

**THE LIVED EXPERIENCE OF CONTINUOUS SUBCUTANEOUS INSULIN
INFUSION IN ADULTS WITH TYPE 1 DIABETES MELLITUS:
A PHENOMENOLOGICAL INQUIRY**

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Abstract

Continuous subcutaneous insulin infusion (CSII) is a complex, medical device for the management of Type 1 Diabetes Mellitus (T1DM) that has gained popularity due to reported improvements in metabolic control and flexibility. Despite the growing number of CSII users, there is limited research exploring the everyday experiences living with this device.

The purpose of my study was to understand the lived experience of adults using CSII therapy to manage T1DM. Accounts of lived experiences from eight individuals were collected through semi-structured interviews and then analysed using Max van Manen's (1990) hermeneutic approach to phenomenology. Four substantive themes with supporting subthemes were identified including *transitioning: not a quick fix*; *CSII: making an invisible illness visible*; *the internal struggle and impact on mental health*; and, *the impact on relationships and the meaning of support*. Viewed together, these themes and subthemes represent the essence of participant experiences; that is, living with CSII eventually took ascendancy over managing T1DM. This research is one of few qualitative studies that explores the lived experience of CSII and has significant implications for healthcare professional practice, education, research, and policy and administration.

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Dedicated to Jackson Glenn and Parker Patrick.

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List of Abbreviations

T1DM	Type 1 Diabetes Mellitus
CSII	Continuous Subcutaneous Insulin Infusion
DM	Diabetes Mellitus
MDI	Multiple Daily Injections
QOL	Quality of Life
HbA1c	Hemoglobin A1c
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic Ketoacidosis

Chapter One. Introduction

The primary focus of this phenomenological study was to understand the lived experience of adults with a Continuous Subcutaneous Insulin Infusion (CSII) device, better known as an insulin pump, for the management of Type I Diabetes Mellitus (T1DM). Phenomenologists seek to determine what a lived experience is like from an individual's point of view. My research goal was to focus on the unique experiences with CSII within its everydayness and interpret the depth of meaning of these experiences. The particular methods employed are discussed in greater detail in chapter three.

T1DM is an incurable, chronic illness that destroys insulin-producing cells in the pancreas. T1DM is the leading cause of stroke, kidney disease, amputation, adult blindness, and nerve damage and the fourth leading cause of global death. Every 10 seconds two people develop Diabetes Mellitus (DM) and one person dies from DM-related causes. T1DM affects 246 million people worldwide and this number is expected to increase to 380 million by 2025. In Canada, more than 300,000 people are currently living with T1DM (Juvenile Diabetes Research Foundation, 2012).

T1DM must be managed with an external source of insulin. This external source can be from either multiple daily injections (MDI) or CSII. In the next decade, it is estimated that 40% of people with T1DM will be using CSII, yet the lived experience of those on CSII is poorly understood (Lee, Im, & Magbual, 2004). Current research for adults using CSII therapy with T1DM is limited to mainly quantitative studies that focus on clinical data and metabolic outcomes such as blood glucose variability. Research is scarce on how CSII affects day-to-day living and what the lived experience for an individual using this device (Garmo, Hornsten, & Leksell, 2013; Hanaire, 2011). The few qualitative studies that have been done have been

criticized for using measuring tools that lack the sensitivity to understand the lived experience (Barnard & Skinner, 2007; Hanaire, 2011). Several studies reviewed (Barnard, Lloyd & Skinner, 2007; Barnard & Skinner, 2007, 2008; Garmo et al., 2013; Nicolucci et al., 2008; Trief, Sandberg, Dimmock, Forken & Weinstock, 2013) reported a lack of qualitative research on how CSII affects day-to-day life. T1DM is a challenging disease with a demanding self-management schedule. It is associated with psychological morbidity and carries great emotional burden, yet little is known about the psychological challenges that occur using CSII therapy to manage T1DM (Balfe et al., 2013; Barnard & Skinner, 2008; Lilly, 2004; Todres, Keen, & Kerr, 2010; Trief et al., 2013).

This phenomenological study of eight individuals with CSII led to a fuller understanding of what it is like to live with CSII to manage T1DM. CSII is of genuine interest to me because I have been using this therapy to manage my T1DM for most of my life. Further details about how I position myself within this research are discussed later in this chapter. This chapter also provides the physiology of T1DM. CSII can be very technical for the novice as witnessed by the stories told. The following section provides a foundation for this phenomenon as it is important for the reader to have a basic yet fuller understanding of T1DM and CSII. This chapter also provides the study background, study rationale and the research goal and question.

Understanding Type 1 Diabetes Mellitus and Continuous Subcutaneous Insulin Infusion

DM is the seventh leading cause of death according to the Center for Disease Control and Prevention (2013) and Statistics Canada (2012). As reported in 2015, in Canada, 3.4 million people are living with this disease, up from 1.7 million and 1.6 million in 2011 and 2006, respectively (Canadian Diabetes Association, 2015a). It is estimated that by 2025 this number will rise to 5 million, a 44% increase (Canadian Diabetes Association, 2015a; Statistics Canada,

2012). In Newfoundland and Labrador, there are 60,200 people with DM, up from 49,572 and 38,983 in 2011 and 2006, respectively. By 2025 this number will reach 84,500, with an increase of 40% (Canadian Diabetes Association, 2015b). T1DM is different from many other diseases as it is largely invisible to the public. The emotional burden, stressors and frustrations of day-to-day management are distressing and associated with a high incidence of psychological morbidity. Depression and anxiety are common for people with this complex disease; in fact, an individual who has T1DM is two times more likely to have depression than an individual who does not (Balfe et al., 2013; Trief et al., 2013). Individuals with this disease have strong fears about DM-related complications that can impact their future and hence quality of life (QOL). Even with good management there is still a high probability that DM-related complications will occur. For individuals with T1DM, the realization that they are not invincible is distressing. As a person living with T1DM, I can personally say that the threat of these debilitating and life-threatening complications can cause great fear and distress. Statistics on the complications of T1DM are ubiquitous but the emotional effects of managing and living day-to-day with this chronic disease have not been fully explored. T1DM is more than the absence of insulin; it has the potential to rob individuals of their hopes and dreams (Balfe et al., 2013; Lilly, 2004; Ritholz et al., 2007; Todres et al., 2010; Trief et al., 2013; World Health Organization, 2009).

In 1997 the term Insulin Dependent Diabetes Mellitus was changed to T1DM, or Type 1 Diabetes Mellitus, as aforementioned. The term “insulin dependent” caused confusion as it tended to shift the focus to the treatment of the disease and not the pathogenesis. T1DM is thought to be an autoimmune disease that destroys insulin-producing beta cells in the pancreas. An individual with T1DM produces no insulin and is therefore dependent on an external source of insulin to survive. Although we have come a long way since the discovery of insulin in 1922

by Frederick Banting and Charles Best, manually delivering the right amount of insulin to manage blood glucose levels can require constant experimentation. Thus, blood glucose levels fluctuate despite the best efforts to manage them (Lilly, 2004). This can lead to the individual feeling controlled by DM instead of feeling like he or she has control over it. Presently, an external source of insulin can be delivered by various methods. MDI with a syringe is still a common method for delivering insulin. This usually involves injecting between two to five insulin filled syringes per day; in the morning, and at lunch, dinner and bedtime. MDI therapy requires a very strict eating routine; when insulin is injected food must be eaten at that time to counteract its effect. External factors such as exercise, stress, sickness, food intake and even insulin absorption can have a dramatic effect on blood glucose and thus, insulin requirements day-to-day can change due to these shifting factors (American Diabetes Association, 2013a; Bruttomesso, Costa, & Baritussio, 2009).

CSII therapy is another option for insulin delivery. CSII is not a new phenomenon, although in the last decade this treatment has been part of a technological explosion in T1DM management with the goal of improving QOL (Lee et al., 2004). Introduced in the late 1970s, CSII was developed for patients with unmanageable T1DM.

Known then as the Blue Brick, the auto syringe model lacked esthetic value and functionality. It was large, bulky, required a screwdriver to adjust insulin dosages, and lacked a safety mechanism to ensure proper insulin delivery. The CSII device has since been transformed by technology becoming smaller, safer,

and more user friendly as presented in Figure 1. CSII is worn continuously, 24 hours a day, 365 days a year. CSII devices are pumps in the form of small computerized devices that deliver

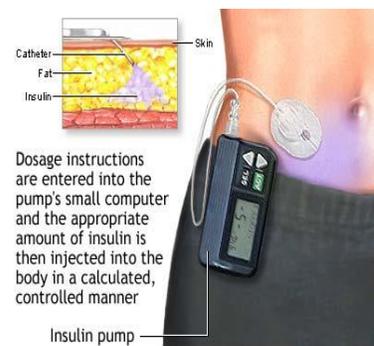


Figure 1. A Modern CSII Device (Medline Plus, 2015)

insulin. Doses of insulin are delivered through a catheter that is inserted underneath the skin into the fatty tissue with the aid of a small needle. It is secured in place with tape and then changed at minimum every three days by the user. This catheter is known as the infusion set. The CSII device is then connected to the infusion set by plastic tubing. CSII is not an artificial pancreas but mimics the natural reaction of a pancreas when managed by the user.

