked to participate in an interview with the test facilitator. The session will take place over the phone. The session will last approximately 1 hour and will be audio recorded for data analysis purposes. Records of the session will not be shared with anyone beyond the project team.

**Risks Related to Participation in the Study**

There are no known medical risks associated with this study. If you experience any discomfort due to the study, you are free to stop the session at any time. You are also free to only address questions you are comfortable answering.

**Benefits to Being in the Study**

You will receive no direct benefits as a result of participating in the study. By taking part in this interview, your input will likely shape the development of new standards for the
design of insulin pumps that may benefit people who require daily diabetes management in the future. Research results will be made available to you at the end of the research study.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may refuse to answer any question you do not want to answer by saying “pass”. Participation, refusal to participate, or withdrawal at any time from this study will have no effect on the level of diabetes care provided.

Rights as a Participant

In no way does signing this consent form waive your legal rights nor does it relieve the investigators or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Confidentiality

All information obtained during the study will be held in strict confidence to the extent possible by law. You will be identified with a participant number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study. The interview may be audio recorded for data analysis purposes. The audio recordings will be transcribed following the interview and deleted once transcribed. You will be asked to refrain from using any personal identifying information; however, in the event that you provide personal identifying information it will not be transcribed. If you withdraw from the study, you have the right to request the withdrawal of your information. Let your study facilitator know.

The information that is collected for the study will be kept in a locked and secure area by the study coordinator for a minimum of two and a maximum of seven years as per
previous studies conducted at the Centre for Global eHealth Innovation. Only the study team or the people or groups listed below will be allowed to look at your records.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

• Representatives of the study organizing committee
• University Health Network Research Ethics Board

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

Reimbursement

You will not incur any personal expenses as a result of your participation in the study. To compensate for your time taken to participate, you will be reimbursed $30 following the session.

Sponsorship

Funding is by the Centre for Global eHealth Innovation.

Conflict of Interest

The researchers have an interest in completing this study. Their interests should not influence your decision to participate in the study.

Questions about the Study
If you have any questions, concerns or would like to speak to the study team for any reason, please call the study coordinator: Isabelle Dutil at isabelle.dutil@mail.utoronto.ca or the principal investigator, Dr. Joseph Cafazzo at 416.340.4800x3634.

If you have any questions about your rights as a research participant or have concerns about this study you may contact the Chair of the University Health Network Research Ethics Board (REB) at 416-581-7848. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.
Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

________________________________________  _______________  ____________
Print Study Participant’s Name          Signature            Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

________________________________________  _______________  ____________
Print Name of Person Obtaining Consent  Signature            Date
Appendix H – IP Interview Pre-test Questionnaire

Pre-Test Questionnaire: Personal Information

1. What age range are you in?
   - □ 18-29 years old
   - □ 30-39 years old
   - □ 40-49 years old
   - □ 50-59 years old
   - □ 60-64 years old
   - □ 65 years old and over

2. Are you:
   - □ Male
   - □ Female

3. How long ago were you diagnosed with type 1 diabetes?

4. How are you currently treating your type 1 diabetes?
   - □ Multiple daily insulin injections
   - □ Insulin pump

For insulin pump users:

5. How many years ago did you start using an insulin pump?

6. Which insulin pump are you currently using?
   - □ Omnipod by Insulet
   - □ Accu-check by Roche
   - □ OneTouch Ping by Animas
   - □ Minimed Paradigm Veo by Medtronic

7. Are you familiar with the other pumps available in Canada?
   - □ Not familiar at all
   - □ Have had training on them
   - □ Have used one for _______ months
If you have used another pump previously, please specify which insulin pump:
____________________
Table 7: Pre-test questionnaire results for IP Perception Study

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Age Range</th>
<th>Gender</th>
<th>Years since T1DM diagnosis</th>
<th>MDI or Insulin Pump?</th>
<th>Years since IP adoption</th>
<th>IP Model</th>
<th>Familiar with other IP/any IP (for MDI)</th>
<th>Used other IP previously</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP-1</td>
<td>16-29</td>
<td>F</td>
<td>3</td>
<td>IP</td>
<td>1</td>
<td>Animas</td>
<td>Only through info session</td>
<td>n/a</td>
</tr>
<tr>
<td>IP-2</td>
<td>30-39</td>
<td>F</td>
<td>3.5</td>
<td>IP</td>
<td>2</td>
<td>Medtronic</td>
<td>Only through info session</td>
<td>n/a</td>
</tr>
<tr>
<td>IP-3</td>
<td>18-29</td>
<td>M</td>
<td>7</td>
<td>IP</td>
<td>6</td>
<td>Insulet</td>
<td>yes</td>
<td>Medtronic</td>
</tr>
<tr>
<td>IP-4</td>
<td>30-39</td>
<td>M</td>
<td>27</td>
<td>IP</td>
<td>10</td>
<td>Roche</td>
<td>yes</td>
<td>Medtronic and older Roche model</td>
</tr>
<tr>
<td>IP-5</td>
<td>30-39</td>
<td>F</td>
<td>22</td>
<td>IP</td>
<td>7</td>
<td>Medtronic</td>
<td>Only through info session</td>
<td>n/a</td>
</tr>
<tr>
<td>IP-6</td>
<td>50-59</td>
<td>F</td>
<td>2.5</td>
<td>IP</td>
<td>1.5</td>
<td>Animas</td>
<td>Only through info session</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-1</td>
<td>50-59</td>
<td>F</td>
<td>13</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-2</td>
<td>18-29</td>
<td>M</td>
<td>16</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-3</td>
<td>18-29</td>
<td>M</td>
<td>1</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-4</td>
<td>30-39</td>
<td>M</td>
<td>4</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-5</td>
<td>18-29</td>
<td>F</td>
<td>11</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>MDI-6</td>
<td>18-29</td>
<td>M</td>
<td>18</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Appendix I – CGM Interview Script

Green: both groups of patients

Red: non CGM users

Blue: current CGM users

[Identifying perceived severity, perceived threats]

Please tell me a little about your diabetes and how you use blood glucose measurements to control your diabetes. [Prompt: Do you believe you check your bG enough to effectively controlling your diabetes? Do you feel a change in your regime is necessary for you to achieve optimal control?]

[Identifying perceived barriers and benefits]

What was your impression of CGM? What did you think the benefits of using a CGM are/could be? What did you think would be difficult for you if you were to start using a CGM?

[Perceived anxiety]

Please describe your feelings during the period when you contemplated adopting a CGM. [Prompts: Did you have any concerns or worries about changing your regime? What concerns affected your decision not to use the CGM?]

[Perceived anxiety]

Please describe your feelings during the period before you adopted a CGM. [Prompts: Did you have any concerns or worries about changing your regime? Was using the CGM what you expected? If not, how was it different?]

Can you describe the process you went through that eventually led you to deciding to use a CGM? [Prompts: Was it what you expected? Was there anything that would have made it easier for you to make this decision?]
[Perceived usefulness]

Do you think that with a CGM, you would manage your diabetes differently than the way you do currently? [Prompts: Why?] Do you think that using a CGM would help you control your diabetes better?

[Perceived usefulness]

Did you find that you managed your diabetes differently when you adopted a CGM? [Prompts: What changes were there in how you managed your diabetes? Has using an CGM helped you control your diabetes better? Please describe the advantages or disadvantages for you of adopting a CGM.]

[Perceived ease of use]

How difficult was it/do you think it would be to use a CGM? What kind of features would have/would make it easier to use? What is most difficult?

[Identifying self-efficacy]

How confident were you that you would be able to use your CGM effectively once you were trained? What were you most confident/least confident about?

Did you think you would be able to use this device on your own or did you think you would need some help from a nurse or physician? [Prompts: Why?]

Do you think you underwent an adjustment period (or more than one) after starting on a CGM? How long do you think it/they lasted? [Prompts: If you identified an adjustment period (s), what do you think happened during that time? Can you identify what it was?]

[Perceived self-efficacy and ease of use]

What kind of training do you think you would need before starting to use a CGM? How much training? [Prompts: Why?]

[Perceptions of external control]
Please describe the training you received before starting the new therapy. (What was the most important part of training? Were there features that you did not get enough training on?)

[Overall impression]

Can you suggest anything else that manufacturers or healthcare providers could do to make using a CGM easier to accept?
Title: Adoption of Continuous Glucose Monitors (CGM): patient perceptions of utility and usability

Investigator: Dr. Joseph Cafazzo, Senior Director
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(416) 340 4800 x 3634

Study Coordinator: Isabelle Dutil, Research Student
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idutil@ehealthinnovation.org

1. Abstract

Continuous glucose monitors are responsible for measuring blood glucose in the interstitial fluid every few minutes. The patient receives glucose level updates via an electronic receiver, providing them with the information necessary to take action with regards to insulin administration. Two CGMs are currently on the market in Canada: Medtronic Paradigm Real-Time system and the Dexcom G4 system which was approved by Health Canada in September 2013.
Despite their use in the type 1 diabetes community, there have been few research studies regarding patient barriers to the adoption and use of CGM.

This study is intended to explore and better understand the burden of care associated with the adoption of CGM. Thus, the goal of the present research is to determine patient perceptions of CGM and how they perceive benefits and barriers of using this technology. Results will likely inform the design of new CGM able to better meet the needs of its users, improving self-efficacy and enhancing the overall patient experience.

2. Background

Continuous glucose monitors are responsible for measuring blood glucose in the interstitial fluid every few minutes. Studies have shown that glucose levels in interstitial fluid temporally lag behind blood glucose values by between 5 and 10 minutes which can be significant if the patient is entering what could be a hypoglycemic episode. Despite this revelation, patients using a CGM are more likely to keep their blood sugar in the target range in comparison to type 1 diabetes patients using conventional “finger-stick” blood glucose testing methods. Limited research has been conducted on the use and adoption of CGM since finances pose a barrier to adoption. However, much like insulin pumps, research that has been conducted shows that some patient groups are more likely to use the device than others. Furthermore, some patient groups are likely to experience more anxiety during CGM than others. Therefore, the purpose of this research is to examine these relationships: why certain patients choose to adopt the technology and why some improve on the CGM while others do not.

3. Rationale

Results of the proposed project will contribute to the understanding of patient perceived barriers of adoption of continuous glucose monitors and the role the device itself plays in either helping or hindering adoption. Addressing these barriers and understanding why patients may or may not consider these medical devices to be useful, easy to use and trustworthy, can inform the design of new glucose monitoring technology.
4. Significance

The identified barriers to adoption and themes that emerge from this project will be easily applicable to various research groups developing new continuous glucose monitors and insulin pumps as well as other medical technologies such as the artificial pancreas for the type 1 diabetes mellitus community.

5. Research Overview

The proposed study research involves semi-structured interviews. An overview of the study is provided below; we are seeking approval for the entire study.

This project will involve conducting semi-structured interviews with adult T1DM patients in order to identify barriers to the adoption and use of continuous glucose monitors. This work will be conducted by Human Factors Specialists who are trained observers and will take place at the Centre for Global eHealth Innovation.

6. Procedure

Participants (adults with type 1 diabetes mellitus) will be asked to spend 1 hour in an in-person semi-structured interview with the test facilitator. The investigators will explain the purpose and methods of the study to the participants and answer any questions they may have.

Prior to being interviewed, participants will be walked through the written consent form (submitted; called Written Consent Form), encouraged to ask any questions, and provided with as much time as needed before signing the form. The consent form will also be signed and dated by the witness (interviewer) in person. Participants will be free to refuse to answer any question that they may find offensive, objectionable or otherwise makes them uncomfortable. All information obtained during the study will be held in strict confidence. Neither participants’ name nor identifying information will be used in any publication or presentation; they will only be identified through a coded identification number.
Interviews will last approximately one hour and participants will receive a $30 honorarium for their time. From experience with past studies, it is believed that a small honorarium is necessary to generate interest. In the interview, questions (based on the Health Belief Model and the Technology Acceptance Model) will be exploratory in nature (open-ended questions). An outline of the questions that will serve as a guide for the interviews has been included for reference in the table below:

<table>
<thead>
<tr>
<th>Theme</th>
<th>Questions</th>
</tr>
</thead>
</table>
| Perceived severity and threats | Please tell me a little about your diabetes and how you use blood glucose measurements to control your diabetes. [Prompt: Do you believe you check your bG enough to effectively controlling your diabetes? Do you feel a change in your regime is necessary for you to achieve optimal control?]  
What was your impression of CGM? What did you think the benefits of using a CGM are/could be? What did you think would be difficult for you if you were to start using a pump? |
| Perceived anxiety           | Please describe your feelings during the period when you contemplated adopting a CGM. [Prompts: Did you have any concerns or worries about changing your regime? What concerns affected your decision not to use the pump?]                                                                                     |
| Perceived anxiety | Please describe your feelings during the period before adopting a CGM. [Prompts: Did you have any concerns or worries about changing your regime? Was using the monitor what you expected? If not, how was it different?]

Can you describe the process you went through that eventually led you to deciding to use a CGM? [Prompts: Was it what you expected? Was there anything that would have made it easier for you to make this decision?]

| Perceived usefulness | Do you think that with a CGM, you would manage your diabetes differently than the way you do currently? [Prompts: Why?]

Do you think that using a CGM would help you control your diabetes better?

Did you find that you managed your diabetes differently when you adopted a CGM? [Prompts: What changes were there in how you managed your diabetes? Has using an CGM helped you control your diabetes better? Please describe the
<table>
<thead>
<tr>
<th>Perceived ease of use</th>
<th>How difficult was it/do you think it would be to use a CGM? What kind of features would have/would make it easier to use? What is most difficult?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceptions self - efficacy</td>
<td>How confident were you that you would be able to use your CGM effectively once you were trained? What were you most confident/least confident about?</td>
</tr>
<tr>
<td></td>
<td>Did you think you would be able to use this device on your own or did you think you would need some help from a nurse or physician? [Prompts: Why?]</td>
</tr>
<tr>
<td></td>
<td>Do you think you underwent an adjustment period (or more than one) after starting on a CGM? How long do you think it/they lasted? [Prompts: If you identified an adjustment period (s), what do you think happened during that time? Can you identify what it was?]</td>
</tr>
<tr>
<td>Perceived self-efficacy and ease of use</td>
<td>What kind of training do you think you would need before starting to use a CGM? How much training? [Prompts: Why?]</td>
</tr>
<tr>
<td>Perceptions of External Control</td>
<td>Please describe the training you received before starting the new therapy. (What was the most important part of training? Were there features that you did not get enough training on?)</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Overall Impression</td>
<td>Can you suggest anything else that manufacturers or healthcare providers could do to make using an insulin pump easier to accept?</td>
</tr>
</tbody>
</table>

A pre-interview survey (submitted; called *Testing Survey*) will be given to each participant immediately prior starting the interview in order to gauge experience level with continuous glucose monitors and to provide context for data analysis.

Participants will be contacted post-interview and be asked if they are willing to answer 4 more questions similar to those asked in the pre-interview survey. Participants will be told the additional information is being asked of them for data clarification and analysis. Participants will be told their continued participation is voluntary. Participants will be reminded they can refuse to answer any question at any time should they feel uncomfortable. They will also be reminded that their diabetes care will remain the same since their continued participation is not directly related to their care.

The semi-structured interviews will be conducted in the labs at Healthcare Human Factors based at UHN. The labs themselves are equipped with multiple cameras mounted on the ceiling in addition to microphones. The labs are adjacent to observational rooms with one-way glass where audio recording as well as editing takes place. Audio recordings of the interviews will be taken for record keeping purposes after written consent from the participant is obtained. All recordings will be kept confidential and shared only among the study team.
Records of these interviews will be kept for a minimum of two years to a maximum of seven years after the completion of the study and then destroyed by shredding of paper or erasing digital information as per previous studies conducted at the Centre for Global eHealth Innovation. Any personal identifiable information will be stored and protected on servers with adequate security measures.