CSII delivers insulin in two ways. One is a steady, continuous delivery, known as the basal rate and the other is an immediate surge of insulin known as the bolus dose. Basal rates are the background insulin needed to keep blood glucose levels within the target range in between meals and overnight when individuals are not eating. Basal insulin represents about half of the daily insulin required. The amount of insulin an individual receives per hour is determined by the basal rate setting. An individual can have multiple basal rates and each rate consists of distinct start and stop times with a different insulin delivery amount for each time. Basal rates can be between 0.00 -35.0 units/hour. Basal rates are specific for each individual, therefore calculated differently for each individual. Together bolus doses and basal rates cover a 24-hour period that begins at midnight and then repeats each day. Basal rates can be affected by factors such as stress, hormones, exercise, and sickness; therefore, basal rates often need to be adjusted frequently, sometimes daily. There are also settings such as temporary basal rates, which offers an immediate short-term change to basal rate settings for a specified time between 30 minutes to 24 hours. This offers a short-term adjustment to the basal insulin delivery to meet exercise demands or when blood glucose levels are high (or hyperglycemia) or low (or hypoglycemia). Settings and adjustments of basal rates are managed by the user (American Diabetes Association, 2013b, 2013c; Medtronic, 2016a, 2016b).

Alternatively, there are also multiple settings on the CSII device that allow different delivery methods of a bolus dose of insulin, which can be delivered all at once or over a period of time chosen by the user. A bolus dose is administered to cover any carbohydrates that are consumed, either food or beverages, and as a correction or supplemental insulin dose to treat hyperglycemia (American Diabetes Association, 2013a). Food is divided into three main categories: carbohydrates, fat, and protein. When carbohydrates are consumed they break down into blood glucose or sugar in the bloodstream. The pancreas then secretes insulin to send this blood glucose to the cells to use as energy; thus, maintaining a stable blood sugar. For individuals with T1DM the pancreas is unable to perform this function, thus CSII is required. This involves carbohydrate counting and being able to determine the exact number of carbohydrates in every piece of food and beverage to match the insulin needed. A carbohydrate counting course is often administered to new users of CSII to educate them on how to determine these daily calculations. Carbohydrate counting can be difficult when eating at restaurants or when food products do not have this information listed on the nutritional label. An estimate of the carbohydrates in the food to be consumed is then made by the individual, which is not always accurate. Accuracy is crucial in ensuring the exact amount of insulin is delivered to cover the number of carbohydrates consumed. Inaccurate calculations or assumptions can lead to hypoglycemia or hyperglycemia. In addition, the food's composition, such as the fat content and glycemic index, has a great impact on how the food is absorbed in the body and thus will impact the insulin required and what bolus program is used to deliver it. For instance, foods high in fat are digested differently and may require different infusion rates, such as dual-wave bolus or square-wave bolus or even a temporary bolus rate. Carbohydrate ratios are set on the device to measure the ratio of insulin to carbohydrates. CSII is capable of multiple carbohydrate ratios

throughout a 24-hour period and each individual will have different ratios that are tailored to them. Again, this setting can require frequent, sometimes daily adjustments (Medtronic, 2016c).

In addition to the features above, there are multiple other settings available on CSII, such as the maximum bolus and basal rate, and insulin sensitivity that determines how much blood glucose will be consumed. There are no exact settings that work for everyone. Thus, each individual requires unique CSII settings to adjust and monitor on a continuous basis (Medtronic, 2016a, Medtronic, 2016b). Although this regime offers less glucose variability than MDI, it is still a piece of equipment that is ultimately controlled by the user; CSII therapy does not miraculously check blood glucose or calculate how much insulin is required.

Although CSII can offer greater flexibility, it is apparent from the above discussion that working with the device can be very demanding and requires frequent blood glucose testing, constant adjustments of basal and bolus rates, and hypervigilance to prevent hypoglycemia and hyperglycemia. Furthermore, CSII is not immune to external factors that can affect blood glucose levels. Moreover, CSII adjustments can be dangerous if not understood or used properly and thus this device is not appropriate for everyone. Individuals require a thorough understanding of how to operate this equipment and to work with it safely. It is well documented in the research literature that CSII is a tool and like any tool requires a skilled operator (Balfe et al., 2013; Barnard & Skinner, 2008; Bruttomesso et al., 2009; Kerr, Nicholls, & James, 2008; Lee et al., 2004; Nicolucci et al., 2008; Scheidegger, Allemann, Scheidegger & Diem, 2007; Trief et al., 2013).

Between 1993 and 2005, CSII users have increased from 15,000 to 282,000 in the United States (Barnard & Skinner, 2008). In 2016, more than 350,000 individuals in the United States were using CSII (McAdams & Rizvi, 2016). The Canadian statistics on CSII usage are not

available but it is estimated that in the next decade 40% of individuals with T1DM will be using CSII (Lee et al., 2004). Given the increasing prevalence of CSII users and its complexity it is paramount that we understand the impact that CSII is having on the everyday lives of individuals managing T1DM (Barnard & Skinner, 2008; Bruttomesso et al., 2009; Kerr et al., 2008; Lee et al. 2004; Neithercott, 2013; Nicolucci et al., 2008; Scheidegger et al., 2007; Todres et al, 2010; Wood, 2011).

Study Rationale

T1DM management in and of itself is demanding. As made apparent, the complexity of CSII demands physical and mental endurance. According to Watt (2007), “good research questions spring from a researcher’s values, passions, and preoccupations” (p. 84). Phenomenological research in particular stems from what deeply interests the researcher and exploration involves a phenomenon or experience that people live through (van Manen, 1997a). I am in a unique position in relation to my research topic and I am passionate about understanding the experiences of living with CSII. I have lived with T1DM for the last 34 years. During this time, I was on MDI for 22 years. I then made the transition to CSII therapy in 2007. When I was considering changing my T1DM management to incorporate CSII, I wanted to know how this treatment would affect my day-to-day management. Clinical data, including blood glucose variability, Hemoglobin A1c (HbA1c), and risks of complications, were all important to me. However, I also wanted to know how wearing an external device at all times would impact my day-to-day living. I wanted to know if it would provide me freedom with regards to exercise, eating and social interactions. I felt restricted with MDI as it often led to hypo- or hyperglycemic episodes. This prohibited me from exercising and I often had to eat not because of my own desires. These issues changed the way I interacted with other people because I felt “different.” I

also wanted to understand how wearing CSII for 24-hours a day would affect my self-image. CSII concealment was important. I wondered how I would conceal CSII when I was wearing a dress or a bathing suit. In contrast, MDI provided me the convenience of storing my supplies in my purse and discretely administering the insulin. Hyperlipidemia was also important, as the CSII needle in the infusion set is much longer than the typical insulin syringe. Once I began using the CSII device I encountered different challenges with daily living that were never discussed in the education session and are not discussed in current research.

I diligently performed a literature review to find out how wearing CSII would impact my daily living, but found very little information. As a person considering this therapy, I found there was a gap in the literature, leaving me to make a life-altering, yet uninformed, decision. In fact, a study by Bernard and Skinner (2007) was the first to provide qualitative data on CSII for adults with T1DM. They reported that their participants were concerned about the visibility of the device, CSII breakdown, cost, and skin integrity issues. Increased control, freedom, independence, family effects, and flexibility were found to be the more positive features of CSII. Further research is needed to understand the lived experience of individuals using CSII. The little that we do know suggests that CSII therapy compounds the stress of managing T1DM and can adversely affect overall well-being (Aberle et al., 2009; Balfe et al., 2013; Barnard & Skinner, 2008; Bruttomesso et. al., 2009; Nicolucci et al., 2008; Rasmussen, Ward, Jenkins, King & Dunning, 2011; Todres et al., 2010; Trief et al., 2013).

Research Goal and Question

I wanted to explore the experiences of individuals who are living with CSII to manage their T1DM. The specific research question was: What is the meaning of the lived experience for adults who are on CSII for the treatment of T1DM? I anticipated that my study findings would

provide an in-depth understanding of the thoughts, feelings, and positive and negative impact of living with CSII in its everydayness. This is important for patients and healthcare providers.

From my experience, the focus of CSII patient education in this province is focused on the technology and on operating and troubleshooting and hence, users do not engage in discussion of their daily experiences. My study findings would enhance awareness among healthcare professionals of the psychosocial impact and ongoing issues.

Chapter Two. Literature Review

A comprehensive literature review was conducted using the CINAHL and PubMed databases. As an adjunct, the Google search engine was also used, along with government agencies and associations, such as the World Health Organization, the Canadian and American Diabetes Associations, the Center for Disease Control and Prevention, and Statistics Canada. Search limitations included research articles written in English and adults 19 years of age or older. Search words included “continuous subcutaneous insulin infusion,” “CSII,” “insulin infusion,” “type I diabetes mellitus,” “insulin pump,” “psychosocial,” “psychological,” “lived experience,” “quality of life” and “daily living.” Research focused on children and infants and type II diabetes was excluded. Each article was reviewed and critically analyzed, and the reference lists were reviewed for additional articles. This process continued until there was a repetition of the articles noted. The quality of the studies was assessed based on the date of the study, the source from which it originated, relevance to the research question, scientific rigor and a critical appraisal of the methodology. Search results produced mainly quantitative studies and very few qualitative studies.

I begin this literature review with an overview of T1DM and its management regimes. This prerequisite information introduces the relevant topics related to T1DM to which I refer throughout this chapter. Next, I focus on the Diabetes Control and Complications Trial (DCCT), a revolutionary research study that set the precedent for all other research and management related to T1DM and intensive insulin therapy. Intensive insulin therapy was either CSII or MDI involving three to four injections per day. When published in 1993, the results of the DCCT renewed interest in CSII therapy as a management option for T1DM and served as the foundation for research related to CSII (The DCCT Research Group, 1993). The majority of

relevant studies focused on the metabolic aspects of CSII. Although not the lived experience, it is important to highlight the many features of CSII, which are much more advanced than previous regimes, such as MDI, as well as provide a brief history of CSII. This is followed by a comparison with MDI in terms of the incidence of hypoglycemia, hyperglycemia, diabetic ketoacidosis (DKA), HbA1c values, and DM-related complications. Also, from the literature I present the process of CSII initiation and implementation with emphasis on candidate selection. Finally, I summarize the literature review with studies about QOL and the psychosocial aspects of CSII.

Type 1 Diabetes Mellitus

The term “diabetes” is based on the Greek word for siphon meaning “flowing through.” This term was coined by Aretaeus, a Greek physician from the first century A.D., who referred to individuals with diabetes as a siphon because water was freely moving in and out of their body (Allman, 2008; Mandal, 2012). In 1675, the Latin term mellitus, meaning “sweet as honey,” was added to the word diabetes by Thomas Willis (Mandal, 2012) because a white powdery substance (sugar) was found in the evaporated urine of individuals with DM (Loughrey, 2010; Mandal, 2012).

For an individual who does not have T1DM, blood glucose is kept within a narrow range by the pancreas, between 4-5.6 mmol/L, by releasing minute amounts of insulin throughout the day and then increasing insulin production during meals to reduce blood glucose. In the event of hypoglycemia, counterproductive hormones are released to increase plasma glucose. Similarly, if hyperglycemia occurs, insulin production is increased for glucose transport to maintain blood glucose within a normal range. Insulin is the gate keeper for regulating the uptake of glucose into cells, serving as an energy source, and is released in response to increasing blood glucose levels.

T1DM is the result of a defect in insulin secretion whereby the insulin-producing beta cells in the pancreas have been destroyed by an unknown cause (Cummins et al., 2010). Without beta cells, insulin is not produced, and glucose cannot be transported in the blood stream to the cells in the body. This results in cell death and elevated levels of plasma or blood glucose. Essentially an individual with T1DM is starving regardless of how much food is eaten (Allman, 2008; Cummins et al., 2010; Misso, Egberts, Page, O'Connor & Shaw, 2010). There is no cure or prevention for T1DM, thus it requires lifelong monitoring of blood glucose levels and an external source of insulin; otherwise death will occur (Misso et al., 2010).

“Control” is a reoccurring term used when talking about T1DM and refers to keeping blood glucose levels as close to normal as possible. Control of blood glucose can be monitored in several ways. The most frequent way, on a day-to-day basis, is finger pricking to produce a drop of blood on a test strip inserted into a blood glucose meter. This test is quick and reveals the blood glucose at that moment in time. A second test is known as HbA1c or glycosylated hemoglobin. This test is a good predictor of long-term control and reflects the average blood glucose over a three-month period. Bloodwork for HbA1c must be done at a clinic and patients must wait several days to a week to get the results (Cummins et al., 2010).

Therapy and management of T1DM have improved significantly over the years, as research continues to educate those in the medical field about the disease. Early in the 20th century a reduced diet of only 450 calories was prescribed by doctors for individuals with T1DM. This would prolong life slightly, but it required patients to be in a state of starvation, leaving them very weak and fragile (Sattley, 2015). It was not until 1921 that Canadian surgeon, Dr. Frederick Banting, and his assistant, Charles Best, discovered insulin, and the first trial with a 14-year-old boy with T1DM was successful, using insulin from the pancreases of cows, or

bovine insulin (Stylianou & Kelnar, 2009). Insulin delivery in the 1920s included one injection per day with a large glass syringe and reusable needles that required sterilization in boiling water after each use. A pumice stone was used to keep the needle tip sharp for injection (Selam, 2010). In 1923, the first bovine insulin, developed from pigs, cows or fish, became available to the public and the first human insulin was produced in 1982 (Sattley, 2015; Stylianou & Kelnar, 2009). Medical breakthroughs continued with the development of urine test strips to test blood glucose in the 1960s, the first single use syringe in 1961, the first blood glucose meter in 1969 and CSII in the 1970s (Sattley, 2015). For over 50 years, a vial of insulin and a syringe was the only insulin delivery method available to individuals living with T1DM, who administered one to two injections per day, also known as conventional therapy. In 1985, the first insulin pen was released and offered benefits such as convenient use in public areas, as needles were often associated with drug use. The insulin pen was also quicker to use and had increased accuracy at measuring low dosages of insulin (Selam, 2010). For these reasons, according to Selam (2010), most people with T1DM chose an insulin pen as the method of insulin delivery rather than syringes. Conventional therapy, either by syringe or insulin pen, was still the standard method of insulin delivery for someone with T1DM until the publication of the DCCT in 1993, when intensive insulin therapy became the method of choice for managing T1DM. Intensive insulin therapy allowed the adjustment of insulin dosages several times per day based on blood glucose levels. Conventional therapy did not offer the same flexibility and thus quickly became an obsolete method of T1DM management (Selam, 2010).

The Diabetes Control and Complication Trial

The DCCT was a ground-breaking controlled clinical trial conducted from 1982 to 1993, that altered the course of T1DM management. It remains one of the most highly cited research

trials to date (Nathan, 2014; The DCCT Research Group, 1993). The DCCT included 1441 participants aged 13-39 years with T1DM between one and 15-years' duration in 29 medical centres in the United States and Canada. This study was based on the premise that intensive insulin therapy designed to achieve glycemic control close to the normal range, would prevent, delay or minimize complications better than conventional therapy (The DCCT Research Group, 1993). In 1993 the results of the DCCT were published and it was shown that maintaining blood glucose levels as close to the normal range as possible helped prevent the onset and progression of microvascular and macrovascular diseases including retinopathy, a disease of the retina at the back of the eye and is the leading cause of blindness in adults under 65 years of age in the United States; nephropathy, the leading cause of kidney failure in the United States; and, neuropathy, or nerve damage. Neuropathy causes alterations in sensation and pain in the fingertips, feet and legs, is a major contributing factor for amputations, and can also affect parts of the nervous system that controls heart rate, digestion, sexual function and blood pressure (National Institute of Diabetes and Digestive and Kidney Disease, 2008a; The DCCT Research Group, 1993).

During the DCCT, the intensive insulin therapy group received insulin either via CSII or MDI with at least three injections per day. Insulin dosages were adjusted daily based on a meal plan, exercise plan, and blood glucose levels. In addition, participants met with the healthcare team at least once per month and had frequent telephone contact with them for support. They also had frequent metabolic tests, such as blood tests to monitor HbA1c, urine tests and electrocardiograms (The DCCT Research Group, 1993). The conventional therapy group received insulin by having one to two injections per day. In addition, they also self-monitored blood glucose and were educated on diet and exercise. This group did not adjust their insulin

dosage daily but maintained a consistent insulin dosage regime. Both groups were followed for a total of 6.5 years with a 99% participant retention rate (The DCCT Research Group, 1993).