All information that allows correlation between unique identifiers with participant’s personal data and all data collected during the study will be kept secure in a locked filing cabinet. Participant identifying information will not be audio-recorded and participants will only be identified by study number. Audio recordings will be transcribed after the interview and then deleted. Furthermore, participants will be asked to refrain from using any personal identifying information. However, in the event of personal identifying information being accidentally released, it will be removed from the study data. Though unlikely, if personal health information is disclosed to an unauthorized party, the following actions will be taken: any further release of information will be stopped, as much information as possible will be retrieved, UHN REB and UHN Privacy Offices will be contacted and notified, and then further actions will be taken based on their recommendations.

7. Analysis

Once a sufficient level of saturation from the interviews is achieved, a general inductive method will be used to analyze the interview transcripts. Notes will be reviewed repeatedly and text segments will be coded for potential themes. As the coding framework is developed, recorded notes will be reanalyzed in light of new themes that may have emerged. Coding will be free of presumptions.

7.1 Participant Recruitment

Potential participants for this study will be identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants will be given a personal invitation (submitted; called Recruitment Form). After initial contact is made by the TGHDC, participants will be contacted by the study coordinator via the phone (submitted; called Phone Script).
At this time, participants will be provided with a details description of the study which will include any information necessary for the participant to give informed voluntary consent.

Potential participants must be an adult (over 18 years of age) with T1DM in order to be included in the study. They must also be able to read, write and speak English and must be willing to participate. Potential participants will be asked to participate on a voluntary basis only.

The total number of participants is to be determined. Participants will be recruited continuously until response saturation is achieved. It is hoped that saturation will be achieved with 8 individuals. Roughly four individuals currently using a continuous glucose monitor and four individuals contemplating adopting (or previously contemplated and rejected) a CGM will be recruited. This will allow the research team to amass a larger scope of barriers and benefits to the adoption of CGM.

7.2 Timeline

This research has been projected to be completed by June of 2014.

7.3 Risks and Benefits

The participants are put at minimal risk in this study. Possible risks include participant discomfort with sharing their opinions with the study coordinator. Participants will be reminded at the start of the interview process that they can withdraw from the study or take breaks at any time should they feel uncomfortable. They will also be reminded that their diabetes care will remain the same since their participation is not directly related to their care.

Participants will not receive direct benefits from participating in this study. Participants are taking part in study where their feedback will enable the development of recommendations for the future design of CGM. In the future, it is possible that these recommendations will be adopted by insulin pumps or other medical device manufacturers (e.g. artificial pancreas manufacturers) and would be available to
participants to assist with their daily diabetes management should they be eligible for a new CGM or artificial pancreas.

However, it is the human factors specialists and CGM researchers that will benefit from a better understand of the needs and perceptions of the participants with regards to the use of these technologies.

8. Dissemination Strategy

We plan to publish our findings in appropriate scientific journals and through presentations at appropriate scientific conferences.

9. Budget

Funding is provided by The Centre for Global eHealth Innovation.
Appendix K – CGM Interview Study Consent Form

Consent to Participate in a Research Study

Principal Investigator  Dr. Joseph Cafazzo, Senior Director
Personal Health and Information Technology
Centre for Global eHealth Innovation
(416) 340 4800 x 3634

Study Sponsor  Centre for Global eHealth Innovation

Study Coordinator  Isabelle Dutil, Research Student,
Centre for Global eHealth Innovation
isabelle.dutil@mail.utoronto.ca
idutil@ehealthinnovation.org

Title  Adoption of Continuous Glucose Monitors: patient perceptions of utility and usability
Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

Despite the relatively prominent use of continuous glucose monitors (CGM) as a diabetes therapeutic tool, to our knowledge, little research has been conducted, examining barriers to adoption of CGMs. Thus, the goal of the present research is to understand patient perceptions of CGMs and how they perceive benefits and barriers of using this technology.

An estimated ten participants, all adults living with Type 1 Diabetes, will be asked to participate in these interview sessions. You have been asked to take part in this research study because you are an adult with Type 1 Diabetes, who can read, speak and understand English.

Procedures

If you agree to participate in the study, you will be asked to participate in an interview with the test facilitator. The session will take place over the phone or in person. The session will last approximately 1 hour and will be audio recorded for data analysis purposes. Records of the session will not be shared with anyone beyond the project team.
Risks Related to Participation in the Study

There are no known medical risks associated with this study. If you experience any discomfort due to the study, you are free to stop the session at any time. You are also free to only address questions you are comfortable answering.

Benefits to Being in the Study

You will receive no direct benefits as a result of participating in the study. By taking part in this interview, your input will likely shape the development of new standards for the design of CGMs that may benefit people who require daily diabetes management in the future. Research results will be made available to you at the end of the research study.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may refuse to answer any question you do not want to answer by saying “pass”. Participation, refusal to participate, or withdrawal at any time from this study will have no effect on the level of diabetes care provided.

Rights as a Participant

In no way does signing this consent form waive your legal rights nor does it relieve the investigators or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Confidentiality

All information obtained during the study will be held in strict confidence to the extent possible by law. You will be identified with a participant number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study. The interview may be audio recorded for data analysis purposes. The audio recordings will be transcribed following the interview and deleted once transcribed. You will be asked to
refrain from using any personal identifying information; however, in the event that you provide personal identifying information it will not be transcribed. If you withdraw from the study, you have the right to request the withdrawal of your information. Let your study facilitator know.

The information that is collected for the study will be kept in a locked and secure area by the study coordinator for a minimum of two and a maximum of seven years as per previous studies conducted at the Centre for Global eHealth Innovation. Only the study team or the people or groups listed below will be allowed to look at your records.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

• Representatives of the study organizing committee
• University Health Network Research Ethics Board

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

Reimbursement

You will not incur any personal expenses as a result of your participation in the study. To compensate for your time taken to participate, you will be reimbursed $30 following the session.

Sponsorship

Funding is by the Centre for Global eHealth Innovation.

Conflict of Interest
The researchers have an interest in completing this study. Their interests should not influence your decision to participate in the study.

**Questions about the Study**

If you have any questions, concerns or would like to speak to the study team for any reason, please call the study coordinator: Isabelle Dutil at [isabelle.dutil@mail.utoronto.ca](mailto:isabelle.dutil@mail.utoronto.ca) or [idutil@ehealthinnovation.org](mailto:idutil@ehealthinnovation.org) or the principal investigator, Dr. Joseph Cafazzo at 416.340.4800x3634.

If you have any questions about your rights as a research participant or have concerns about this study you may contact the Chair of the University Health Network Research Ethics Board (REB) at 416-581-7848. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.
Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

_________________________  ______________________  ____________
Print Study Participant’s Name  Signature  Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________  ______________________  ____________
Print Name of Person Obtaining Consent  Signature  Date
Appendix L – CGM Interview Pre-test Questionnaire

Pre-Test Questionnaire: Personal Information

1. What age range are you in?
   - ☐ 18-29 years old
   - ☐ 30-39 years old
   - ☐ 40-49 years old
   - ☐ 50-59 years old
   - ☐ 60-64 years old
   - ☐ 65 years old and over

2. Are you:
   - ☐ Male
   - ☐ Female

3. How long ago were you diagnosed with type 1 diabetes?

4. How are you currently treating your type 1 diabetes?
   - ☐ Multiple daily insulin injections
   - ☐ Insulin pump

For CGM users:

5. How many years ago did you start using a CGM?

6. Which CGM are you currently using?
   - ☐ Medtronic
   - ☐ Dexcom

7. How often do you use your CGM?

8. Are you familiar with the other CGM available in Canada?
   - ☐ Not familiar at all
   - ☐ Have had training on them
☐ Have used one for _______ months

If you have used another CGM previously, please specify which one: ____________________
Table 8: Pre-test questionnaire results for CGM Perception Study

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Age Range</th>
<th>Gender</th>
<th>Years since T1DM diagnosis</th>
<th>MDI or Insulin Pump?</th>
<th>Years since IP adoption</th>
<th>Years since CGM adoption</th>
<th>CGM Model</th>
<th>How often do you use CGM?</th>
<th>Familiar with other or in general CGM? (for NCGM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM-1</td>
<td>60-64</td>
<td>M</td>
<td>45</td>
<td>IP</td>
<td>5</td>
<td>5</td>
<td>Medtronic</td>
<td>always</td>
<td>yes</td>
</tr>
<tr>
<td>CGM-2</td>
<td>18-29</td>
<td>M</td>
<td>25</td>
<td>IP</td>
<td>4</td>
<td>4</td>
<td>Medtronic</td>
<td>Every 2 weeks</td>
<td>yes</td>
</tr>
<tr>
<td>CGM-3</td>
<td>30-39</td>
<td>M</td>
<td>8</td>
<td>IP</td>
<td>6</td>
<td>0.5</td>
<td>Dexcom</td>
<td>always</td>
<td>yes</td>
</tr>
<tr>
<td>CGM-4</td>
<td>18-29</td>
<td>F</td>
<td>17</td>
<td>IP</td>
<td>8</td>
<td>4</td>
<td>Medtronic</td>
<td>Every 2 weeks</td>
<td>yes</td>
</tr>
<tr>
<td>CGM-5</td>
<td>50-59</td>
<td>M</td>
<td>8</td>
<td>IP</td>
<td>5</td>
<td>5</td>
<td>Medtronic</td>
<td>always</td>
<td>yes</td>
</tr>
<tr>
<td>CGM-6</td>
<td>18-29</td>
<td>F</td>
<td>16</td>
<td>IP</td>
<td>8</td>
<td>0.2</td>
<td>Dexcom</td>
<td>always</td>
<td>yes</td>
</tr>
<tr>
<td>NCGM-1</td>
<td>18-29</td>
<td>F</td>
<td>11</td>
<td>IP</td>
<td>1</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NCGM-2</td>
<td>18-29</td>
<td>M</td>
<td>2</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NCGM-3</td>
<td>18-29</td>
<td>F</td>
<td>17</td>
<td>MDI</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NCGM-4</td>
<td>50-59</td>
<td>F</td>
<td>16</td>
<td>IP</td>
<td>4.5</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NCGM-5</td>
<td>18-29</td>
<td>M</td>
<td>14</td>
<td>IP</td>
<td>11</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NCGM-6</td>
<td>18-29</td>
<td>M</td>
<td>17</td>
<td>IP</td>
<td>11</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>
Table 9: Additional demographic questions posed to participants after completion of study (fewer participants responded to survey than participated in interview)

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Highest degree or level of school completed</th>
<th>Approximate household income</th>
<th>Current Profession</th>
<th>Comfort with technology</th>
<th>Last HbA1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCGM-1</td>
<td>Bachelor’s degree</td>
<td>$50,000 to $74,999</td>
<td>Logistics</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>6.8</td>
</tr>
<tr>
<td>NCGM-3</td>
<td>Bachelor’s degree</td>
<td>$35,000 to $49,999</td>
<td>Accounting Clerk</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>7.2</td>
</tr>
<tr>
<td>NCGM-4</td>
<td>Master’s degree</td>
<td>Prefer not to answer</td>
<td>Project Manager</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>8.4</td>
</tr>
<tr>
<td>NCGM-5</td>
<td>Bachelor’s degree</td>
<td>$35,000 to $49,999</td>
<td>Tech Assistant</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>7.6</td>
</tr>
<tr>
<td>CGM-1</td>
<td>Bachelor’s degree</td>
<td>$50,000 to $74,999</td>
<td>Retired engineer</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>6.4</td>
</tr>
<tr>
<td>CGM-2</td>
<td>Master’s degree</td>
<td>$75,000 to $99,999</td>
<td>Statistician</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>7.4</td>
</tr>
<tr>
<td>CGM-4</td>
<td>Master’s degree</td>
<td>$25,000 to $34,999</td>
<td>Student</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>7.7</td>
</tr>
<tr>
<td>CGM-6</td>
<td>1 or more years of college, no degree</td>
<td>$25,000 to $34,999</td>
<td>Student</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>7.7</td>
</tr>
</tbody>
</table>
Appendix M – Description of 5 Insulin Pumps Evaluated in Usability Study

Medtronic Paradigm

The Medtronic Paradigm is a traditional pump in that long tubing connects the insulin reservoir to the infusion set, approximately 1.5 feet in length which requires the patient to keep the pump on their person, whether it’s on their belt loop or in their bra. This can limit the number of locations where the infusion set can be inserted. The pump has five hard-keys: up/down arrows, an ACT button, ESC button and a quick bolus button, ‘B’ (See Figure 29).

If the screen is asleep, pressing the ACT button brings the user to the main menu which feeds can feed up to 7 menus (depending on whether menus have been activated): 1. Bolus, 2. Suspend, 3. Sensor, 4. Capture Event, 5. Basal, 6. Reservoir + Set, 7. Utilities.

If a basal or bolus dose is being delivered, this is indicated by a circle icon on the top left hand corner of the screen (See Figure 30). If there is an occlusion or the delivery has been stopped, the circle appears filled. On the top right hand corner is a battery icon with 5 segments. On the right side of the screen is a scroll bar icon so that a user is able to glance at the bar and estimate how long the home menu is. In each menu, the menu title is written in all capital letters to indicate which menu the user is navigating (See Figure 31).

The bolus calculator on the Medtronic pump is called the Bolus Wizard. The advanced bolus features are called dual or square wave bolus.

Figure 29: Medtronic Paradigm Pump
Main Menu

Figure 30: Example of difference
The pump has a ‘normal’ bolus feature that allows a user to choose the number of units to be delivered and to deliver them without inputting carbs eaten or bG reading. This allows the user to have a certain degree of freedom.

Animas OneTouch Ping

The Animas One-Touch Ping is a traditional pump in that the cartridge attaches to tubing, approximately 1.5 feet in length. This requires patients to keep the pump on their belt loop or bra for example, depending on preference. The Animas pump can be navigated with three pumps: up/down arrows and an OK soft key (See Figure 32). In order to select a menu or option, it must first be highlighted. In order to scroll through numbers or options in a menu (e.g. setup advanced menu), the number must be highlighted and flashing. No home button exists on this pump. A Home option at the bottom of the screen is available in most menus (or a Back button), that can allow the user to return to the main menu.

When the pump is first turned on, a status screen is displayed, showing battery level (segmented into thirds), basal rate, time and the insulin on board (See Figure 34). The main menu feeds seven menus: 1. Bolus, 2. Suspend/Resume, 3. History, 4. Basal, 5. Setup, 6. Prime/Rewind, 7. Status (See Figure 33). The bolus calculator in this Animas pump is called “ezCarb” and the advanced bolus feature is called a ‘Combo’ bolus. Features and options such as low reservoir warning and I:C ratios are found in the setup, advanced menu. There are 10 ‘Setup Adv.’ pages in this menu which include
the Max Limits page for example, in addition to other predictable setup options such as timeout time and contrast.

Six status pages are available in the Status menu, including active basal, insulin on board (IOB), delivery today, combo bolus, temp basal and codes.

The pump has a ‘normal’ bolus feature that allows a user to program and deliver any desired insulin dose, up to 16U, without inputting their bG reading or the number of carbs being ingested.