In the DCCT the risk of retinopathy was similar in both the conventional and intensive insulin therapy group until 36 months. After 36 months, the incidence of retinopathy started to decrease for the intensive insulin therapy group compared with the conventional therapy group. After five years, the intensive insulin therapy group had a 50% reduced risk of retinopathy and the risk of retinopathy continued to decrease as more time elapsed. At six years, participants in the intensive insulin therapy group, compared to the conventional therapy group, had a 76% reduced risk of developing retinopathy and for patients who had mild eye disease at the start of the study their risk of progression of retinopathy was reduced by 54% compared to the conventional group (The DCCT Research Group, 1993).

The development and progression of nephropathy was reduced by 50% for patients in the intensive insulin therapy group compared to the conventional therapy group in the DCCT (National Institute of Diabetes and Digestive and Kidney Disease, 2008a). Likewise, the risk of developing neuropathy was reduced by 69% for participants in the intensive insulin therapy group compared to the conventional therapy group (The DCCT Research Group, 1993). One of the key findings from the DCCT was that the earlier initiation of intensive insulin therapy resulted in reduced risk and progression of DM-related complications (The DCCT Research Group, 1993).

HbA1c level is the gold standard for measuring glycemic control for individuals with T1DM and reflects the individual's average blood glucose over the previous 2-3 months (Hood, 2012; Pickup & Sutton, 2008; Shalitin, Gil, Nimri, de Vries, Gavan, & Phillip, 2010).

Hemoglobin is a protein in red blood cells that carries oxygen. HbA1c measures what percentage

of hemoglobin is coated with glucose (or is glycosylated); thus, a higher HbA1c would indicate a high blood glucose level (Lee et al., 2004). When the DCCT ended in 1993, it was noted that there was considerable variability in the way that glycosylated hemoglobin was being reported by laboratories. This variation made it challenging for physicians in clinical practice to have a reference for target glycosylated hemoglobin levels for individuals with T1DM. When the DCCT results were released in 1993, a committee was established to standardize the way glycosylated hemoglobin was reported by laboratories. The result was that all laboratories would report it as HbA1c (Little, Rohlfing, & Sacks, 2011). The standardization of HbA1c and the results of the DCCT prompted the American Diabetes Association to begin recommending a target HbA1c level of less than 7% for individuals with T1DM in 1994 (Lee et al., 2004; Little et al., 2011). A lower HbA1c level meant tighter glycemic control and this reduced complications, as published by the DCCT. Guesswork on what the standards and treatment should be for individuals with T1DM had been eliminated, as intensive insulin therapy was proven to be the most effective. The results from the trial also profoundly affected the relationships between healthcare professionals and patients with T1DM (Cefalu & Ratner, 2014; Lilly, 2004). The proven effectiveness of intensive insulin therapy, in terms of tight glycemic control, perpetuated healthcare professional focus on physiological measures when using MDI or CSII therapy (Nicolucci et al., 2008) and possible psychological issues continued to be overlooked (Lilly, 2004). The DCCT also renewed interest in CSII as a viable option for the management of T1DM (Nicolucci et al., 2008).

The results of the DCCT were so ground-breaking that an independent oversight committee halted the study in 1993, one year ahead of schedule, due to these conclusive results (The DCCT Research Group, 1993). The conventional therapy group (control group) in the DCCT was quickly advised to switch to intensive insulin therapy and was then educated on this

treatment option (Nathan, 2014). In the intensive therapy group, CSII was used by 30-40% of the participants throughout the study (Hammond, Boardman, & Greenwood, 2006; Johansson, Adamson, Lins, & Wredling, 2005). Participants in the DCCT were limited to a younger age group between ages 13-39 years and the study was not long enough to explore the effects intensive insulin therapy had on the incidence and predictors of cardiovascular disease and the advanced stages of DM-related complications. Thus, this became the focus of a longitudinal, observational study known as the Epidemiology of Diabetes Interventions and Complications, which was initiated after the DCCT (Cefalu & Ratner, 2014; Lepore et al., 2009; Nathan, 2014; National Institute of Diabetes and Digestive and Kidney Disease, 2008a). The entire cohort in the DCCT was then invited to participate in the Epidemiology of Diabetes Interventions and Complications study (Nathan, 2014). The results of the Epidemiology of Diabetes Interventions and Complications study revealed that lower glycemic control achieved with intensive insulin therapy was associated with a 42% reduction in any cardiovascular disease event and a 57% reduction in a non-fatal heart attack, stroke, or death from cardiovascular causes. More than 99% of participants completed the study in the DCCT and the retention of the original cohort was 88% for the Epidemiology of Diabetes Interventions and Complications study after 20 years (Nathan, 2014).

The History of CSII

The idea of continuous insulin delivery was introduced in the early 1960s by Arnold Kadish, who developed the first closed-loop insulin pump device in 1963, as pictured in Figure 2. The device was the size of a backpack and therefore was dismissed at the time due to its

impracticality (Alsaleh, Smith, Keady, & Taylor, 2010). It was not until 1974 that the idea of continuous insulin infusion re-emerged, and the first computer controlled closed-loop insulin delivery device, known as the Biostator, was developed, as shown in Figure 3. The device consisted of a pump, for the continuous withdrawal and mixing of

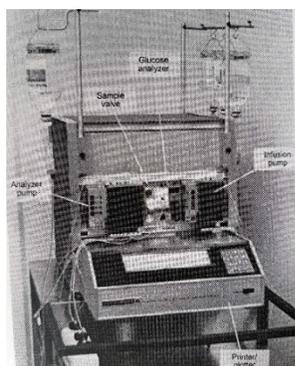


Figure 3. The Biostator (Alsaleh, Smith, Keady, & Taylor, 2010)

concentration; a computer that had programmed algorithms to calculate the amount of insulin to be infused based on blood sugar level; a computer-operated infusion pump that infused the insulin; and finally, a printer and plotter that recorded blood glucose readings. Due to its complexity,

size and the equipment required, the Biostator was only used for research (Alsaleh et al., 2010). The first study of CSII delivered via insulin pumps was conducted in 1978 at Guy's Hospital in the United Kingdom by Dr. John Keen and Professor Harry Pickup, who developed a CSII pump known as the Mill Hill Infuser, as shown in Figure 4.

This device was a portable, battery-operated miniature syringe pump with a dual-rate insulin delivery system.

Keen and Pickup reported a successful and practical use of insulin delivery via CSII for individuals with T1DM

(Alsaleh et al., 2010). It was not until 1978 that the first commercial CSII device was marketed.

This was known as the auto syringe, or blue brick, as shown in Figure 5 (Alsaleh et al., 2010; Cummins et al., 2010; Davies & Baum, 1988). The auto syringe was a small, battery-powered

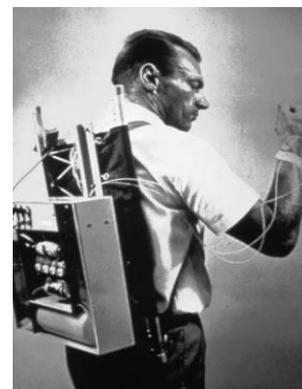


Figure 2. The First CSII Device (Alsaleh, Smith, Keady, & Taylor, 2010)

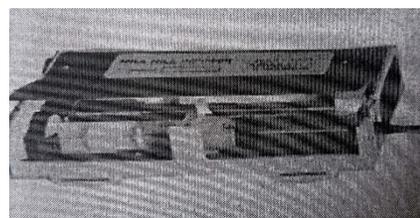


Figure 4. The Mill Hill Infuser (Alsaleh, Smith, Keady, & Taylor, 2010)

CSII device developed as a research tool to improve glycemic control in adults with T1DM

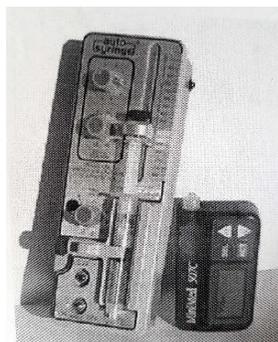


Figure 5. The Auto Syringe (Alsaleh, Smith, Keady, & Taylor, 2010)

(Davies & Baum, 1988). In the 1980s, the first microprocessor controlled CSII device, as shown in Figure 6, known as the Nordisk infuser, was introduced, and designed by the team at Guy's Hospital and the team that developed the Mill Hill device

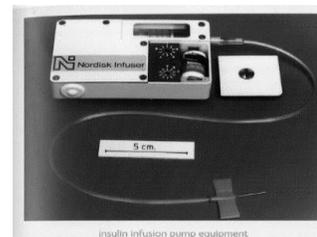


Figure 6. The Nordisk Infuser (Novo Nordisk History (2011)

(Alsaleh et al., 2010). The internal processor

allowed individually adjusted programmable basal rates. Unfortunately, the device had no memory, so the rates had to be adjusted daily (Craστο, Jarvis, & Davies, 2016).

The popularity of CSII quickly grew after its introduction in the late 1970s and by the early 1980s CSII was being considered as a possible alternative for insulin delivery for individuals with T1DM. Although medical and pharmaceutical companies began to invest in CSII development in the early 1980s, the demand for CSII devices quickly declined due to their large size, as well as safety and efficacy concerns (Alsaleh et al., 2010). CSII devices were large, heavy, and not user-friendly with some requiring a screwdriver to adjust settings. Thus, the use of CSII was met with resistance from patients, and CSII devices were reserved only for the difficult-to-manage cases often with unsatisfactory results (Alsaleh et al., 2010). The publication of the DCCT in 1993 renewed interest in CSII because it showed that intensive insulin therapy, either by CSII or MDI, prevented or delayed the onset of DM-related complications (Bruttomesso et al., 2009; Cummins et al., 2010). To maintain optimal glycemic control to reduce the chances of complications, CSII became a more flexible intensive insulin therapy

alternative to MDI, thus the technology improved greatly after the DCCT, as did its popularity (Bruttomesso et al., 2009; Cummins et al., 2010; Scheidegger et al., 2007).

Modern CSII devices have been transformed by technology in both form and function, as they have become lightweight, smaller, battery-operated, and able to hold enough insulin for several days. Alarms are present for battery life, low insulin, and faulty electronics, reducing the fear of malfunction and increasing reliability (Cummins et al., 2010; Thabit & Hovorka, 2016). Previously, cosmetic improvements to CSII, such as colour selection, were the focus (Grunberger et al., 2014). Now, new features such as tubeless systems, disposability, colour touch screens, USB rechargeable batteries, and pre-filled insulin cartridges make them more electronically appealing and easier to use (Cummins et al., 2010; Grunberger et al., 2014). CSII can now have basal rates pre-set multiple times during the day and night, bolus boosts can be administered before meals, and basal rates can be reduced during periods of increased activity (Cummins et al., 2010; Thabit & Hovorka, 2016). Settings on CSII allow for a continuous infusion of a low volume basal rate of insulin for fasting periods and increased rate boluses to cover meals. This mimics the insulin delivery produced by the beta cells of the pancreas offering increased flexibility to those with T1DM (Bruttomesso et al., 2009; Cummins et al., 2010).

CSII Compared to MDI

Since the publication of the DCCT, numerous studies have been conducted to determine which method of intensive insulin therapy (CSII or MDI) is preferred. In the literature, the benefits of CSII over MDI include increased flexibility, convenience, and independence. Individuals on CSII have reported worrying less about hypoglycemia, increased satisfaction for both themselves and their family members, and claim that it interferes less with their lives than MDI (Barnard & Skinner, 2008). The primary advantage of CSII over MDI is that insulin

adjustments can be planned and made immediately based on blood glucose levels (Thabit & Hovorka, 2016). Due to these reported benefits of CSII, “MDI is typically referred to as the poor man’s pump” (Cummins et al., 2010, p.12). Below, I review the literature comparing CSII with MDI with regard to hypoglycemia, HbA1c, hyperglycemia, DKA, and DM-related complications. First, however, I will define hypoglycemia and discuss the symptoms.

Hypoglycemia Defined

Individuals with T1DM commonly fear hypoglycemia. Often described as “the worst feeling in the world” (Trief et al., 2013), typical symptoms include hunger, sweating, tremors, palpitations, and headaches activated by adrenaline and noradrenaline released into the bloodstream by the central nervous system (Cummins et al., 2010). These symptoms are warnings that alert individuals with T1DM to take action to increase their blood glucose. And typically start when blood glucose levels reach 3.6 mmol/L (Cummins et al., 2010). However, in some individuals with T1DM these warning symptoms do not occur. This is known as “hypoglycemic unawareness” or more recently termed “impaired hypoglycemia awareness” (Cummins et al., 2010; Iqbal & Heller, 2016). The reported prevalence of impaired hypoglycemia awareness in T1DM is 20-25%, rising to 50% for individuals who have had T1DM for more than 25 years (Iqbal & Heller, 2016). When blood glucose levels fall below 3 mmol/L, cognitive impairment can occur leading to drowsiness, confusion, and incoordination before the warning symptoms, which make it difficult, if not impossible, for individuals to assist themselves (Cummins et al., 2010; Iqbal & Heller, 2016). Since the brain uses glucose as fuel, an acute hypoglycemic episode causes transient changes in brain function resulting in neurobehavioral or cognitive changes, such as problems with short- and long-term memory, information processing and attention and unconsciousness (Cummins et al., 2010; Iqbal &

Heller, 2016). In addition to these physical effects, hypoglycemia has a significant psychological impact brought on by the high levels of anxiety and fear (Cummins et al., 2010; Nicolucci et al., 2008; Trief et al., 2013). The physical symptoms of hypoglycemia are short-lived when treated, but the long-term psychological effects are so profound that the individual has a greater fear of a reoccurring hypoglycemic episode than DM-related complications and as such will do anything to avoid its reoccurrence (Cummins et al., 2010; Trief et al., 2013). This usually involves keeping blood glucose levels elevated above what is recommended to avoid hypoglycemia (Cummins et al., 2010; Pickup & Hammond, 2009). This fear and worry affect not only the individual living with T1DM, but also their family (Cummins et al., 2010; Scheidegger et al., 2007; Trief et al., 2013). Family members describe seeing their loved one's experience of hypoglycemia as a terrifying event (Trief et al., 2013). Family members often fear their loved ones will lose consciousness during a hypoglycemic event and then having the responsibility of reacting correctly in such an emergency (Scheidegger et al., 2007). In addition, family members report that the symptoms of hypoglycemia, such as moodiness, irritability and impatience, are difficult to deal with (Trief et al., 2013).

The National Institute for Health and Care Excellence is a non-governmental public body in the United Kingdom. Although independent of government in its work, it was created by government to advise the United Kingdom National Health Service to standardize best practices and provide national guidance on health technology, clinical practice, public health, social care and quality standards. In 2003, the National Institute for Health Care Excellence defined severe or disabling hypoglycemia as the state when third-party assistance is required. In 2008, these guidelines were revised to reflect the large number of individuals with varying degrees of hypoglycemia, acknowledging that hypoglycemia can be detrimental to QOL. The new

guidelines identify severe or disabling hypoglycemia as repeated and unpredictable occurrences that result in persistent anxiety about having low blood glucose and the adverse effects on QOL (National Institute for Health and Clinical Excellence, 2008; Pickup & Hammond, 2009).

Comparing the Incidence of Hypoglycemia

The DCCT results in 1993 indicated that severe hypoglycemia was three times higher in individuals on intensive insulin therapy compared to conventional therapy (The DCCT Research Group, 1993), being 65% and 35%, respectively (Cummins et al., 2010; Pickup & Sutton, 2008). No researchers had compared the frequency of severe hypoglycemia between CSII and MDI users; however, since then researchers are reporting conflicting results. In 2002, Bode, Sabbah, Gross, Fredrickson, and Davidson argued that one of the advantages of CSII was a reduction in hypoglycemia. However, that same year, after reviewing the evidence, Pickup and Keen (2002) found that there had been an increase in hypoglycemic episodes for patients on CSII. A cross-sectional and longitudinal study using questionnaires by Scheidegger et al. (2007) found that participants experienced fewer severe hypoglycemic events with CSII compared to MDI. Researchers noted that fear was reduced among users of CSII and their families, but did not elaborate. However, Ritholz et al. (2007) discovered that when individuals switched to CSII from MDI, fear was diminished, and participants shared that they felt “normal” because they could eat or skip a meal without fear. A longitudinal, prospective observational study by Giménez et al. (2007) over a 24-month period ($N=153$) showed that participants who switched from MDI to CSII had a significant reduction in severe hypoglycemic events, from 31% to 5%. Pickup and Sutton (2008) performed a meta-analysis of 22 studies exploring the incidence of severe hypoglycemia comparing CSII to MDI. They found that severe hypoglycemia was markedly reduced with CSII compared to MDI. Pickup and Sutton also found no evidence to suggest that

CSII increased the incidence of severe hypoglycemia as was previously suggested. Similarly, Bruttomesso et al. (2009) found that participants who switched from MDI to CSII had a 75% reduction in severe hypoglycemia. They reported that CSII increases hypoglycemic awareness so that patients experienced warning signs of low blood glucose earlier and could respond. In 2010 a Cochrane review of 23 randomized controlled trials ($N=976$) showed that in eight out of 15 studies, there was a 50% reduction in the frequency of severe hypoglycemic episodes for individuals on CSII compared to MDI. However, more than one definition of hypoglycemia was being used within the studies (Misso et al., 2010). In contrast, a meta-analysis and systematic review (Yeh et al., 2012) found that there was no difference in the frequency of severe hypoglycemia episodes between CSII and MDI. These results are supported by the latest empirical findings (Pozzilli et al., 2016; Thabit & Hovorka, 2016). Pozzilli et al. (2016) argued, based on their evidence, that CSII does not reduce the frequency and incidence of severe hypoglycemia over MDI and moreover, Thabit and Hovorka (2016) claimed that a lack of consistency in scales and definitions and a low number of participants contest the conclusions that CSII reduces severe hypoglycemia over MDI.