**Insulet Omnipod**

The Insulet Omnipod different from the other four insulin pumps included in this study in that there is no traditional infusion line that requires the patient to keep the pump attached to their belt loop or in their bra for example, depending on the patient’s preference. The Omnipod consists of a disposable infusion pump (Pod) and a personal diabetes manager (PDM): the Pod being a tubing-less reservoir that can adhere to the patient’s skin while the PDM, can be kept in the patient’s pocket, backpack or purse (within 2 feet) (See Figure 34).

The PDM is a hand-held, battery-powered remote controller of the Pod. The PDM and Pod communicate through Bluetooth. Wireless connection is only required to set a bolus delivery, change systems settings, perform BG measurements or change the Pod. When the Pod is filled with insulin, the PDM is used to activate it and when ready to be discarded, the Pod must be deactivated. After a 3 day expiry limit, the Pod will alarm if it has not be changed. The PDM provides the other audio alarms, alerts, and reminders related to insulin delivery, reservoir level, Pod functioning and battery life.

**Figure 34: Insulet Omnipod system: Pod (left) and PDM (right)**
The PDM has seven functional buttons, a back-lit coloured display and a BG meter. The BG meter facilitates BG measurement where data can be stored easily. The PDM has a row of soft-keys near the bottom of the screen that allow for option selection when presented at the bottom of the screen, such as “confirm” or “save” as well as “back”. Below the soft keys is a circular button that allows for up/down functionality as well as the on/home button and help button denoted by a question mark.

The battery level on the PDM is shown in the top left hand corner and depending on the action being done by the POD, whether it’s a basal dose or bolus dose that will also be denoted by an icon at the top of the screen. The time and date are also visible. The home menu feeds the bolus menu, a ‘more actions’ menu, a temp basal menu, My records menu, Settings menu, Suspend/resume menu and depending on user settings, food library and BG history menus as well (See Figure 35).

The PDM provides the ability to calculate a suggested bolus dosage. This acts as a “convenience” to the user to aid in determining bolus dosage needed based on carbohydrates ingested, most recent BG reading, user-set correction factor, insulin to carbohydrate ratio, target BG and duration of insulin action.

When turning the pump on, the pump status is displayed, showing the POD expiry date in addition to any pertinent information regarding bolus doses and basal rates.
Roche AccuChek

The Roche AccuChek is much like the Medtronic pump in that it incorporates traditional tubing. Unlike the Medtronic, the pump comes with a remote control or meter that allows a user to program a bolus for example, from the meter without having to expose their pump from under their shirt. The pump has an automated bolus calculator or diary functions. The pump has two soft keys, a menu button and a check mark (See Figure 36). On the side of the pump are up and down arrows. The menus are designed so that a series of menu options are available only when the pump is running, while a different set exists when the pump is not running. This is likely to limit safety risks when using the pump; certain functions are not enabled to ensure insulin delivery happens seamlessly for example.

The remote meter has two soft-keys directly below the screen for use when options for confirmation and “back” are presented at the bottom of the screen. Below the two soft keys is a circle of buttons (up, down, left, right) with a button in the centre for maneuvering through menus. A soft ON-button is situated in the lower left side of the remote meter. This device also doubles as a glucose meter as test strips can be fed into the bottom of the meter to be test and logged (See Figure 37).

When the pump is running, there are a dozen menus available. From any menu, further menus can be reached by pushing the ‘menu’ button. There is no indication on the screen as to the number of menus accessible in any given source menu.

Tandem t-slim

The Tandem t-slim is the only insulin pump in this group not available in Canada. This pump differs from the previous as it has a colour touch screen. Like the majority of the pumps being evaluated, it is comprised

Figure 37: Roche AccuChek remote meter

Figure 38: Tandem t:slim main menu
of traditional tubing and requires the user to keep the pump either in their belt or in their bra.

From the main menu there are two menu options: Bolus and Options (See Figure 38). At the top left hand corner, the battery icon can be found, with percentage of power remaining indicated below the icon. The icon is green in colour until it reaches approximately 25% when it turns yellow, followed by red as the battery drains. The amount of insulin remaining in the cartridge is indicated on the top right hand corner.

If the user presses the top right, status information is displayed such as the bolus rate (See Figure 39). The time and date are found at the top, in the middle of the screen. Insulin on Board is indicated at the bottom of the screen. On the top of the pump is a hard key, called the Wake button, for turning the screen on and off. By default, if the screen is dark, the pump is locked. The logo on the right hand side of the pump doubles as a ‘Home’ button.

This particular device differs from the previous four mentioned in that a user does not have the ability to choose a dose of insulin without either putting in a blood glucose reading or using the carbohydrate calculator (See Figure 40). This adds a level of safety not currently present in the four others pump available on the market. However, it does remove a feeling of independence from the user since they are no longer able to choose the dose they feel appropriate and deliver it.
Appendix N – Counterbalance for Usability Study

Below in Figure 41 find the counterbalance for the insulin pump usability study.

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<th>Participant #</th>
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**Legend**

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<td>Animas</td>
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<td>D</td>
<td>Insulet</td>
</tr>
<tr>
<td>E</td>
<td>Tandem</td>
</tr>
</tbody>
</table>

**Figure 41: Insulin pump testing order for usability study**
Appendix O – Training Scripts for all 5 Insulin Pumps Evaluated in Usability Study

Medtronic Training Script

This is the Medtronic Paradigm pump. It’s a traditional pump in that there is traditional tubing that’s usually around 2 feet in length. The pump can be kept on your belt in a holder or in your bra. The cartridge [point out] is where the insulin is held. This is the home screen of the pump and if you want to see pump status information; you can press the ESC button. From the home menu you can perform any tasks you might need. To see the main menu again, you can press the ACT button. The up and down arrow buttons are used for navigating up and down in menus or for dialing numbers up or down. The B button is not going to be including either in the training or in the scenarios. At the top of the screen you can see the date and the battery icon.

a. **Time/Date:** When you first get the pump you might want to personalize it with the date and time. You can change the date and time from the Utilities menu on the Main Menu. When the number is flashing you can then dial up or down to change the date, time, etc.

b. **Input BG:** Let’s say you want to input your next BG reading because you were using the pump as a log book. From the main menu, you can move to the capture event menu and from there you can input the reading you got when you tested (hypothetically in this case). You can dial up or down and then choose to save the reading or not.

c. **Bolus:** If you want to deliver a bolus, you can do so by clicking on the Bolus menu. There are a few ways in which a bolus can be delivered. If you wanted to make use of the Bolus calculator, you could do that or you could deliver the bolus manually which means you choose the number of units to be delivered on your own. If you use the Bolus calculator, you can input your BG reading or not, enter the number of carbs you are eating and the pump will make a recommendation regarding how many units you should deliver. Because I just put in my BG reading it’s already there. I can put in the carbs I’m eating hypothetically; let’s say 5g. Now I’m going to deliver.

d. **Suspend:** If you want to suspend a bolus for whatever reasons, can click on the suspend menu option on the main screen and once you are ready to resume insulin delivery, can press resume.
e. IC Ratio: When you get a pump, you and your diabetes educator would determine what carb ratios are appropriate for you at any given time of the day. Those ratios allow your Bolus calculator to make recommendations. If you and your pump nurse or whoever it might be, decide to change your insulin carb ratios or add them in the first place, from the main menu, you can navigate to the Bolus Menu and from there, you can go to the Bolus Setup, edit the setting -> Wizard. There you can enter the start time and the ratio. You can theoretically have as many ratios as you want.

f. Extended: If you wanted, you are able to deliver a bolus over time. This can be used if you exercise for example and you know that your blood sugar changes over time and you want to compensate accordingly. You can put a % of how much is delivered at any given time like 0% now, 100% or 10% now, 90% later. If you want to extend the amount of time over which your bolus is delivered, you can do so on an insulin pump. There is a time parameter and you can dial up or down the unit being hours: minutes. From the bolus menu, go to bolus setup - you must first ensure that the bolus menu is on. Input the units you want and over the amount of time that you want. You can then deliver the bolus.

g. Locking: If you were going to exercise, sleep or anything like that and you didn’t want to change any of your pump settings, you might want to lock your keypad. You can do so form the Utilities menu as well. To unlock, you can press the B and upwards arrow at the same time.

h. Reservoir Warnings: If you are interested in setting up a low reservoir warning, meaning that you want an alert when you only have so many units of insulin left, you can navigate to the Utilities menu and find the alarm menu where you will be able to input the units at which you want to receive that alert. If you wanted you could also set up a time so that based on your basal rate for example, the pump would be able to tell you when you only have 3 hours’ worth of insulin left.

i. History: If you are interested in seeing previous bolus doses, etc. from the main menu, navigate to the bolus menu and click on bolus history.

j. BG History: If you are interested in knowing your previous BG reading since you can’t remember what it was, from the blank screen (when pump screen is sleeping), click the ESC
button and you can see what it was. There is also a history option in the Capture Event menu where you can see BG readings you inputted previously like the one I did a few minutes ago.

Alright, we’re all done the training! I’ll let you get started on the scenarios.

**Animas One Touch Training Script**

This is the Animas One Touch Ping pump. It’s a traditional pump in that there is traditional tubing that’s usually around 2 feet in length. The pump can be kept on your belt in a holder or in your bra. The cartridge [point out] is where the insulin is held. To get the screen to come alive, you can press the OK button. This is the status screen where you can see the battery icon, the time, basal rate, etc. We aren’t going to be talking about basal doses in this study. If you want to get to the main menu, you can click main menu; press OK to select an option. There are two arrows here: up and down and they allow you to navigate the menus and dial numbers up and down. This is the main menu and from there you can perform most tasks you might need.

**a. Time/Date:** When you first get the pump you might want to personalize it with the date and time. In order to setup your pump settings such as the date and time, on the pump, you can by going to the main menu, reaching the setup settings and changing the time/date. If you want to change a specific parameter or a specific number, you have to click OK once to select it and then again until it’s flashing. When you’re satisfied with a number, you can press OK and the pump will automatically move your cursor to the next changeable parameter.

**b. Bolus:** In order to give a bolus in a testing pump as this, the first thing to do it to go to the bolus menu from the main menu, click on the ezCarb option and enter the carbs to be consumed. You could also click on Normal bolus and just input the number of insulin units you wish to give yourself, manually. If you do choose to use the ezCarb option and enter the carbs to be consumed it will make a recommendations. From there, you can click on the Show Result and under bolus total screen, you can dial up the suggested bolus amount shown at the top of the screen, calculated by the bolus calculator based on your I:C ratio applicable at the time. If you want to ignore the suggested amount you can just choose a different value that you feel is more appropriate. You can then hit GO when ready to deliver.
c. **Suspend:** If you go to deliver a bolus and then change your mind or it’s incorrect, can select the suspend/resume. If you want to resume, you have to go back to the Main Menu and his that same option again in order to resume insulin delivery.

d. **IC ratios:** When you get a pump, you and your diabetes educator would determine what carb ratios are appropriate for you at any given time of the day. Those ratios allow your Bolus calculator to make recommendations. If you and your pump nurse or whoever it might be, decide to change your insulin carb ration or add them in the first place you can do so on the pump. In order to setup IC ratios, that has to be done on the pump itself. In this case, you would go to Settings, Advanced, then the advanced 7 menu and click the I:C ratio and change any applicable values. You first have to put in the time unit followed by the ratio itself. You can have up to 12 ratios. You can add the next one by clicking on the side arrow here. If you want to navigate home, you can do so from here as well.

e. **Extended:** If you are interested in delivering that bolus over a longer stretch of time, which is possible on an insulin pump, you can go to the bolus menu and click on the combo bolus function. You can then enter the amount to be delivered in units and the time period over which you want it delivered. Press GO when ready to proceed.

f. **Locking:** If you were going to exercise, sleep or anything like that and you didn’t want to change any of your pump settings, to lock and unlock this pump, hold the up and down arrows at the same time.

g. **Reservoir Warnings:** When you first get a pump, you will likely have to set up a reservoir alarm limit. This means that you want an alert when you only have so many units of insulin left. In order to do, click on the advanced menus from the setup options and choose advanced 6 on the pump itself. You can then change the low cartridge warning.

h. **History:** On the pump itself, you can check bolus history over the last day by going to the system status, pump status from the main menu. You can go to history -> and choose TDD and see entries OR you can see individual bolus doses by going to Bolus history and scrolling through the entries.

Alright, we’re all done the training! I’ll let you get started on the scenarios.
Insulet Omnipod Training Script

This pump is different from the more, perhaps, traditional pumps because there is no tubing. This smaller piece, called a POD is what you attach to your body. The other piece is called a Personal Diabetes Manager or PDM. You can keep it in your pocket or your purse for example, since you aren’t as restricted by tube length. The POD and PDM have to be within 2 feet to communicate.

I’m just going to set up the cannula here since if it’s not infusing saline in this case, the PDM won’t work for the purposes of this study. Any and all insulin delivery is set up using this PDM. PODs expire within 72 hours and there is an 8 hour cushion. The battery is now shown directly; if the battery is dying you will get an alert.

There are three buttons here below the screen and they will allow you to execute commands that are displayed right at the bottom the screen. The rest of the buttons will allow you to navigate through the menus and dial up or down numbers, for example since there is an up/down arrow. You can use the side arrows to move into menus. The home button is at the bottom. The battery icon is at the top of the screen and there is a status menu here that will tell you when to change the POD.

a. **Time/Date:** When you first get the pump you might want to personalize it with the date and time and you would go to the Settings menu, System Setup and then enter the data and time. You can also choose your format.

In order to perform tasks like this, you always have to suspend the infusion of saline in this case. Suspension can last up to 2 hours before you have to reset delivery parameters. The minimum suspension time is 30 minutes but if you want to restart insulin delivery before the 30 minutes have passed, you can do that.

b. **Input BG:** If you want to add a BG reading to your PDM for record keeping since it can act as a logbook, from the main menu, select the More Actions menu and Add a BG reading in order to do so. You can then save the reading.

c. **Bolus:** If you want to bolus, it is the first option on the main menu. It will ask you if you want to use the bolus calculator to which you can say yes or no. If you say yes, the pump will ask you
to input the number of carbs you’re eating. It will make a recommendation and can choose to deliver it or not.

d. Suspend: If you want to suspend the bolus, click on the bottom left “cancel” option.

e. IC Ratio: When you get a pump, you and your diabetes educator would determine what carb ratios are appropriate for you at any given time of the day. Those ratios allow your Bolus calculator to make recommendations. You and your pump nurse or whoever it might be, decide to change your insulin carb ratio or decide to add them in the first place, you can navigate to the system setup, choose, bolus/basal/calcs, followed by ratios/factors/targets and then change the IC ratio. It will walk your through each step of setup [show how].

f. Extended: If you wanted, you are able to deliver a bolus over time. This can be used if you exercise for example and you know that your blood sugar changes over time and you want to compensate accordingly. You can put a % of how much is delivered at any given time like 0% now, 100% or 10% now, 90% later. Instead of pressing Enter where you might have before when setting up a regular bolus to be delivered completely upfront, you can press extend and input whatever numbers you need to.

g. Locking: If you want to lock your PDM in case you are throwing it into your purse or your pocket, you can navigate to the system setup menu, from Settings, find PDM options and select for the PDM lock function to be: off. You can also change backlight time out like you would a cell phone for example. If you want to unlock it, you’ll see that the only menus that are able to be navigated in a locked state are those that can take you to the unlock option.

h. Alarms: If you are interested in setting up a low reservoir warning, meaning that you want an alert when you only have so many units of insulin left go to System Setup, and go to Alarms and reminders to change your low reservoir alarm parameters.

i. History: If you want to go through previous history on the pump, can go to the My Records menu and see carb history, alarm history or all history.