Comparing HbA1c Values

When blood glucose levels are elevated, glucose binds to the hemoglobin (American Diabetes Association, 2013d) for approximately 2-3 months or throughout the lifespan of a red blood cell. An HbA1c level measures the percentage of hemoglobin that is coated with glucose and is an indicator of average blood glucose levels over a 2-3-month period (American Diabetes Association, 2013d; Hood, 2012). A higher HbA1c is reflective of higher blood glucose levels and a lower HbA1c is correlated with lower blood glucose levels (American Diabetes Association, 2013d; Shalitin et al., 2010).

For an individual without T1DM the normal level for HbA1c is less than 5.7% (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). The American Diabetes Association recommends that the optimal HbA1c level be equal to or below 7% for adults with T1DM over the age of 19 years, which is equivalent to a blood glucose level of 8.6 mmol/L (Hood, 2012; Lee et al., 2004; National Institute of Diabetes and Digestive and Kidney Disease, 2014b; Shalitin et al., 2010). HbA1c is an average of blood glucose levels including fluctuations that may be higher or lower than 8.6 mmol/L. As tighter control of blood glucose levels occur and levels approach the recommended HbA1c of 7%, extraneous factors such as illness, exercise, and insulin dose miscalculation contribute to an increased risk for hypoglycemia (McCall, 2012). Thus, achieving an HbA1c of 7% or less can be very challenging for someone with T1DM. As an HbA1c level approaches 7.2% individuals with T1DM experience a three-fold increase in hypoglycemic episodes (Lee et al., 2004).

Originally, it was thought that there was minimal difference in HbA1c levels between MDI and CSII (Pickup & Hammond, 2009; Shalitin et al., 2010). Giménez et al. (2007) completed a longitudinal, prospective, observational study involving 152 participants with T1DM. Participants switched their T1DM management from MDI to CSII and were then followed for a period of 24 months. CSII participants showed a significant reduction in HbA1c levels from 7.9%, at the start of the study, to 7.3% after 24 months. Similarly, Kerr et al. (2008) found that switching to CSII from MDI decreased HbA1c by 0.5 – 0.9%. This reduction was typically seen after one year on CSII. Pickup and Sutton (2008) also reported significant improvements in HbA1c levels with CSII compared to MDI. Shalitin et al. (2010) two years later verified these results with a larger study of 421 patients, who had been using CSII for at least one year. HbA1c values were 0.5% lower among the CSII users. Moreover, lower levels were

sustained for at least 6 years and the longer an individual was on CSII, the greater the reduction in HbA1c. It is significant to note that even with CSII, only 38% of individuals met the American Diabetes Association HbA1c recommended target of 7%. There were notable limitations to this study because adults were less than 40 years of age and both children and adolescents were part of this sample (Shalitin et al., 2010).

A Cochrane review in 2010 comparing CSII to MDI examined 23 randomized studies involving 976 patients with T1DM. It was concluded that there is a statistically significant improvement in HbA1c with CSII, with an average reduction of 0.3%, especially among individuals managing T1DM with CSII for longer than one year (Misso et al., 2010). The review had many limitations including short study timelines, studies dating back to the 1980s and overall good glycemic control at baseline (Grunberger et al., 2014).

The highest reduction in HbA1c levels are among those who have elevated baseline HbA1c values (Franklin, 2016; Hammond et al., 2006; Shalitin et al., 2010). For example, patients studied with a baseline HbA1c above 9% significantly reduced their values when switching from MDI to CSII (Pickup & Sutton, 2008; Shalitin et al., 2010). Studies show that 15-20% of individuals on MDI have an elevated HbA1c above 9% (Clements et al., 2015; Pickup & Sutton, 2008). Although Clements et al. (2015) argued that reductions in HbA1c level are only modest, regardless of the baseline HbA1c level, a comprehensive review by Pozzilli et al. (2016) and Franklin (2016) indicated again that CSII is more effective at reducing HbA1c than MDI if patients have a higher HbA1c at baseline.

Effect on Hyperglycemia and Diabetic Ketoacidosis

According to the World Health Organization (2006), hyperglycemia is the term for the high blood sugar that occurs when individuals with T1DM have too much glucose in their

bloodstream. Specifically, hyperglycemia is having a blood glucose greater than 7 mmol/L when fasting and greater than 11 mmol/L two hours after a meal. Having a blood glucose greater than 7 mmol/L for a prolonged period can cause damage to internal organs resulting in DM-related complications; however, symptoms may not be evident until blood glucose exceeds 11 mmol/L (World Health Organization, 2006). Symptoms include frequent urination, blurred vision, weakness, feeling tired, losing weight, and increased thirst. Prolonged hyperglycemia can result in DKA. DKA is an acute, life-threatening condition resulting from insufficient insulin. In response, the body starts to break down muscle, producing ketone bodies that result in unpleasant symptoms as well as complications (Bode et al., 2002; Goguen & Gilbert, 2018). DKA can also be caused by stressors such as surgery and illness, which causes secretion of glucagon and other hormones, as part of the stress response (Lee et al., 2004; Saboo & Talaviya, 2012).

There has been conflicting evidence of DKA related to the use of CSII. A recent study found that CSII users are at a higher risk for DKA than MDI users due to device malfunctions, such as battery failure and infusion set or tubing occlusion (Thabit & Hovorka, 2016). Furthermore, the absence of a long-acting insulin depot with CSII also increases the risk for DKA (Bruttomesso et al., 2009; Joshi & Choudhary, 2015; Saboo & Talaviya, 2012). This is particularly concerning at night when insulin deprivation can last for hours while the individual is sleeping (Bruttomesso et al., 2009). This can lead to unconsciousness and ultimately death and is a great stressor for those managing their T1DM with CSII (Saboo & Talaviya, 2012; Thabit & Hovorka, 2016). A cross-sectional survey reported that half of the participants ($n=92$) had a CSII malfunction including the suspension of insulin delivery and keypad problems (Thabit & Hovorka, 2016). In fact, 40% of DKA cases are the result of CSII malfunctions (Bruttomesso et al., 2009). All of the above leads to feelings of vulnerability and dependency on others when

attempting to prevent DKA (Garmo et al., 2013). Despite the increased risk of DKA with CSII, early morning hyperglycemia, known as the dawn phenomenon, is reduced with CSII compared to MDI (Bode et al., 2002; Schade & Wolpert, 2005). Bode et al. (2002) noted that the reduction in the dawn phenomenon was due to the fact that CSII has a single infusion set that lasts for three days, delivering a consistent absorption of insulin to the same area via adjustable pre-programmed basal rates. With MDI, this consistency is not possible, as injection sites vary throughout the day, thus changing the absorption ratio of the insulin (Bode et al., 2002).

Conflicting with the above research, Cummins et al. (2010) found four studies in their systematic review examining the rates of DKA with CSII in adults. Studies ranged from 2002 to 2007 with mixed reviews. Two studies reported a significant decrease in DKA rates with CSII (Hunger-Dathe et al., 2003; Rodrigues, Reid, Ismail, & Amiel, 2005); and, two studies did not report any significant level of reduction with CSII (Linkeschova, Raoul, bott, Berger, & Spraul, 2002; Reda, Von Reitzenstein, & Dunn, 2007). A longitudinal, prospective observational study in 2007 by Giménez et al. reported no change in the frequency of DKA after CSII was initiated. In contrast, Shalitin et al. (2010) found that CSII therapy slightly increased the rates of DKA. Cummins et al. (2010) concluded that the conflicting results make the review of this topic difficult and further research is needed to determine the exact effect, if any, CSII has on hyperglycemia and DKA.

Effect on Diabetes-Related Complications

In 1926, Prof. MacLean of St. Thomas' Hospital wrote an article in the *Postgraduate Medical Journal* about the momentous impact the discovery of insulin had for individuals living with T1DM. Prior to this discovery, just 5 years before, individuals with T1DM commonly died at an early age due to DM-related complications (Chatterjee & Davies, 2015). With the discovery

of insulin, T1DM went from a fatal disease to a chronic degenerative disease with complications arising 15-20 years after insulin therapy was initiated. The discovery of DM-related complications was a new concept, as individuals were now living longer with T1DM due to insulin management (Nathan, 2014). Nearly a century later, DM-related complications remain a significant contributor to T1DM morbidity and mortality (Chatterjee & Davies, 2015). Both hypoglycemia and hyperglycemia are associated with long-term complications, that are typically seen 10-15 years after the initial diagnosis of T1DM (Chatterjee & Davies, 2015; Cummins et al., 2010).

There is a paucity of research directly comparing whether CSII has a potential benefit in preventing or reducing DM-related complications compared to MDI (Giménez et al., 2007; Hammond et al., 2006). However, based on the significant improvements in HbA1c levels with CSII it has been argued that CSII has the potential to reduce DM-related complications by 20% compared to MDI (Bruttomesso et al., 2009; Hammond et al., 2006). CSII reduces microvascular complications by 25% (Hammond et al., 2006), amputations by 1.7%, severe vision loss by 4.9%, heart attack by 2.6%, and end-stage renal disease by 1.9% (Cummins et al., 2010). In addition, there is also an increase in life expectancy between 0.71-0.76 years for individuals on CSII compared with MDI (Bruttomesso et al., 2009; Cummins et al., 2010).

CSII Initiation and Implementation

Candidate Selection

With the growing popularity of CSII in the 1990s and more individuals with T1DM wanting to initiate this therapy, it became necessary to establish guidelines and criteria for candidate selection. However, there was no consensus on what those criteria should be, thus many different criteria and guidelines were established and often overlapped (Cummins et al.,

2010). The first attempt to standardize guidelines in 2001 was by Pickup and Keen. Pickup and Keen stated that CSII candidates were patients, who after 3 months of intensive therapy via MDI and re-education on injection techniques, failed to achieve good glycemic control. The lack of good glycemic control was defined as having frequent hypoglycemia and increased blood glucose in the early dawn. In addition, potential candidates should be motivated, willing, and compliant, and perform frequent blood glucose monitoring, and be free of psychological and psychiatric problems (Pickup & Keen, 2001). Since 2001, additional pre-requisites, such as elevated HbA1c and unpredictable swings in blood glucose, have been added to this list (Cummins et al., 2010).

In 2003, the National Institute for Health and Care Excellence guidance introduced guidelines for selecting patients who would be suitable candidates for CSII. These guidelines stated that CSII was to be used for candidates in which MDI has failed to maintain an HbA1c below 7.5% and who have the commitment and competence to be able to operate the technology effectively. These guidelines were based on the first appraisal of CSII, including the appraisal by Pickup and Keen in 2001, which included 14 trials on adults with T1DM (Cummins et al., 2010). In 2005, The Agence D'évaluation des Technologies et des Modes D'intervention en Santé based in Quebec, Canada, published guidelines stating CSII was recommended for individuals with inadequate glycemic control, severe hypoglycemic episodes (two or more per year), hypoglycemic unawareness causing incapacitating anxiety or reduced QOL, and nocturnal hypoglycemia (Cummins et al., 2010).

In 2007, the Insulin Pump Working Group Report and the Department of Health suggested that candidates selected for CSII should be highly motivated, have realistic expectations, monitor blood glucose a minimum of four times per day, work with a multi-

disciplinary team, and have previously tried MDI to manage diabetes. In addition, candidates would have to meet one of the following conditions: repeated episodes of hypoglycemia, unawareness of hypoglycemia, or a high HbA1c with episodes of hypoglycemia (Cummins et al., 2010).

In July 2008, a re-appraisal of CSII prompted the National Institute for Health and Care Excellence to make two revisions to their previous 2003 guidelines. The revised guidelines did not incorporate previous recommendations by the Insulin Pump Working Group and the Department of Health, as the National Institute for Health and Care Excellence is a non-governmental agency. The National Institute for Health and Care Excellence stipulated that CSII was now recommended for adults and children over the age of 12 if disabling hypoglycemia was the result of their attempt to achieve target HbA1c levels and if HbA1c levels remained high using MDI. High HbA1c was defined to be greater than 8.5% (Pickup & Hammond, 2009).

Challenges of CSII

As previously mentioned, CSII has its own set of challenges. CSII requires:

- a highly-motivated individual;
- active involvement;
- frequent blood glucose testing;
- in-depth knowledge of T1DM;
- technological skills;
- frequent healthcare visits;
- the capacity to count carbohydrates;
- finances for supplies; and
- trust in the device for life (Barnard & Skinner, 2007; Franklin, 2016).

While the popularity of CSII has continued to grow, some individuals choose to discontinue CSII as their T1DM management therapy for several reasons. It has been documented that wearing CSII at all time and attempting to conceal it can be distressing and anxiety provoking (Joshi & Choudhary, 2015; Scheidegger et al., 2007). Individuals may feel self-conscious, as it is a constant reminder that they have T1DM (Franklin, 2016). In fact, Balfe et al. (2013) discovered that patients had feelings of stigmatization and an intense desire to suppress the disease and appear as normal. Some individuals have even stated that they had a strong desire to keep T1DM a secret. Other reasons cited for discontinuing CSII included decreased glycemic control, DKA, weight gain, and issues with infusion sites, such as occlusions and skin reactions (Barnard & Skinner, 2007; Joshi & Choudhary, 2015). Out of 22 studies reviewed by Cummins et al. (2010), only two studies indicated a 100% continuation rate.

Although the findings are similar to above, the study by Hayes, Frearson, Keller, Cartmale, and Lewis-Hayes (2011) was the first hermeneutic phenomenological exploration as to why individuals discontinue CSII. In addition to the factors above, participants also cited lack of control as another reason for discontinuing CSII. In particular, they felt powerless when faced with technical failures, CSII malfunction, tubing disconnections without warning, and infusion sets falling off. Participants also claimed that their expectations of CSII were not met. Failed expectations included CSII not improving glycemic control. Lastly, some participants felt there was a lot happening in their lives, such as moving, divorce, and having children, and there was little time left to focus on the demands of CSII (Hayes et al., 2011).

Quality of Life

Minimizing the impact T1DM has on an individual's QOL is an important goal for those living with this disease (Barnard & Skinner, 2008; Joshi & Choudhary, 2015; Weissberg-

Benchell, Antisdel-Lomaglio, & Seshadri, 2003). A meta-analysis conducted in 2003 found that research examining how CSII impacts QOL was limited (Weissberg-Benchell et al., 2003). It is often assumed that CSII will improve QOL for individuals with T1DM; however, current research on CSII and QOL have produced conflicting results. While an improvement in metabolic control with CSII is often assumed to improve QOL, there is no correlation. The increased responsibility that comes with using this complex, technological device accounts for this discrepancy (Valenzuela et al., 2006).

In 2007, Barnard et al. performed a systematic literature review of 17 studies from 1988 to 2005 that had examined how CSII affected QOL. Inclusion criteria were studies that looked at any facet of QOL that may have included diabetes-specific treatment satisfaction and flexibility; participants had to have had T1DM; and no restrictions on age, gender, or glycemic control. Barnard et al. concluded that there were no consistent gains to QOL from CSII. They found that although CSII provided a benefit to T1DM management, it came at a cost--programming, concealment, daily activities, relying on a machine, and frequent changes of infusion sets were some of the negative aspects. To provide a fulsome picture of the QOL of the CSII user, Barnard et al. realized they had to adopt the QOL definition put forward by Gill and Feinstein (1994). Gill and Feinstein defined QOL in terms of purpose or fulfillment, personal control, personal and intellectual growth, material possessions, and interpersonal relationships. They emphasized that QOL is a uniquely personal perception that explains how individuals feel about their health status and non-medical aspects of their life. QOL can only be measured by determining what individuals perceive to be meaningful and satisfying in their lives (Gill & Feinstein, 1994). Furthermore, Barnard et al. had identified design flaws in the studies reviewed. Overall, they concluded that the question of whether CSII improved QOL for individuals with T1DM

remained unanswered and recommended further research with an emphasis on the issues impacting QOL.