Alright, we’re all done the training! I’ll let you get started on the scenarios.
Roche AccuChek Training Script

This is the Roche AccuChek pump. It’s a traditional pump in that there is traditional tubing that’s usually around 2 feet in length. The pump can be kept on your belt in a holder or in your bra. The cartridge [point out] is where the insulin is held. There is also a remote and the two communicate through Bluetooth. Some functions can be used/programmed on both the pump and the remote and some on one of the other. On the pump you have to think of almost two columns of menu options: those available when the pump is running and those when the pump is off. Some menu options aren’t available when the pump is on and some aren’t when the pump is off. This first menu is the “status” screen which is like the resting position of the pump, like a main menu.

If you want to navigate through the pump there are four buttons. The “menu” or “file” button at the top allows you to move through the menus and through the parameters or options in each menu. If you want to confirm something or save it, you have to press the checkmark button. If you want to dial up or down numbers or options, you can use the two buttons on the side of the pump.

a. **Time/Date:** When you first get the pump you might want to personalize it with the date and time. Navigate to time and date settings. Use the file/menu button to move from one unit to the next (month, year, etc.) and the up and down arrows to change the date, etc. when done the process, press the check mark. If you change one, the other should also change (pump/remote). There may be a time delay.

b. **Input BG:** In this system, the remote meter double as a glucometer so that you can input your test strips and it will determine your BG and log the information. You cannot use this system and manually enter BG reading you got from a different glucometer.

c. **Bolus:** If you wanted to deliver a bolus, **on the remote meter**, go to Bolus Advice, and move to the bolus entry. You can input the number of carbs you want to eat. You would then confirm the bolus and this info would be sent to the pump and the bolus would be delivered.
If you wanted to deliver the bolus on the pump itself, pump ON, click on standard bolus menu, dial up on the arrows on the side of the pump and then press the check mark and the bolus would be delivered.

d. Suspending: If you wanted to suspend the bolus because it was incorrectly programmed for example, you can stop the pump itself, by pressing on that menu option.

e. IC ratios: When you get a pump, you and your diabetes educator would determine what carb ratios are appropriate for you at any given time of the day. Those ratios allow your Bolus calculator to make recommendations. you and your pump nurse or whoever it might be, decide to change your insulin carb ration or want to add them in the first place, on the meter, you would go to the settings menu, click on Bolus Advice and then click on Time Blocks; from there you could change the ratios for different times of day. You can only input end time and then ratio you want. You can ignore sensitivity and the other parameters that can be changed on this menu.

f. Extended bolus: If you wanted to deliver an extended bolus on the pump, you might click on the extended bolus menu, dial up the units using the side buttons. Press the file button and move to the time input. Once that’s completed, you could then start the infusion by pressing the checkmark.

You cannot deliver an extended bolus from the meter.

g. Locking pump: If you want to lock the remote meter, go to Settings, then meter, then Key Lock and click on or off. On the pump, if it’s running, you can go to pump settings and click the up or down arrow to lock or unlock and then save the setting. You can unlock the pump from the remote meter in the Pump menu (and also lock it in the same menu) or follow the instructions on the pump screen itself.

h. Bolus History: If you wanted to check your bolus history on the pump, you can check this if the pump is OFF. Go to “My data” and check bolus data this way.

On the remote meter, you can go to main menu and click on My data and click “View Data”.

i. BG history: on remote meter, if you click on “view data” under my data, you would be able to see the BG reading that was last inserted. This particular machine is different because you can
test your BG on it; that’s what it expects. You could also click on “Reports” and look up bG averages for the last week, month, etc.

Alright, we’re all done the training! I’ll let you get started on the scenarios.

**Tandem t:slim Training Script**

This is the Medtronic Paradigm pump. It’s a traditional pump in that there is traditional tubing that’s usually around 2 feet in length. The pump can be kept on your belt in a holder or in your bra. The cartridge [point out] is where the insulin is held. This pump is different because it is a touch screen. It’s also only available in the USA right now.

If you hit the silver button on the top of the screen, the screen lights up and to unlock you tap the number icons as they are highlighted. If you want to lock the screen, you can just hit that top silver button once more.

Because it’s a touch screen there are number pads on the screens where applicable. If you want to return to the main menu, you can use the “back” options available for example, or alternatively, you can press on the Logo on the right side. The battery icon is right at the top of the screen on the left and the date is in the centre of the top toolbar. The pump status is available if you tap the top right cartridge icon.

**a. Time/Date:** When you first get the pump you might want to personalize it with the date and time. From home screen, tap on Options tab and then My Pump. Click Pump Settings and from there, Time and Date can be edited. Once done, verify and tap Done/Save where necessary.

**b. Input BG:** If you wanted to put in a new BG reading, you would go to the Bolus menu, enter the reading, but then leave the menu without bolusing since that would not have been your purpose.

**c. Bolus:** Basal has to be running in order for this to be programmable. Click on Bolus from the home screen and click on the Carbs button and enter the number of carbs to be ingested. Press done when completed and note the number of units. Press next, confirm and make sure extended is OFF. Then deliver. You can also input your BG and the pump will recommend whether a
bolus is necessary or not to restore your BG to the target range you would have previously programmed.

d. Suspend: If you want to suspend the bolus just delivered, press the “x” button on the home screen on the right side of the bolus tab.

e. IC Ratio: When you get a pump, you and your diabetes educator would determine what carb ratios are appropriate for you at any given time of the day. Those ratios allow your Bolus calculator to make recommendations. If you and your pump nurse or whoever it might be, decide to change your insulin carb ratios or add them in the first place, click on the Options menu, followed by My Pump and Personal Profiles. Click on the “Day” option and “Add” to add a certain IC ratio that you might have chosen with your diabetes nurse. You can assume that the correction factor will have already been inputted.

f. Extended: If you wanted, you are able to deliver a bolus over time. This can be used if you exercise for example and you know that your blood sugar changes over time and you want to compensate accordingly. You can put a % of how much is delivered at any given time like 0% now, 100% or 10% now, 90% later. Click on the Bolus menu from the home screen and enter the number of carbs to be delivered let’s say. Give the blood glucose measurement in mg/L which is the American unit rather than mmol/L. Confirm the calculation and click to turn the extended function ON. You can decide how much insulin you want delivered now and how much later and over how much time you want it delivered. Confirm to proceed.

g. Locking: Screen locks after 2 minutes of inactivity. I showed you the unlock earlier.

h. Reservoir Warnings: If you are interested in setting up a low reservoir warning, meaning that you want an alert when you only have so many units of insulin left, you can navigate to Options tab, followed by My Pump, Alert Settings, alerts, low insulin and then change the number of units. Press done/save to confirm the change you made.

i. Bolus History: To find bolus history, go the Options tab and click on the History menu. From there, click on the Bolus menu tab and click on the most recent date in order to view recent bolus history.
j. **BG History**: To find bolus history, go the Options tab and click on the History menu. From there, click on the BG menu tab and click on the most recent date in order to view recent BG history.

Alright, we’re all done the training! I’ll let you get started on the scenarios.
Appendix P – Testing Environment Photos

(Top) testing room; (Bottom) observation room where cameras were controlled and second reviewer took notes
Title: Adoption of Insulin Pumps: patient perceptions of utility and usability

Investigator: Dr. Joseph Cafazzo, Senior Director
Healthcare Human Factors
Centre for Global eHealth Innovation
(416) 340 4800 x 3634

Study Coordinator: Isabelle Dutil, Research Student
Centre for Global eHealth Innovation
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1. Abstract

Insulin pumps are designed for continuous subcutaneous insulin infusion (CSII) in the treatment of type 1 diabetes mellitus. Four insulin pumps are currently on the market in Canada (Medtronic, Insulet, Animas and Roche), with another entering the market soon (Tandem).

Despite their widespread use in the type 1 diabetes community, there have been few research studies regarding patient barriers to the adoption and use of insulin pumps. Furthermore, little attention has been paid to comparing the usability of these tools.

This study is intended to explore and better understand the burden of care associated with the adoption of CSII. Thus, the goal of the present research is to determine patient
perceptions of CSII and how they perceive benefits and barriers of using this technology. The usability of three insulin pumps will also be evaluated to understand ease of use and the usefulness of the technology. Results will likely inform the design of new insulin pumps able to better meet the needs of its users, improving self-efficacy and enhancing the overall patient experience.

2. Background

Since 2000, up to 700,000 type 1 diabetes patients have adopted a CSII device, the majority of who live in the United States. Reported advantages to the use of CSII include tighter glycemic control, a reduction in hypoglycemic episodes and greater precision with insulin dosing. However, despite these published clinical advantages, several studies examining glycemic control of CSII users have shown that some patients improve on insulin pumps while others do not. Furthermore, other research has also shown that some patients experience anxiety when adopting insulin pumps while others do not. Therefore, the purpose of this research is to examine these relationships: why certain patients choose to adopt the technology and why some improve on the CSII while others do not. This study will differ from previous qualitative studies since it will include a comparative usability testing of the medical devices.

3. Rationale

Results of the proposed project will contribute to the understanding of patient perceived barriers of adoption of insulin pumps and the role the device itself plays in either helping or hindering adoption. Addressing these barriers and understanding why patients may or may not consider these medical devices to be useful, easy to use and trustworthy, can inform the design of new insulin pump technology.

4. Significance

The identified barriers to adoption and themes that emerge from this project will be easily applicable to various research groups developing new insulin pumps and other medical technologies such as the artificial pancreas for the type 1 diabetes mellitus community.
5. Research Overview

The proposed study research is separated into two phases: the first phase involving a semi-structured interview and the second, usability tests. An overview of the study is provided below; we are seeking approval for the entire study.

5.1 Phase 1

The first phase of this project will involve conducting semi-structured interviews with adult T1DM patients in order to identify barriers to the adoption and use of insulin pumps. This work will be conducted by Human Factors Specialists who are trained observers and will take place at the Centre for Global eHealth Innovation.

5.2 Phase 2

In this second phase, three insulin pumps (Omnipod by Insulet, Minimed Paradigm Veo by Medtronic and T-slim by Tandem) will be evaluated in order to assess their usability, effectiveness and ease of use in the simulation lab at Healthcare Human Factors at UHN. These three insulin pumps have been chosen because they differ in approach and design.

6. Procedure

6.1 Phase 1

Participants (adults with type 1 diabetes mellitus) will be asked to spend 1 hour in an in-person semi-structured interview with the test facilitator. The investigators will explain the purpose and methods of the study to the participants and answer any questions they may have.

Prior to being interviewed, participants will be walked through the written consent form (submitted; called Written Consent Form for Phase 1), encouraged to ask any questions, and provided with as much time as needed before signing the form. The consent form will also be signed and dated by the witness (interviewer) in person. Participants will be free to refuse to answer any question that they may find offensive, objectionable or otherwise makes them uncomfortable. All information obtained during
the study will be held in strict confidence. Neither participants’ name nor identifying information will be used in any publication or presentation; they will only be identified through a coded identification number.

Interviews will last approximately one hour and participants will receive a $30 honorarium for their time. From experience with past studies, it is believed that a small honorarium is necessary to generate interest. In the interview, questions (based on the Health Belief Model and the Technology Acceptance Model) will be exploratory in nature (open-ended questions). An outline of the questions that will serve as a guide for the interviews has been included for reference in the table below:

<table>
<thead>
<tr>
<th>Theme</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perceived severity and threats</strong></td>
<td>1. Please tell me about your diabetes and how you are managing it currently. [Prompt: Which insulin pump are you currently using?] Do you consider your diabetes to be under control? Do you consider your current treatment therapy to be more effective than your previous therapy in controlling your diabetes? Do you want to change your treatment therapy now?</td>
</tr>
<tr>
<td></td>
<td>2. What prompted you to change treatment therapies? [Prompts: Did your doctor/family members suggest it?]</td>
</tr>
<tr>
<td><strong>Perceived anxiety</strong></td>
<td>3. Can you describe the period before you switched from your original treatment therapy to the one you</td>
</tr>
<tr>
<td>Perceived benefits and barriers</td>
<td>4. What was your impression of the new therapy when you started using it? What benefits to you did you see? What did you find difficult when you adopted the therapy?</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Perceived usefulness</td>
<td>5. Did you find that you were managing your diabetes differently when you changed your regime? [Prompts: Please describe any advantages and disadvantages that you saw when you changed treatment therapies]</td>
</tr>
<tr>
<td>Perceptions of external control</td>
<td>6. Please describe the training you received before starting the new therapy</td>
</tr>
<tr>
<td>Perceived self-efficacy and ease of use</td>
<td>7. Can you describe how you felt using your insulin pump on your own after you completed training? [Prompts: Did you have any help (call nurse)? Was there any task in particular that you found easy or difficult to perform? Was there something that could have been done to make it easier for you?]</td>
</tr>
<tr>
<td>Overall perception</td>
<td>8. A continuous glucose monitor is a device that determines glucose</td>
</tr>
</tbody>
</table>
levels every few minutes via a disposable sensor placed under the skin. The sensor is linked to a non-implanted transmitter that communicates glucose levels to another device, worn like a pager. Had you heard of CGM prior to receiving this information? [Prompts: If so, from whom?]

9. What is your impression of this therapy? What do you think the benefits to you could be? What do you think would be difficult for you if you were to adopt this therapy? Would you consider using this therapy?

6.2 Phase 2

The objective of this second part of the research study is to conduct formal usability testing on three insulin pumps. Adults with type 1 diabetes mellitus will be asked to spend roughly two hours interacting with three insulin pumps. Interaction scenarios have been developed for usability testing. The investigators will explain the purpose and methods of the study to the participants and answer any questions they may have. Prior to beginning the usability testing, participants will be walked through the written consent form (submitted; called Written Consent Form for Phase 2), encouraged to ask any questions, and provided with as much time as needed before signing the form. The consent form will also be signed and dated by the witness (interviewer) in person. Participants will be free to refuse to answer any question that they may find offensive,
objectionable or otherwise makes them uncomfortable. All information obtained during the study will be held in strict confidence. Neither participants’ name nor identifying information will be used in any publication or presentation; they will only be identified through a coded identification number.

Usability testing will last approximately two hours and participants will receive a $50 honorarium for their time. From experience with past studies, it is believed that a small honorarium is necessary to generate interest. The tasks that will be used to assess the usability of the insulin pumps are summarized below:

<table>
<thead>
<tr>
<th>Task</th>
<th>Completing Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time and Date</td>
<td>Main menu&lt;br&gt;Navigate to “settings” menu&lt;br&gt;(different name in different pump)&lt;br&gt;Choose correct menu from “settings”&lt;br&gt;Select date/time&lt;br&gt;Put in specific information&lt;br&gt;Return to main menu</td>
</tr>
<tr>
<td>Navigate History</td>
<td>Navigate to bolus history menu from main menu</td>
</tr>
<tr>
<td>Bolus Delivery</td>
<td>Enter carbohydrate content to be consumed&lt;br&gt;Confirm bolus&lt;br&gt;Start bolus</td>
</tr>
</tbody>
</table>
| **Bolus Delivery over Time** | Go to bolus menu and select an advanced bolus menu  
Begin new bolus |
| **Check last BG value** | Navigate to status screen  
Check time/value of last BG taken |
| **Battery check** | Icon on screen or via menus |
| **Reservoir threshold setup** | Navigate to menu  
Set warning to 20 units  
Return to main menu |
| **Bolus Suspension** | Suspend the bolus being delivered |
| **Carb Ratio Setup** | Setup specific ratios/times  
(Will be provided) |
| **Enter BG** | Navigate to correct menu for entering blood glucose measurement  
Input correct number |
| **Lock keypad** | Navigate to correct menu  
Lock pump |
A pre-testing survey (submitted; called Testing Surveys) will be given to each participant immediately prior starting the scenarios in order to gauge experience level with insulin pumps and to provide context for data analysis. A post-testing survey (submitted; called Testing Surveys) will also be given after the completion of testing in order to gather qualitative participant insights on any usability issues they found particularly troublesome and the overall perceived ease of use of the insulin pumps.

The semi-structured interviews and usability tests will be conducted in the labs at Healthcare Human Factors based at UHN. The labs themselves are equipped with multiple cameras mounted on the ceiling in addition to microphones. The labs are adjacent to observational rooms with one-way glass where audio and video recording as well as editing takes place. Audio recordings of the interviews and audio/video recordings usability tests will be taken for record keeping purposes after written consent from the participant is obtained. Video recordings are necessary during usability testing in order to capture gestures or any kind of interaction with the technology in order to evaluate usability. The investigators will endeavor to videotape only non-identifying features of the participant by focusing the camera on the participant’s hands and the insulin pump. In the unlikely event that identifying features are captured, the investigators will blur the features. All recordings will be kept confidential and shared only among the study team.

Records of these interviews and usability tests will be kept for a minimum of two years to a maximum of seven years after the completion of the study and then destroyed by shredding of paper or erasing digital information as per previous studies conducted at the Centre for Global eHealth Innovation. Any personal identifiable information will be stored and protected on servers with adequate security measures.

All information that allows correlation between unique identifiers with participant’s personal data and all data collected during the study will be kept secure in a locked filing cabinet. Participant identifying information will not be audio-recorded and participants will only be identified by study number. Audio recordings will be transcribed
after the interview and then deleted. Furthermore, participants will be asked to refrain from using any personal identifying information. However, in the event of personal identifying information being accidentally released, it will be removed from the study data. Though unlikely, if personal health information is disclosed to an unauthorized party, the following actions will be taken: any further release of information will be stopped, as much information as possible will be retrieved, UHN REB and UHN Privacy Offices will be contacted and notified, and then further actions will be taken based on their recommendations.

7. Analysis

7.1 Phase 1

Once a sufficient level of saturation from the interviews is achieved, a general inductive method will be used to analyze the interview transcripts. Notes will be reviewed repeatedly and text segments will be coded for potential themes. As the coding framework is developed, recorded notes will be reanalyzed in light of new themes that may have emerged. Coding will be free of presumptions.

7.1.1 Participant recruitment

Potential participants for this study will be identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants will be given a personal invitation (submitted; called Recruitment Form for Phase 1). After initial contact is made by the TGHDC, participants will be contacted by the study coordinator via the phone (submitted; called Phone Script for Phase 1). At this time, participants will be provided with a details description of the study which will include any information necessary for the participant to give informed voluntary consent.

Potential participants must be an adult (over 18 years of age) with T1DM in order to be included in the study. They must also be able to read, write and speak English and must be willing to participate. Potential participants will be asked to participate on a voluntary basis only.
The total number of participants is to be determined. Participants will be recruited continuously until response saturation is achieved. It is hoped that saturation will be achieved with 10 individuals. Roughly five individuals currently using an insulin pump and five individuals contemplating adopting (or previously contemplated and rejected) an insulin pump will be recruited. This will allow the research team to amass a larger scope of barriers and benefits to the adoption of insulin pumps.

7.2 Phase 2

Errors include incorrect completion, deviations in completing the task or unintentional slips when completing the task. In addition, qualitative feedback from participants collected in the surveys will also be reported by frequency to allow for contextualization of the quantitative data.

7.2.1 Participant recruitment

Potential participants for this study will be identified by the Toronto General Hospital Diabetes Clinic (TGHDC). Participants will be given a personal invitation (submitted; called Personal Invitation for Phase 2). After initial contact is made by the TGHDC, participants will be contacted by the study coordinator via the phone (submitted; called Phone Script for Phase 2). At this time, participants will be provided with a details description of the study which will include any information necessary for the participant to give informed voluntary consent.

Potential participants must be an adult (over 18 years of age) with T1DM using an insulin pump, in order to be included in the study. Participants on a pump are being recruited in order to limit training time prior to usability testing. They must also be able to read, write and speak English and must be willing to participate. Potential participants will be asked to participate on a voluntary basis only.

The total number of participants is to be determined. Participants will be recruited continuously until response saturation is achieved. It is hoped that saturation will be achieved with 10 individuals.
7.4 Timeline

This research has been projected to be completed in July and August of 2014.

7.5 Risks and Benefits

The participants are put at minimal risk in this study. Possible risks include participant discomfort with sharing their opinions with the study coordinator. Participants will be reminded at the start of the interview and usability testing process that they can withdraw from the study or take breaks at any time should they feel uncomfortable. They will also be reminded that their diabetes care will remain the same since their participation is not directly related to their care.

Participants will not receive direct benefits from participating in this study. Participants are taking part in study where their feedback will enable the development of recommendations for the future design of insulin pumps. In the future, it is possible that these recommendations will be adopted by insulin pumps or other medical device manufacturers (e.g. artificial pancreas manufacturers) and would be available to participants to assist with their daily diabetes management should they be eligible for a new insulin pump or artificial pancreas.

However, it is the human factors specialists and insulin pump researchers that will benefit from a better understand of the needs and perceptions of the participants with regards to the use of these technologies.

8. Dissemination Strategy

We plan to publish our findings in appropriate scientific journals and through presentations at appropriate scientific conferences.

9. Budget

Funding is provided by The Centre for Global eHealth Innovation.
Consent to Participate in a Research Study

**Principal Investigator**  
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**Study Sponsor**  
Centre for Global eHealth Innovation

**Study Coordinator**  
Isabelle Dutil, Research Student,  
Centre for Global eHealth Innovation  
416.340.4800 x5514  
idutil@ehealthinnovation.org

**Title**  
Adoption of Insulin Pumps: patient perceptions of utility and usability

**Introduction**

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask
the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

**Background and Purpose**

In Canada, four insulin pumps are available to type 1 diabetes patients. A fifth is being designed and considered for the Canadian marketplace. Despite its prominence as a diabetes therapeutic tool, to our knowledge, little or no research has been conducted, comparing the usability of these five tools. A device's usability can refer to its ease of use and how intuitive the device is to the user. This project will engage adults with type 1 diabetes mellitus in the evaluation of three existing pumps. Three of the five insulin pumps have been chosen because they differ in approach and design. It is the goal of the research team to gain a better understanding of the usability of each insulin pump. Results will likely inform the design of new insulin pumps able to better meet the needs of its users, improving self-efficacy and enhancing the overall patient experience.

An estimated ten participants, all adults living with Type 1 Diabetes and using an insulin pump, will be asked to participate in these interview sessions. You have been asked to take part in this research study because you are an adult with Type 1 Diabetes, who can read, speak and understand English.

**Procedures**

If you agree to participate in the study, you will be asked to use 3 different insulin pumps in several different scenarios. You will be asked to use the pumps to complete tasks that are typical to an insulin pump users daily diabetes management. As you do activities, you will be asked to “think aloud” and share your thoughts and opinions regarding the safety, usefulness and ease of use of each pump. Please comment on anything you like or dislike, as well as potential areas of improvement as you proceed through the tasks. You will not be asked to use the pump on yourself to administer insulin. The patient information provided will be fictitious.
Before the session, you will be asked to complete a pre-test questionnaire consisting of background information related to your experience with insulin pumps. After using the devices, you will be asked to complete a survey on your general impressions and specific preferences or concerns about each pump.

The session will take place at the human factors lab located within the Centre for Global eHealth Innovation, Toronto General Hospital. The session will last between 1 and 2 hours and will be video recorded for data analysis purposes. In videotaping, the investigators will endeavor to capture only non-identifying images of your hands interacting with the insulin pumps provided. Any identifying features (e.g. face) accidently captured by the camera will be blurred by the investigators. Records of the session will not be shared with anyone beyond the project team.

**Risks Related to Participation in the Study**

There are no known medical risks associated with this study. If you experience any discomfort due to the study, you are free to stop the session at any time. You are also free to only address questions you are comfortable answering.

**Benefits to Being in the Study**

You will receive no direct benefits as a result of participating in the study. By taking part in this study, your input will shape the development of new standards for the design of insulin pumps that you may be able to use at a later time to assist with daily diabetes management. Research results will be made available to you at the end of the research study.

**Voluntary Participation**

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may refuse to answer any question you do not want to answer by saying “pass”. Participation, refusal to participate, or withdrawal at any time from this study will have no effect on the level of diabetes care provided.
Rights as a Participant

In no way does signing this consent form waive your legal rights nor does it relieve the investigators or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Confidentiality

All information obtained during the study will be held in strict confidence to the extent possible by law. You will be identified with a participant number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study. The interview may be audio and video recorded for data analysis purposes. The audio recordings will be transcribed following the interview and deleted once transcribed. Video recordings will be reviewed for the interviewer to take notes after the interview and will be deleted once reviewed. You will be asked to refrain from using any personal identifying information; however, in the event that you provide personal identifying information it will not be transcribed. If you withdraw from the study, you have the right to request the withdrawal of your information. Let your study facilitator know.

The information that is collected for the study will be kept in a locked and secure area by the study coordinator for a minimum of two and a maximum of seven years as per previous studies conducted at the Centre for Global eHealth Innovation. Only the study team or the people or groups listed below will be allowed to look at your records.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

• Representatives of the study organizing committee
• University Health Network Research Ethics Board
All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

**Reimbursement**

You will not incur any personal expenses as a result of your participation in the study. To compensate for your time taken to participate, you will be reimbursed $50 at the end of the session.

**Sponsorship**

Funding is provided by the Centre for Global eHealth Innovation.

**Conflict of Interest**

The researchers have an interest in completing this study. Their interests should not influence your decision to participate in the study.

**Questions about the Study**

If you have any questions, concerns or would like to speak to the study team for any reason, please call the study coordinator, Isabelle Dutil at 416.340.4800 x5514 or the principal investigator, Dr. Joseph Cafazzo at 416.340.4800 x3634.

If you have any questions about your rights as a research participant or have concerns about this study you may contact the Chair of the University Health Network Research Ethics Board (REB) at 416-581-7848. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.
Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

_________________________    ________________________    ________________
Print Study Participant’s Name    Signature    Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions

_________________________    ________________________    ________________
Print Name of Person Obtaining Consent    Signature    Date
Appendix R – Usability Study Script

Testing

Before testing:

We are working with the Toronto General Hospital Diabetes Clinic to conduct a study, which will be able to inform insulin pump training in the future for patients considering adopting an insulin pump. We use a user-centric approach to evaluate product designs.

The session you are about to go through is part of that process. As we progress through the [morning/afternoon] you will be helping us to understand your needs and what is important to you. We are in no way evaluating or testing you.

There are no wrong answers. We would like you to tell us what you are thinking as you go through the exercises. We also encourage you to ask questions as you go; while we may not answer them immediately, we will answer all of your questions at the end of the interview.

You are in complete control of the session today so if you would like to take a break or stop participating for any reason please let us know. Enter facilitator:

Thank you very much for joining us. You will be asked to undergo a number of tasks on an insulin pump that a user would have to complete on a typical day. I’m first going to introduce you to the pump and then have you interact with it. There are three pumps that you will be interacting with today. During the scenarios, I will be in the room with you, and I might ask for your opinion about a feature for example, or ask you to explain something you said. We ask that you think aloud, which means we want to hear your entire stream of consciousness [give example].

OK – let’s get started

Task 1
“You have just received your new pump and you want to customize it. Please enter the correct time (12:15 pm) and date (July 1, 2014) and then return to the main menu.”

GIVE PUMP TO PARTICIPANT

HAND TASK WRITTEN DOWN TO PARTICIPANT

---

Set up Pump

Turn on

Device Set-Up

Main menu

Navigate to “settings” menu (different name in different pump)

Choose correct menu from “settings”

Select date/time

Put in specific information

Return to main menu

**Medtronic**: Utilities menu, time/date

**Roche**: Settings, time and date settings

**Insulet**: settings menu, system setup, date/time

**Animas**:

-on remote meter: main menu, meter settings, customize, settings, time format and then date format
-on pump: main menu, setup, time/date

**Tandem**: Options, My Pump, Pump Settings, Time and Date, click on “

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Task 2

“You are at your doctor’s office and he asks you to tell him about your most recent insulin bolus history. Please read him that information.”

**Navigate History**

Navigate to bolus history menu from main menu

*Medtronic:* Bolus menu, Bolus history

*Roche:* **They can do either**

-On remote meter: My data menu, view data and then right-click “select view” for bolus data OR go to view data and looks at report menu to look at bG trends

-On pump: My data, bolus data (1st screen), use side buttons to scroll through dates

*Insulet:* My records menu, insulin delivery, can do insulin totals for today or bolus history or all history menu

*Animas:* Main menu, system status, pump status, status 3: delivery today OR go to history -> TDD (this will show total bolus amount delivered over a past day) and see the entries OR to see individual bolus doses go to Bolus history and
scroll through the entries

**Tandem**: Options, history, bolus, click on most recent date and read through information

**Task 3**

**Make sure that pump is pre-programmed for this**

“You are about to eat [30 g] carbohydrate and you want to give yourself a bolus but you did not test your blood sugar. Please program this information into the pump so that you can maintain your blood glucose.”

**Bolus Set-Up**

Enter carbohydrate content to be consumed

Confirm bolus

Start bolus

**Need to pre-set pumps with Carb:insulin ratios and turn all calculators ON before testing**

**Medtronic**: bolus menu, set bolus

From Main Menu -> Bolus -> Use
Bolus Wizard -> “Enter BG” screen
skip -> Enter Food -> enter 25g ->
Review “Estimate Details” screen->
ACT to proceed-> Set Bolus Estimate
screen: Confirm dose by hitting ACT

**Roche:** **Done on Meter!!**

**From Meter:** Bolus Advice ->under
“Carbs” enter amount to be consumed -
-> “Confirm” bolus -> screen will come
up that asks if you want to continue
despite not testing BG: select YES ->
Confirm Bolus screen: select “Deliver”

**on pod, view data, add data on little
handheld remote; need to also turn on
Bolus calculator: Home, Settings,
System Setup, Bolus/basal/calcs, turn
bolus calc on

**Insulet:** **glitch with time/date setup;
if get error message, expect
participants to read/understand error
and continue if they feel it to be
appropriate

Home Screen -> Bolus -> skip screen
that ask for blood sugar -> Answer
YES to “Are you Going to Eat Now” -
> Enter 25g carbohydrate-> ENTER to
accept selected bolus

**Animas:**
**Setup bolus calculator in advance:**
Main menu, setup, advanced, screen 2, bolus turn ON (input settings on screen 7)

Main Menu -> Bolus -> ezCarb -> enter carbs to be consumed -> Show Result -> Under Bolus Total Screen: dial up the suggested bolus amount -> hit GO

**Tandem:** (In order for a bolus to be delivered, the basal has to be running)

On home screen, click Bolus, click on “carbs” button and enter 30g and press done on top right, note number of units calculated which is written on the top of the screen (can view calculation at the bottom), press next, confirm request, make sure extended is “OFF”, press deliver

Task 4
“You are interested in suspending your bolus because you just realized you programmed it incorrectly.

**Suspend bolus**

Suspend the bolus being delivered

**Medtronic:** Suspend -> hit ACT twice to Resume

**Roche:** STOP YOUR PUMP

**Insulet:** Suspend or press Cancel on the bolus delivery page
Resume the bolus after prompting

**Animas:** select Suspend/Resume to stop pump -> go back to Main Menu and hit Suspend/Resume again button to Resume

**Tandem:** click on “x”

**Task 5**

“You are now interested in giving yourself a more advanced bolus, called a [extended] bolus. This means instead of delivering the whole bolus all at once, it will spread the bolus out over many hours. We will ask you deliver 6 units over 5 hours.

**Might have to prompt to tell them it’s in the bolus menu. Will also have to tell them they are giving no insulin upfront.**

**Advanced Bolus**
Go to bolus menu and select an advanced bolus menu
Begin new bolus

**Medtronic:** bolus menu, dual/square bolus, ON
Go to Bolus menu, manual bolus, select square wave bolus, set estimate as 6 units, and set duration to 5 hrs

**Roche:** ON PUMP****extended bolus->
Bolus Amount: 6 units -> Bolus duration:
5 hours -> RUN (check button)

**Insulet:** extended bolus; Same steps as Task 3 except put “Extend” instead of “Enter”. Select 0% to deliver now and enter 5 hours as the duration; enter and confirm

**Animas:** bolus menu, combo bolus - >enter amount to be delivered 6 units ->
Duration 5 hours -> normal:extend:
0%:100%-> GO

**Tandem:**
90g of carbohydrate being delivered and BG will be 150mg/dL, click done, confirm, click on “extended”, click on “Deliver now” and put 0% and then deliver later will change, click on time to make it 5 hours, click next, confirm

**Task 6**
“You lost track of time at work during a meeting and when you get back to your desk, you want to know if it’s time for you to check your blood sugar again. Please use your pump to see when you took your last blood sugar and what its value was.”

**need to program

---

**Blood sugar check**

Navigate to status screen

Check time/value of last BG taken

**Medtronic:** capture event, history, read value

**Roche:** on remote meter, go to “MY DATA” to check last BG value, can also look at averages by going to reports; won’t be any values there but participant should be able to get there

**Insulet:** status screen, left bottom button on screen “Last BG” at top OR My Records, BG history

**NOT POSSIBLE ON ANIMAS PUMP**

**Tandem:** Options, History, down arrow to BG, click on most recent date
Task 7

“Can you also check the battery level on the pump?”

Check battery

*Medtronic:* icon on screen

*Roché:* icon on screen not available on pump; only get alert message on screen when battery is dying

*Insulet:* icon on screen

*Animas:* icon on status screen

*Tandem:* number (%) and icon

Task 8

“You are interested in setting up a threshold at which the pump tells you your insulin is running low. The threshold will be 20 units. Once you have done so, please return to the main menu.”

Set Low Reservoir Warning

Navigate to menu
Set warning to 20 units
Return to main menu

*Medtronic:* Utilities menu, alarm menu, low resv warning, insulin units

**NOT POSSIBLE ON ROCHE PUMP**

*Insulet:* Settings, system setup, alerts/reminders, low reservoir
Animas: setup, advanced, click next until setup adv 6 on the pump itself, change warning Low Cartridge Warning

Tandem: Options, My Pump, Alert settings, alerts, low insulin, change units, done.

Task 9

“You want to set up carb ratios in your pump for use later. The ratios you want to input include:

06:00 - 1:10 (1 unit of insulin per 10g of carbohydrate)
17:00 – 1:12

then go back to the main menu”

Setup carb ratios

Setup specific ratios/times

Medtronic: Bolus menu, bolus setup, bolus wizard setup, edit settings, carb ratios

Roche: **on meter only,

Settings -> Bolus Advice ->Time Blocks -> select appropriate time block
and scroll down to “Carb Ratio” to input ratio

*Insulet:* Settings, system setup, bolus/basal/calcs, ratios/factors, IC ratios

*Animas:* menu, setup, advanced, click next until setup adv 7, click 1:C ratio and change values

*Tandem:* Options, my pump, personal profiles, click on “Day”, click “add” and certain information will already be provided like correction factor

**Task 10**

“It’s been a few hours since your last blood glucose measurement. You measure it now and want to input the information onto your insulin pump. The value you measure is 9.1.”
Enter BG value

Navigate to correct menu for entering blood glucose measurement

Input correct number

Medtronic: capture event menu, enter BG menu Capture event menu must be turned on first in utilities

Roche: not available (see if they realize you can’t without measuring)

Insulet: More actions menu, add BG reading

NOT POSSIBLE ON ANIMAS

Tandem: have to put it in as a bolus without delivering; overall, not really available

Task 11

“You are getting ready for some exercise and you want to make sure you don’t change any of your settings by accident. Please lock the pump”

Locking keypad

Navigate to correct menu
**Medtronic**: utilities menu, lock keypad
(To unlock: press B and Up Arrow Key)

**Roche**: settings, meter, key lock, on and save; if you want to lock pump, go to Pump settings, Key lock

**Insulet**: settings, system setup, PDM options, PDM Lock on/off

**Animas**: Meter Settings, lock buttons
(on the handheld; hold down the up and down arrows at the same time until the screen says “locked” – do the same to unlock)

**Tandem**: top button

**Task 12**

**“Please now unlock the pump”**
### Appendix S – Usability Study Pre-test Questionnaire Results

#### Table 10: Pre-test questionnaire results for IP usability study participants

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Age Range</th>
<th>Gender</th>
<th>How long ago were you diagnosed with T1DM?</th>
<th>How Familiar are you with insulin pumps?</th>
<th>Reason for Familiarity</th>
<th>Pump most familiar with (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>18-29 years</td>
<td>M</td>
<td>16 years ago</td>
<td>Somewhat familiar</td>
<td>My brother is also diabetic and has switched over to an insulin pump</td>
<td></td>
</tr>
<tr>
<td>P2</td>
<td>18-29 years</td>
<td>F</td>
<td>Almost 7 years ago</td>
<td>Somewhat familiar</td>
<td>I've been working with kids with type one diabetes for about 5 years now in order to help them bolus correctly and out of curiosity I have been interacting with pump users and asking them about pump use.</td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>50-59 years</td>
<td>F</td>
<td>11 years ago</td>
<td>Somewhat familiar</td>
<td>Attended a training session to determine if I wanted to go on the pump</td>
<td></td>
</tr>
<tr>
<td>P4</td>
<td>18-29 years</td>
<td>F</td>
<td>3 years ago</td>
<td>Not familiar at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P5</td>
<td>18-29 years</td>
<td>M</td>
<td>4 years ago</td>
<td>Not familiar at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P6</td>
<td>18-29 years</td>
<td>F</td>
<td>15 years ago</td>
<td>Somewhat familiar</td>
<td>Attending diabetic summer camp during my adolescence where other campers were on insulin pumps</td>
<td></td>
</tr>
<tr>
<td>P7</td>
<td>18-29 years</td>
<td>M</td>
<td>3 years ago</td>
<td>Somewhat familiar</td>
<td>Went to an information session regarding different types of pumps.</td>
<td></td>
</tr>
<tr>
<td>P8</td>
<td>18-29 years</td>
<td>F</td>
<td>17 years ago</td>
<td>Somewhat familiar</td>
<td>Seriously considered pump</td>
<td>Animas</td>
</tr>
<tr>
<td>P9</td>
<td>18-29 years</td>
<td>M</td>
<td>5 years ago</td>
<td>Not familiar at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P10</td>
<td>50-59 years</td>
<td>F</td>
<td>32 years ago</td>
<td>Somewhat familiar</td>
<td>Previously considered going on pump</td>
<td>Medtronic</td>
</tr>
</tbody>
</table>
Table 11: Additional Demographic Questions; fewer responses than participants interviewed as these questions were posed after completing the study

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Highest degree or level of school completed</th>
<th>Approximate household income</th>
<th>Current Profession</th>
<th>Comfort with technology</th>
<th>Last HbA1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2</td>
<td>College degree</td>
<td>$35,000 to $49,999</td>
<td>Student</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>Unsure? I think 6?</td>
</tr>
<tr>
<td>P3</td>
<td>Educated in UK. GCE &amp; O’Level Exams</td>
<td>$50,000 to $74,999</td>
<td>Executive assistant</td>
<td>Somewhat comfortable (e.g. I use computers at work)</td>
<td>8.4</td>
</tr>
<tr>
<td>P4</td>
<td>Master’s degree</td>
<td>$75,000 to $99,999</td>
<td>Clinical Research coordinator/social worker</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>6.6</td>
</tr>
<tr>
<td>P5</td>
<td>Bachelor’s degree</td>
<td>$150,000 or more</td>
<td>Teacher</td>
<td>Comfortable (e.g. use computer at home, have smart phone)</td>
<td>7.1</td>
</tr>
<tr>
<td>P7</td>
<td>Bachelor’s degree</td>
<td>$100,000 to $149,000</td>
<td>Student</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>6.9</td>
</tr>
<tr>
<td>P8</td>
<td>Bachelor’s degree</td>
<td>$35,000 to $49,999</td>
<td>Accounting clerk</td>
<td>Very comfortable (e.g. I’m an early adopter of new technologies; very comfortable with any new gadget quickly)</td>
<td>7.2</td>
</tr>
<tr>
<td>P10</td>
<td>Bachelor’s degree</td>
<td>$100,000 to $149,000</td>
<td>Health and safety</td>
<td>Somewhat comfortable (e.g. I use computers at work)</td>
<td>8.1</td>
</tr>
</tbody>
</table>
## Appendix T – Usability Study Post-test Questionnaire

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Pumps Tested (in order)</th>
<th>Question #1: Which insulin pump was easier to use?</th>
</tr>
</thead>
</table>
| P1             | Medtronic, Roche, Tandem | Tandem  
Comment: so so much easier, `i would definitely pay extra for it. Smart phone interfaces are now available on almost all phone models, why should it be different for something so important as an insulin pump |
| P2             | Roche, Animas, Medtronic | Medtronic  
Comment: By a lot!! I had a very strong preference |
| P3             | Animas, Insulet, Roche   | Animas  
Comment: Simplistic and logical. |
| P4             | Insulet, Tandem, Animas  | Tandem  
Comment: The touch screen was easy to use and most of the options were intuitive. It was also easy to get to the home screen and locking/unlocking it was very easy also. |
| P5             | Tandem, Medtronic, Insulet | Tandem  
Comment: touch screen very similar to smart phones, easy transition |
| P6             | Insulet, Animas, Tandem  | Tandem  
Comment: touch screen was a lot faster |
| P7             | Tandem, Insulet, Medtronic | Tandem  
Comment: The menus were the most intuitive and easy to follow on pump one, and the touch screen made entering data much easier and quick. |
| P8             | Medtronic, Tandem, Roche | Tandem |
| P9             | Roche, Medtronic, Animas | Animas |
| P10            | Animas, Roche, Insulet   | Roche  
Comment: I liked this pump but would be better if you could use just the one thing instead of the two |
<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Pumps Tested (in order)</th>
<th>Question #2: Which insulin pump was better at showing you the information you needed?</th>
</tr>
</thead>
</table>
| P1              | Medtronic, Roche, Tandem | Tandem  
*Comment:* Getting through information on the other pumps was vastly more confusing. The display on the tandem showed things like battery life in percentage form which was great. |
| P2              | Roche, Animas, Medtronic | Medtronic |
| P3              | Animas, Insulet, Roche | Roche |
| P4              | Insulet, Tandem, Animas | Tandem  
*Comment:* Lots of summaries were given and the home screen provided some details as well, like battery life, extended bolus info, etc. |
| P5              | Tandem, Medtronic, Insulet | Insulet |
| P6              | Insulet, Animas, Tandem | Tandem  
*Comment:* Number values added to the battery/insulin status was essential |
| P7              | Tandem, Insulet, Medtronic | Tandem  
*Comment:* Pump 1 had a nicer and bigger screen that displayed information much simpler than the other pumps. |
<p>| P8              | Medtronic, Tandem, Roche | Tandem |
| P9              | Roche, Medtronic, Animas | Animas |
| P10             | Animas, Roche, Insulet | Roche |</p>
<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Pumps Tested (in order)</th>
<th>Question #3: Which insulin pump was better at drawing your attention to important messages/items?</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>Medtronic, Roche, Tandem</td>
<td>Tandem</td>
</tr>
<tr>
<td>P2</td>
<td>Roche, Animas, Medtronic</td>
<td>Medtronic</td>
</tr>
<tr>
<td>P3</td>
<td>Animas, Insulet, Roche</td>
<td>Animas</td>
</tr>
<tr>
<td>P4</td>
<td>Insulet, Tandem, Animas</td>
<td>Tandem  &lt;br&gt; <em>Comment:</em> Lots of info found on main screen, which was easy to read and notice.</td>
</tr>
<tr>
<td>P5</td>
<td>Tandem, Medtronic, Insulet</td>
<td>Tandem</td>
</tr>
<tr>
<td>P6</td>
<td>Insulet, Animas, Tandem</td>
<td>Tandem  &lt;br&gt; <em>Comment:</em> the colours were helpful</td>
</tr>
<tr>
<td>P7</td>
<td>Tandem, Insulet, Medtronic</td>
<td>Tandem</td>
</tr>
<tr>
<td>P8</td>
<td>Medtronic, Tandem, Roche</td>
<td>Medtronic</td>
</tr>
<tr>
<td>P9</td>
<td>Roche, Medtronic, Animas</td>
<td>Animas</td>
</tr>
<tr>
<td>P10</td>
<td>Animas, Roche, Insulet</td>
<td>Animas</td>
</tr>
</tbody>
</table>
**Question #4:**
Which insulin pump enabled you to perform the following tasks more efficiently

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Pumps Tested (in order)</th>
<th>Pump Setup</th>
<th>Check bolus history</th>
<th>Bolus Setup</th>
<th>Suspend bolus Setup</th>
<th>Extend bolus Setup</th>
<th>Check bG history</th>
<th>Check battery</th>
<th>Low res. Setup</th>
<th>I:C ratios Setup</th>
<th>bG in-put</th>
<th>Pump Lock</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>Medtronic, Roche, Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
</tr>
<tr>
<td>P2</td>
<td>Roche, Animas, Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>Animas, Insulet, Roche</td>
<td>Animas</td>
<td>Roche</td>
<td>Animas</td>
<td>Insulet</td>
<td>n/a</td>
<td>animas</td>
<td>animas</td>
<td>animas</td>
<td>animas</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>P4</td>
<td>Insulet, Tandem, Animas</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td></td>
</tr>
<tr>
<td>P5</td>
<td>Tandem, Medtronic, Insulet</td>
<td>Medtronic</td>
<td>Insulet</td>
<td>Tandem</td>
<td>Insulet</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td></td>
</tr>
<tr>
<td>P6</td>
<td>Insulet, Animas, Tandem</td>
<td>Animas</td>
<td>Tandem</td>
<td>Insulet</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td></td>
</tr>
<tr>
<td>P7</td>
<td>Tandem, Insulet, Medtronic</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
<td>Tandem</td>
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</tr>
<tr>
<td>Participant No.</td>
<td>Pumps Tested (in order)</td>
<td>Question #5: Which insulin pump did you prefer?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td>Medtronic, Roche, Tandem</td>
<td>Tandem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2</td>
<td>Roche, Animas, Medtronic</td>
<td>Medtronic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>Animas, Insulet, Roche</td>
<td>Animas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P4</td>
<td>Insulet, Tandem, Animas</td>
<td>Tandem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>P5</td>
<td>Tandem, Medtronic, Insulet</td>
<td>Tandem</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P6</td>
<td>Insulet, Animas, Tandem</td>
<td>Tandem</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>P7</td>
<td>Tandem, Insulet, Medtronic</td>
<td>Tandem</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>P8</td>
<td>Medtronic, Tandem, Roche</td>
<td>Tandem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Participants preferred pumps in the following order:

- **P8**: Medtronic, Tandem, Roche
- **P9**: Roche, Medtronic, Animas
- **P10**: Animas, Roche, Insulet
<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Pumps Tested (in order)</th>
<th>Question #6: Additional Comments or any comments on how any/all systems could be improved.</th>
</tr>
</thead>
<tbody>
<tr>
<td>P9</td>
<td>Roche, Medtronic, Animas</td>
<td>Animas</td>
</tr>
<tr>
<td>P10</td>
<td>Animas, Roche, Insulet</td>
<td>Roche</td>
</tr>
<tr>
<td>P1</td>
<td>Medtronic, Roche, Tandem</td>
<td>all pumps should have interfaces like the tandem,</td>
</tr>
<tr>
<td>P2</td>
<td>Roche, Animas, Medtronic</td>
<td>Back buttons would be helpful on something like animas since there were soo many options. This is a thing I really liked about medtronic's pump</td>
</tr>
<tr>
<td>P3</td>
<td>Animas, Insulet, Roche</td>
<td>duration of lighting</td>
</tr>
<tr>
<td>P4</td>
<td>Insulet, Tandem, Animas</td>
<td>Pump 2 was the easiest to use, most compact, and fairly light. It can also be plugged in, which is convenient because you don't need to carry around extra batteries. I wonder though if there is a way to also use a battery in case of emergency and there is not an electrical outlet available? Having actual numbers to press on the screen was also easy to use and made the inputting faster - pumps 1 and 3 took longer to input information since you had to use the up and down arrows to input numbers. Pump 3 was more intuitive than Pump 1 (i.e., in terms of the buttons), however it was annoying to press 'ok' to edit a choice and then confirm a choice.</td>
</tr>
<tr>
<td>P5</td>
<td>Tandem, Medtronic, Insulet</td>
<td>make them smaller or more similar to pump 2 with the pod and bluetooth capabilities</td>
</tr>
<tr>
<td>P6</td>
<td>Insulet, Animas, Tandem</td>
<td>I prefer a pump setting where I can override the recommended dose if necessary</td>
</tr>
<tr>
<td>P7</td>
<td>Tandem, Insulet, Medtronic</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------</td>
<td></td>
</tr>
<tr>
<td>P8</td>
<td>Medtronic, Tandem, Roche</td>
<td>I recommend that the last pump not be so complicated. The other pumps were great.</td>
</tr>
<tr>
<td>P9</td>
<td>Roche, Medtronic, Animas</td>
<td>Would prefer to control pump from my phone.</td>
</tr>
<tr>
<td>P10</td>
<td>Animas, Roche, Insulet</td>
<td>pump 1 was easier but i think if they could modify pump 2 it would be my preference</td>
</tr>
<tr>
<td>Task</td>
<td>Usability Issue</td>
<td>Possible Consequences</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Programming I:C ratios</td>
<td>Expected I:C ratios to be inputted into bolus delivery program</td>
<td>I:C ratios programmed as a bolus could pose a patient safety risk as this would result in immediate delivery of an incorrect dosage of insulin</td>
</tr>
<tr>
<td>Suspending bolus delivery</td>
<td>Unclear whether a bolus or basal was being suspended when suspend option selected</td>
<td>Users felt bolus vs. basal suspend not well conveyed which could lead to a patient safety risk as users could leave the basal un-resumed</td>
</tr>
<tr>
<td>Programming square wave bolus time parameter</td>
<td>Users did not understand the layout for the extended bolus setup and didn’t notice the time parameter</td>
<td>This could pose a significant patient safety risk as the time parameter would be left on a default value which may be incorrect, likely leading to delivery of insulin at the wrong dose at the wrong time.</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Doesn’t use bolus calculator</td>
<td>Though this is not necessarily a patient safety risk if a bolus is programmed correctly, errors could lead to risk</td>
</tr>
<tr>
<td>Battery life check</td>
<td>Battery icon does not convey enough information in order to make informed decisions</td>
<td>Users felt the provided information was not sufficient; could lead to patient safety issues</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Unclear what can be</td>
<td>In the context of bolus programming, when</td>
</tr>
<tr>
<td>Checking bolus history</td>
<td>Unclear nomenclature</td>
<td>Non-intuitive short terms could lead to patient safety issues if a participant misinterprets an action</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Inputting BG value</td>
<td>“Capture event” not intuitive menu title; participants felt it to be non-descriptive</td>
<td>User frustration; inefficiency</td>
</tr>
<tr>
<td>Setting low reservoir alarm</td>
<td>Non-intuitive/unexpected location; participants felt menu title (user settings) did not convey menu contents accurately</td>
<td>User frustration; inefficiency</td>
</tr>
<tr>
<td>[General use]</td>
<td>Inconsistency between ACT and ESC</td>
<td>User frustration; inefficiency</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Location in bolus menu unclear; non-intuitive menu option title</td>
<td>User frustration; inefficiency</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Non-intuitive location;</td>
<td>User frustration; inefficiency</td>
</tr>
</tbody>
</table>
Figures 42-44 show the frequency at which these errors were committed. The data denotes the number of users who committed the errors out of 6 who tested the pump in the usability study.

<table>
<thead>
<tr>
<th>Category</th>
<th>Error Description</th>
<th>Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locking</td>
<td>Feature too involved and overly complicated according to participants; should be straight forward</td>
<td>3</td>
<td>User frustration; inefficiency</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Main menu location unclear</td>
<td>2</td>
<td>User frustration; inefficiency</td>
</tr>
</tbody>
</table>

**Medtronic: High Severity Error Frequency**

![Bar Chart](image.png)

**Figure 42: Medtronic High Severity Error Frequency**
Figure 43: Medtronic Moderate Severity Error Frequency
Figure 44: Medtronic Low Severity Error Frequency
### Appendix V – Usability Issues in Order of Error Severity for Animas Pump

<table>
<thead>
<tr>
<th>Task</th>
<th>Usability Issue</th>
<th>Possible Consequences</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suspending bolus</strong></td>
<td>Unclear whether in suspend mode or not</td>
<td>Participants felt pump “status” not well conveyed; poses potentially significant patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Suspending bolus</strong></td>
<td>Not enough warning given that bolus can be cancelled from delivery screen especially if dosage is very small (quick delivery)</td>
<td>Participants did not notice “cancel bolus” message on delivery screen and once they did, did not have enough time to act; not suspending bolus dosage can pose patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Suspending bolus</strong></td>
<td>Unclear whether resume means bolus or basal</td>
<td>Participants were unsure whether resume option would restart previously cancelled bolus; were unable to proceed with confidence; could pose a significant patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Setting I:C ratios</strong></td>
<td>Time parameter difficult to interpret; format in general unclear according to participants</td>
<td>Difficulty interpreting the I:C ratio format could pose a significant patient safety risk as all subsequent bolus doses are based on the ratios programmed</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Unclear how to deliver bolus</td>
<td>Inability to program bolus would likely pose a significant patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td>Feature</td>
<td>Issue Description</td>
<td>Risk</td>
<td>Rating</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Recommendation for bolus dosage not visible/unclear</td>
<td>One user did not see recommendation for bolus above dosage parameter and guessed dosage; this could pose a significant patient safety risk as this user recalled incorrectly</td>
<td>H</td>
</tr>
<tr>
<td>Battery life check</td>
<td>Initially participants were unable to find the battery icon; once found, not enough information conveyed</td>
<td>Users felt the provided information was not sufficient; could lead to patient safety issues</td>
<td>M</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Layout generally unclear including arrows</td>
<td>Users misinterpreted the setup of the display; associating the page up/down menus to be representative of “done” or “home” actions; user frustration, inefficiency</td>
<td>M</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Doesn’t use calculator</td>
<td>Though this is not necessarily a patient safety risk if a bolus is programmed correctly, errors could lead to risk</td>
<td>M</td>
</tr>
<tr>
<td>Programming time/date</td>
<td>AM/PM not clear when programming</td>
<td>Participants were unsure whether the clock was 12 or 24 hours by default as there was no clear indication initially; noticed the “A” and “P” eventually which they assumed referred to “AM”/“PM”; non-standard notation could be source of confusion</td>
<td>M</td>
</tr>
<tr>
<td>Locking</td>
<td>Unlock method not shown on screen when locked</td>
<td>If user unable to recall how to unlock, could result in safety risk; likelihood of forgetting</td>
<td>M</td>
</tr>
<tr>
<td>Category</td>
<td>Issue Description</td>
<td>Impact</td>
<td>Notes</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>[general use]</td>
<td>Users forgot about selecting a parameter twice to edit</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Maximum Timeout time too short; did not meet user needs</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Setting low reservoir limit/I:C ratio setup</td>
<td>Advanced settings menu confusing and unclear architecture</td>
<td>Users found advances menus difficult to navigate and most could not understand their location in the menu; user frustration and inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Format for setting ratios unclear</td>
<td>Time format in addition to multiple of pages for ratios was unclear to users initially; user frustration, inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Setting low reservoir limit</td>
<td>Name of menu and location not of low cartridge not intuitive</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>ezCarb not considered to be intuitive name; does not explain its function effectively</td>
<td>User frustration; inefficiency if unable to determine how to deliver bolus with calculator</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>User felt the font type was unclear</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Users wanted to handle pump</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>User expected I:C ratio to be on display on status screen</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------------------------------------------------------</td>
<td>------------------</td>
<td>---</td>
</tr>
<tr>
<td>Checking bolus history</td>
<td>Layout not expected: most recent first rather than oldest</td>
<td>User frustration</td>
<td>L</td>
</tr>
</tbody>
</table>

Figures 45-47 show the frequency at which these errors were committed. The data denotes the number of users who committed the errors out of 6 who tested the pump in the usability study.

![Animas: High Severity Error Frequency](image)

**Figure 45: Animas High Severity Error Frequency**
Figure 46: Animas Moderate Severity Error Frequency
Figure 47: Animas Low Severity Error Frequency
### Appendix W – Usability Issues in Order of Error Severity for Insulet Pump

<table>
<thead>
<tr>
<th>Task</th>
<th>Usability Issue</th>
<th>Possible Consequences</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting I:C ratios</td>
<td>Time setting not intuitive</td>
<td>Participants were unable to associate end time of a ratio with start time of the next ratio; could pose safety risk if not correctly programmed as subsequent bolus calculations will be based on ratios</td>
<td>H</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Unclear how to delete I:C ratios</td>
<td>The inability to delete an I:C ratio could pose a safety risk if it was unintentionally programmed and doesn’t fit the user’s needs</td>
<td>H</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>I:C ratio menu confused with carb presets</td>
<td>Not having I:C ratios programmed poses the greatest risk with an issue such as this</td>
<td>H</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Expected I:C ratios to be inputted into time/date field</td>
<td>Inputting time/date incorrectly would have patient safety ramifications as the pump alerts users when the Pod needs to be replaced, etc. and those alerts are only as accurate as the dates inputted. Furthermore, not having I:C ratios programmed could pose a patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td>Locking</td>
<td>Confusion between locking and suspending</td>
<td>One participant misinterpreted the difference between the two actions and suspended the pump when told lock it and vice versa; this</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>“Bolus calcs” not understood</td>
<td>The term “bolus calc” and the menu name associated with it was not understood by participants; could pose a problem if user is not accurate with manual dosing</td>
<td>M</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Doesn’t use bolus calculator</td>
<td>Though this is not necessarily a patient safety risk if a bolus is programmed correctly, errors could lead to risk</td>
<td>M</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Wants to leave bolus delivery screen w/o cancelling</td>
<td>Participants expected to see the delivery screen display for a few moments and then to be forced back to the main menu; had they “cancelled” the display they would have canceled the bolus, which may have led to a patient safety risk.</td>
<td>M</td>
</tr>
<tr>
<td><strong>Programming extended bolus</strong></td>
<td>Extend option when programming a bolus not prominent enough</td>
<td>The participant continued to program the bolus expecting the next screen and then the next to have the extend option and almost delivered the bolus upfront; had she not, she could have unintentionally delivered a bolus. Had she delivered and not noticed, a patient safety risk could have ensued though the likelihood is not necessarily high.</td>
<td>M</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Users' Concern</td>
<td>Severity</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Battery life check</td>
<td>Users did not feel enough battery life information was conveyed via the icon. Users felt the provided information was not sufficient; could lead to patient safety issues.</td>
<td></td>
<td>M</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Unclear that “bolus” on main menu is a menu since no arrow displayed on the right side of the screen. Users misinterpreted the meaning of the title “bolus” thinking the main menu was the bolus menu as it appeared to be more like a heading than the gateway to more menus; could lead to patient safety risk.</td>
<td></td>
<td>M</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Unclear what menus/parameters can be bypassed; led to participant paralysis in task completion. In the context of bolus programming, when not given the BG reading, participant were unsure whether they could proceed with programming without this information since it was being asked of them; could be a patient safety risk as participant may either delay their dosage or not deliver it at all.</td>
<td></td>
<td>M</td>
</tr>
<tr>
<td>Suspending bolus</td>
<td>Expected reminder to restart basal to be sooner when programming a new bolus. This would not likely cause a patient safety risk since there is a prompt to have the user restart the basal; however it did not meet user expectations.</td>
<td></td>
<td>M</td>
</tr>
<tr>
<td>Suspending bolus</td>
<td>30 min minimum for suspension not expected or intuitive; smaller intervals necessary. User frustration.</td>
<td></td>
<td>L</td>
</tr>
<tr>
<td>Setting date/time</td>
<td>Time/date did not meet one participant’s needs</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------------------------------------</td>
<td>------------------</td>
<td>---</td>
</tr>
<tr>
<td>Locking</td>
<td>Users felt the process to lock the pump was overly complicated and time intensive</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Users felt the maximum timeout was too short</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Purpose of status menu unclear</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Users unsure which menu was the main menu</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Keypad did not fit needs or expectations and often display mistaken for touchscreen</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Unclear purpose of question mark button; users expected it to be a help function at all times;</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>Programming BG reading</td>
<td>Not intuitive location</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>“more actions” menu</td>
<td>Name did not convey</td>
<td>User frustration</td>
<td>L</td>
</tr>
</tbody>
</table>
importance of options contained according to users; used for putting in IC ratios, delivering bolus, time/date setup

“settings” menu

The settings menu purpose was unclear as participants felt it did not contain options expected

User frustration

L

Figures 48-50 show the frequency at which these errors were committed. The data denotes the number of users who committed the errors out of 6 who tested the pump in the usability study.
Figure 48: Insulet High Severity Error Frequency

Figure 49: Insulet Moderate Severity Error Frequency
Figure 50: Insulet Low Severity Error Frequency
### Appendix X – Usability Issues in Order of Error Severity for Roche Pump

<table>
<thead>
<tr>
<th>Task</th>
<th>Usability Issue</th>
<th>Possible Consequences</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Programming extended bolus</strong></td>
<td>Participants unable to access extended bolus time parameter; non-intuitive</td>
<td>Participants unintentionally bypassed time parameter as it was unclear how to access it; default time may be incorrect leading to patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Setting I:C ratio</strong></td>
<td>Unclear where to input ratio; participant programmed ratio in bolus menu</td>
<td>Programming a ratio for later use in a bolus menu where bolus deliveries are immediate could have significant patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Setting I:C ratio</strong></td>
<td>Unclear how to delete I:C ratio on the remote</td>
<td>The inability to delete an I:C ratio could pose a safety risk if it was unintentionally programmed and doesn’t fit the user’s needs</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Unclear how to deliver bolus</td>
<td>Uncertainty regarding how to program a bolus could result in patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming extended bolus</strong></td>
<td>Unclear how to deliver extended bolus</td>
<td>Uncertainty regarding how to program an extended bolus could result in patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Unclear whether bolus was delivered if programmed on remote; no indication</td>
<td>User may be unsure of delivery and w/o consulting history, may deliver a subsequent dose that could lead to patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Unclear where to program</td>
<td>Using the “Time blocks” menu for bolus</td>
<td>H</td>
</tr>
<tr>
<td>Section</td>
<td>Issue</td>
<td>Impact</td>
<td>Risk Level</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Programming extended bolus</td>
<td>Confirmation expected before extended bolus was delivered</td>
<td>Participant expected to be asked to confirm programmed parameters before starting bolus; could lead to patient safety harm if user not prepared to deliver</td>
<td>H</td>
</tr>
<tr>
<td>Programming extended bolus</td>
<td>Unclear where to program an extended bolus; users expected to be able to on remote and used “Time blocks” menu</td>
<td>Using the “Time blocks” menu for extended bolus programming could lead to significant patient safety harm</td>
<td>H</td>
</tr>
<tr>
<td>Setting I:C ratio</td>
<td>Time parameter difficult to interpret; format in general unclear according to participants</td>
<td>Difficulty interpreting the I:C ratio format could pose a significant patient safety risk as all subsequent bolus doses are based on the ratios programmed</td>
<td>H</td>
</tr>
<tr>
<td>Suspending bolus</td>
<td>Unclear what resume will mean</td>
<td>Users were unsure whether resuming meant resuming the cancelled bolus or the basal; participants were afraid to restart the pump which could have significant patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td>Suspending bolus</td>
<td>Unclear whether a bolus or basal dose can be suspended; participants expected it in the</td>
<td>It is not possible to suspend a bolus from the remote; this reality is not well conveyed and users searching on the remote could be at risk</td>
<td>H</td>
</tr>
<tr>
<td>Feature</td>
<td>Description</td>
<td>Issue</td>
<td>Severity</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>bolus menu</td>
<td>if they are intending to suspend a dose immediately but are unable to locate the function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locking</td>
<td>Confusion regarding locking and suspending</td>
<td>One participant misinterpreted the difference between the two actions and suspended the pump when told lock it and vice versa; this could have significant patient safety risks especially if suspending an insulin infusion unintentionally</td>
<td>H</td>
</tr>
<tr>
<td>Battery life feedback</td>
<td>Battery life is only indicated when an alert is displayed indicating that the battery is low</td>
<td>The warning does not necessarily allow for a lot of preparation time for battery replacement; not being prepared could have patient safety risk</td>
<td>H</td>
</tr>
<tr>
<td>[general use]</td>
<td>Meaning of pump vibration not always clear</td>
<td>The reason for vibration was not always clear or indicated which made participants question their actions which could be a patient safety risk; some wanted to stop the pump thinking they had accidently programmed a bolus even though they hadn’t</td>
<td>M</td>
</tr>
<tr>
<td>Locking</td>
<td>No clear indication on screen of how to unlock the pump</td>
<td>The inability to unlock a pump could pose a significant patient safety risk if it occurred in a case where a participant needed to delivery a bolus immediately; the likelihood of this problem occurring often is low</td>
<td>M</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Doesn’t use calculator</td>
<td>Though this is not necessarily a patient safety risk if a bolus is programmed correctly, errors could lead to risk</td>
<td>M</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>[general use]</td>
<td>Participants felt the pump menus contained non intuitive nomenclature and short terms/abbreviations</td>
<td>Non-intuitive short terms cause confusion primarily; this was usually in reference to a history menu for example and would likely not result in significant patient safety issues</td>
<td>M</td>
</tr>
<tr>
<td>[general use]</td>
<td>Navigation through the pump menu on the remote was unclear and not intuitive</td>
<td>Because navigation was a challenge and the displays were difficult to interpret according to users, this could be a safety risk if a button is unintentionally pressed, leading to an unexpected insulin delivery for example.</td>
<td>M</td>
</tr>
<tr>
<td>[general use]</td>
<td>There can be a delay between the remote and pump; there is no real indication of the impending bolus delivery which can be problematic</td>
<td>Because there is no indication of whether an order has been sent to the pump from the remote, this could be a potential safety risk as a user may reprogram a bolus not realizing the delay</td>
<td>M</td>
</tr>
<tr>
<td>[general use]</td>
<td>Participants were unsure about what functions could be performed on the remote, on the pump, both or neither</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>One menu at a time is shown on the pump screen and there</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>No clear indication of whether there is a main menu or if one, where it is</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>[general use]</td>
<td>Lack of back button source of frustration</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Two bolus advice menus on remote were a source of confusion</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Bolus advice menu not intuitive menu title and format was unclear</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Participants were given both the remote and pump for use in completing tasks; users did not see benefit of remote since it could not be used in all cases</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>Three participants unsure of how to hold the pump in order to be able to access all buttons</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td></td>
<td>easily (including side buttons)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------</td>
<td>-----------------------</td>
<td>-----</td>
</tr>
<tr>
<td>[general use]</td>
<td>Some users felt there were too many buttons available to navigate</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>Searching bolus history</td>
<td>Location for bolus history not intuitive and when found, unclear format</td>
<td>User frustration; inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Inputting BG reading</td>
<td>Users expected to be able to do manually; didn’t like company dictating which meter was used</td>
<td>User frustration</td>
<td>L</td>
</tr>
</tbody>
</table>

Figures 51-53 show the frequency at which these errors were committed. The data denotes the number of users who committed the errors out of 6 who tested the pump in the usability study.
Figure 51: Roche High Severity Error Frequency
Figure 52: Roche Moderate Severity Error Frequency
Figure 53: Roche Low Severity Error Frequency
## Appendix Y– Usability Issues in Order of Error Severity for Tandem Pump

<table>
<thead>
<tr>
<th>Task</th>
<th>Usability Issue</th>
<th>Possible Consequences</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Programming extended bolus</strong></td>
<td>One user did not understand the layout for the extended bolus setup and didn’t notice the time parameter</td>
<td>This could pose a significant patient safety risk as the time parameter would be left on a default value which may be incorrect, likely leading to delivery of insulin at the wrong dose at the wrong time.</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming bolus</strong></td>
<td>Meaning of delivery screen unclear for participants: will it remain the duration of the delivery or is it just an indication that the delivery has begun?</td>
<td>This can pose a significant patient safety risk as one participant saw the screen disappear and assumed the delivery had ended which is not the case. Can have safety ramifications if insulin is delivered unintentionally.</td>
<td>H</td>
</tr>
<tr>
<td><strong>Programming extended bolus</strong></td>
<td>Meaning of quick bolus confused with extended by one participant</td>
<td>A quick bolus is a default bolus dosage; an extended bolus does not have the same purpose and if confused, can have significant safety risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>Setting I:C ratios</strong></td>
<td>Participants felt “personal profiles” menu title was not intuitive and did not impart the importance of the menu</td>
<td>This would not likely pose a patient safety risk. However, one participant began programming the ratio in the bolus menu but soon after realized the format of the ratio did not fit the menu settings</td>
<td>M</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>Participants found the “personal profiles” menu misleading and confusing</td>
<td>Participants who selected the correct menu were confused by the options presented: day, weekday, weekend and returned to the main; this would not likely cause a patient safety risk but would lead to user frustration</td>
<td>M</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Entering BG value</td>
<td>Users felt it was not intuitive to input BG readings in the bolus menu; expected a menu in the Options tab.</td>
<td>This does not likely pose a patient safety risk unless participants choose not to input a BG at all. Not updating BG history is not advised as the pump is only as effective as the information it is fed.</td>
<td>M</td>
</tr>
<tr>
<td>Entering BG value</td>
<td>Participant expected confirmation to either save BG or confirmation that it was saved before exiting menu</td>
<td>This does not pose a likely patient safety risk and the history menu can be checked for confirmation. Inputting the BG a second time would not cause patient harm either.</td>
<td>M</td>
</tr>
<tr>
<td>Entering BG value</td>
<td>One participant felt that inputting BG in the bolus menu might pose a risk, especially if she had no intention of delivering a bolus but did no accidently</td>
<td>The pump is able to make recommendations regarding bolus dosing based on BG inputs. However, a user intentionally delivering a bolus can pose a patient safety risk.</td>
<td>M</td>
</tr>
<tr>
<td>Battery life check</td>
<td>One user did not see the battery icon at the top of the screen</td>
<td>This would not likely pose a patient safety risk as the participant saw the icon after having looked through menus for battery details;</td>
<td>M</td>
</tr>
<tr>
<td>Category</td>
<td>Issue Description</td>
<td>Potential Impact</td>
<td>Severity</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Locking</td>
<td>One user did not understand the steps necessary to unlock the pump. She kept tapping the screen w/o noticing the pump prompts</td>
<td>This would not likely lead to a patient safety risk; rather user frustration</td>
<td>M</td>
</tr>
<tr>
<td>Setting threshold alarm</td>
<td>Confused with auto-off feature; non-intuitive nomenclature</td>
<td>Not likely to cause a patient safety error since auto-off feature is measured in time units rather than insulin units; caused user confusion; root cause likely non-intuitive names</td>
<td>M</td>
</tr>
<tr>
<td>Programming extended bolus</td>
<td>User confused extended bolus with the setup of temporary basal rate</td>
<td>This would be a moderate error as it would not likely cause a safety issue since the temporary rate is set with different parameter than an extended bolus; however the confusion between the meaning of the two features could pose a risk</td>
<td>M</td>
</tr>
<tr>
<td>Setting IC ratios</td>
<td>Participants expected to find a menu for setting up insulin:carb ratios in the bolus menu</td>
<td>Low severity errors will not have patients safety consequences; these usability issues add to participant frustration or inefficiencies in completing tasks</td>
<td>L</td>
</tr>
<tr>
<td>Programming bolus</td>
<td>Pump does not allow</td>
<td>User frustration: participants saw the value in</td>
<td>L</td>
</tr>
<tr>
<td>Feature</td>
<td>Issue</td>
<td>User Experience</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Participant to bypass bolus calculator; must either enter BG value or grams of carbohydrate being eaten</td>
<td>this forcing function but did not like being limited by the pump; wanted to be able to program a dose manually</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checking bolus history</td>
<td>Location of bolus history not intuitive; participants looked in “personal profiles” menu expecting that menu to contain history</td>
<td>User frustration, inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Programming extended bolus</td>
<td>Users expected the option to extend the bolus to be earlier in the programming workflow</td>
<td>User frustration; minor delay in insulin delivery (depending on extension parameters)</td>
<td>L</td>
</tr>
<tr>
<td>[general use]</td>
<td>User(s) was not able to distinguish between what parameters could be edited or not</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>Checking bolus history</td>
<td>User(s) expected to see bolus history in the pump info menu</td>
<td>User frustration, delay in completing task, inefficiency</td>
<td>L</td>
</tr>
<tr>
<td>Time/date setup</td>
<td>User(s) expected a 24 hour clock option which was not available</td>
<td>User frustration</td>
<td>L</td>
</tr>
<tr>
<td>Setting I:C ratios</td>
<td>One user expected the status menu to be a gateway to each</td>
<td>User frustration, inefficiency, delay in completing task</td>
<td>L</td>
</tr>
</tbody>
</table>
Figures 54-56 show the frequency at which these errors were committed. The data denotes the number of users who committed the errors out of 6 who tested the pump in the usability study.

**Figure 54: Tandem High Severity Error Frequency**
Figure 55: Tandem Moderate Severity Error Frequency
Figure 56: Tandem Low Severity Error Frequency
Appendix Z – Inter-rater Reliability Report

In order to help verify the qualitative coding scheme used to measure the occurrence of errors and other performance facts, a second reviewer watched videos of each pump being tested by a total of two participants. The primary reviewer did the same, based their data collection on the same videos for this task to ensure the same material was being analyzed and compared.

Review Sample Size

Ten participants were tested, each on three of the five insulin pumps included in study. One session on each pump was reviewed by a second independent reviewer.

Instructions Given to Second Reviewer

Instructions given to the second reviewer consisted of a brief overview of the study, an explanation of the study setup and an explanation of the data sheet that was provided. This was to ensure a common methodology among the two reviewers. The two reviewers independently coded the data from the selected participants.

Findings

Because of the qualitative nature of this study, the data collected was reviewed by a second reviewer. Upon completion of the data analysis, the two sheets were compared for any genuine disagreements in interpretation.

For the Medtronic pump, there was agreement among the two reviewers with identification of 6 issues and 3 task deviations for the video footage reviewed. The reviewers disagreed with 1 severity rankings on one issue as described in the table below.

For the Animas pump, the two reviewers were in complete agreement with the five issues identified and their severity rankings. The reviewers also agreed with the fact that no deviations were committed in the observed session.
For the Insulet pump, the two reviewers were in complete agreement with the 4 issues identified as well as their severity rankings. They also agreed on the 6 task deviations.

For the Roche pump, the two reviewers identified the same deviations and the same issues. However, they disagreed upon the severity ranking of two. This is further described in the table below.

For the Tandem pump, the two reviewers agreed on the two issues identified as well as their severity. The same two deviations were noted.

Below are the differences tabulated in Table 12.
### Table 12: Table of issues where two reviewers disagreed on severity ranking of identified issues

<table>
<thead>
<tr>
<th>Pump Model</th>
<th>Issues</th>
<th>Identified by 1st reviewer</th>
<th>Severity</th>
<th>Identified by 2nd reviewer</th>
<th>Severity</th>
<th>Reason for disagreement and resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDTRONIC</td>
<td>Notation and terminology non-intuitive: E.g. “S”, “N” and “BG7”</td>
<td>yes</td>
<td>M</td>
<td>yes</td>
<td>L</td>
<td>The two reviewers saw the consequences of not understanding terminology in the history menu for example different. The first reviewer believed that a misunderstanding could leave to error or inappropriate interpretation of insulin dosage. The issue was discussed by the two reviewers and in the end, the second reviewer did concede that in fact, this issue could potentially cause a safety risk, albeit with a small likelihood.</td>
</tr>
<tr>
<td>ROCHE</td>
<td>Checkmark vs. file menu button not intuitive</td>
<td>yes</td>
<td>H</td>
<td>yes</td>
<td>M</td>
<td>The two reviewers did originally did not agree with this issue being a high severity patient safety risk. However, it is worth noting that the second reviewer, though an engineer with human factors experience, was not very familiar with insulin pumps. In discussing this issue, he admitted to not realizing the</td>
</tr>
</tbody>
</table>
consequences of this issue and conceded. He agreed it should be ranked as a high severity issue.

<table>
<thead>
<tr>
<th>Lack of feedback on battery status</th>
<th>yes</th>
<th>M</th>
<th>yes</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>In this particular case, the two reviewers approached the issue differently. The first reviewer believed this was a safety risk. However, because patients using the pump would be aware of how low battery messages are conveyed, believed they would likely be prepared and therefore it would not necessitate a high severity ranking. However, the second reviewer made the case that the low battery message could appear at any time or could be easily ignored or mistaken for a different alarm. The first reviewer conceded and agreed it should be considered a high severity error.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix AA– Hierarchy of Effectiveness

Figure 57: Hierarchy of Effectiveness [119]