Scheidegger et al. (2007) were the first researchers to use the Diabetes-Specific Quality-of-life Scale to compare CSII and MDI effects on QOL. The Diabetes-Specific Quality-of-life Scale is designed to assess physical, emotional, and social burdens in everyday life and the fears associated with hypoglycemia for individuals managing T1DM. Items such as leisure time flexibility, worries about the future, and social relations were included in this assessment tool. The Diabetes-Specific Quality-of-life Scale was capable of discerning the differences between the two T1DM management therapies. This questionnaire was administered to participants using CSII ($n=78$) and using MDI ($n=81$) in a cross-sectional design. Any participants who switched regimes from MDI to CSII were followed as part of a longitudinal study ($n=19$). Consistently, results were favorable for CSII on QOL measures. CSII users scored higher on increased flexibility in leisure activities and routines, fewer dietary restrictions, and higher treatment satisfaction than MDI users. Reduced hypoglycemic episodes were apparent in both groups, but only slightly. HbA1c levels among CSII users was an average 0.6% lower than MDI users, and for those who had switched from MDI to CSII, HbA1c decreased significantly from 7.9% to 7.0%, respectively (Scheidegger et al., 2007).

Barnard and Skinner (2007, 2008) carried out two qualitative studies examining QOL issues with CSII for individuals with T1DM. Barnard and Skinner (2007) were the first to use qualitative methods to assess QOL among those with CSII. Using an exploratory design, they conducted telephone interviews ($N=80$) and found both positive and negative aspects of CSII on QOL. CSII negative aspects included visibility, concealment, and costs, as well as lack of knowledge about CSII from healthcare professionals. However, despite these challenges

participants overwhelmingly proclaimed an increased QOL, although benefits were unique for each participant. Benefits included increased freedom and flexibility, not having to carry DM supplies, increased independence, reduced blood glucose fluctuations, reduced hypoglycemic episodes, and reduced fear of hypoglycemia. Also, family members experienced reduced fear of hypoglycemia and could provide care without hesitation. CSII made participants feel they had control over T1DM rather than it controlling their lives. Barnard and Skinner reported that a qualitative research design was the most appropriate approach to study the impact of CSII on QOL and recommended further research to explore both the positive and negative effects (Barnard & Skinner, 2007).

The second study by Barnard and Skinner in 2008 used a large-scale cross-sectional design to compare QOL among those with CSII ($n=216$) versus those with MDI ($n=555$). They adapted the World Health Organization's Quality of Life Abbreviated Questionnaire, which had domains for DM-specific areas such as physical health and relationships. Both cohorts were matched for age, gender, and frequency of blood glucose testing. Participants reported a better QOL with CSII with less DM-related distress, fewer emotional problems, fewer treatment-related problems, fewer food-related problems, and less fear of hypoglycemia. Participants also reported a higher satisfaction with CSII, more flexibility with eating, and a less regimented schedule. CSII users also reported increased independence and less fluctuation in blood glucose (Barnard & Skinner, 2008).

One of the criticisms of both the 2007 and 2008 studies by Barnard and Skinner was their involvement with Roche Diagnostics, a CSII manufacturer. Roche Diagnostics funded the studies and employees of the company recruited and conducted the interviews with the participants, so participants of both studies were currently using CSII and were customers of

Roche Diagnostics. In addition, the response from participants in the MDI group for the 2008 study was very low possibly reflecting a bias in that those on CSII are more motivated and more willing to take part in studies, thus making it difficult to find a comparison group with common characteristics (Barnard & Skinner, 2007; Cummins et al., 2010).

Nicolucci et al. (2008) performed the largest ($N=1341$) non-randomized case control study of its time exploring QOL with CSII compared to MDI. Questionnaires were administered to participants between the ages of 18-55 years who regularly attended a diabetes clinic. The case group included participants who had been on CSII for more than 6 months, while the control group included participants who were on MDI for a minimum of 6 months. Nicolucci et al. reported similar benefits to QOL as previous studies by Scheidegger et al. (2007) and Barnard and Skinner (2007, 2008), and concluded that CSII improved QOL by improving treatment satisfaction.

Todres et al. (2010) carried out a qualitative descriptive phenomenological study using in-depth interviews to explore what it was like to live with CSII ($N=4$) after switching from MDI. Participants reported both challenges and benefits. Challenges included living with a “machine,” trusting the technology, wearing a device at all times, and letting go of previous management routines. Another negative aspect was the emotional implications of increased responsibility of self-management that resulted in fear of disapproval by health care professionals and questioning their worthiness of deserving such advanced technology. Despite these challenges participants reported that CSII increased their QOL by providing better self-management strategies, a sense of control and freedom over activities, increased spontaneity, self-acceptance, self-confidence, and personal empowerment. Participants also reported that CSII created a more collaborative relationship with health care professionals, who encouraged them to

take control and responsibility for self-management by increasing knowledge about the disease and CSII. CSII also improved QOL for significant others because of the increased flexibility and improved health with their loved ones (Todres et al., 2010). Although, transitioning to CSII was noted to be a more significant life transition than being diagnosed with T1DM, the increased sense of control and self-confidence that came with using CSII provided a sense of feeling well and subsequently fewer fluctuations in emotions, as reported in a qualitative, interpretative inquiry by Rasmussen et al. (2011).

In a qualitative focus group study by Trief et al. (2013) partners of patients with CSII stated that the risk and presence of hypoglycemia caused significant worry, stress, and anxiety; participants feared hypoglycemia, referring to it as life draining, because of the burden to their partners and as such exercised constant vigilance in trying to prevent it. Researchers in this study identified that both participants and their partners reported benefits to their QOL with CSII because the technology made T1DM more manageable--reducing the frequency and intensity of hypoglycemia, increasing freedom to travel, and decreasing the overall burden of self-management (Trief et al., 2013). Joshi and Choudhary (2015) in their meta-analysis found similar positive and negative aspects among those using CSII in comparison to those using MDI and concluded that CSII improved DM-related QOL.

Thabit and Hovorka (2016) completed a literature review comparing CSII and MDI and found that participant's treatment satisfaction scores were significantly higher in those on CSII, with higher overall scores for QOL domains and improvement in mood and mental health. They concluded that CSII had psychosocial benefits improving QOL beyond glycemic control favoring CSII over MDI (Thabit & Hovorka, 2016). Another comprehensive literature review by Pozzilli et al. (2016) also found that CSII improved QOL and was the preferred method of

insulin delivery because it increased flexibility, allowed insulin doses to be adjusted, and allowed insulin to be administered painlessly.

Psychological and Psychosocial Impacts

DM distress is a general term used to refer to the psychological impact of managing the disease and the accompanying emotional burdens and stressors. Psychological morbidity, such as depression and anxiety, are prevalent in individuals living with T1DM (Balfe et al., 2013) and two times higher for an individual with DM than an individual without DM (Trief et al., 2013). Depression has always been seen as a symptom of living with DM and it is only recently that researchers have begun to argue that depression is a form of DM distress (Balfe et al., 2013). Depression is often experienced as a normal consequence of living with T1DM, but is often underdiagnosed because symptoms such as decreased energy, impaired memory and weight loss, are often seen with poor glycemic control. Thus, these symptoms of mental illness are often overlooked (Dahan & McAfee, 2009; Rasmussen et al., 2011). The psychological impact of T1DM often impacts disease management and is often associated with poor glycemic control, increasing the risk of complications. In fact, stress management is the second most important topic that individuals with T1DM want to discuss with healthcare professionals (Balfe et al., 2013; Dahan & McAfee, 2009). While T1DM is one of the more physically and psychologically demanding chronic illnesses, impacting every aspect of an individual's life, it is now being recognized that using CSII to manage T1DM actually exacerbates DM distress (Balfe et al., 2013; Bruttomesso et al., 2009; Cox & Gonder-Frederick, 1992; Trief et al., 2013). For this reason, the psychological consequences of having to use CSII is an important topic for research. Below is a discussion of the studies that have examined to some degree the psychological and psychosocial impact of CSII.

Ritholz et al. (2007) conducted a focus group study ($N=30$) and found that the psychological impact of CSII was related to glycemic control. Participants who had a lower HbA1c level were more likely to take an active role in their self-management and reported that CSII had a positive psychological impact due to reduced social stigma, increased social acceptance, increased feelings of normalcy, and greater self-efficacy and self-regulation. In contrast, participants with higher HbA1c were more passive in their self-management of T1DM and reported more negative psychological effects of CSII, including increased workload and unmet expectations that CSII would make T1DM management easier (Ritholz et al., 2007). Nicolucci et al. (2008) criticized such studies for relating glycemic control to psychological impact instead of focusing on the overall psychological impact of CSII. Nicolucci et al. acknowledged that CSII could have a negative impact on one's emotional and physical comfort because individuals are having to be dependent on a piece of technology and the technology makes T1DM visible to the public. However, they also added that survey results did not indicate that CSII caused psychological harm, which they attributed to CSII being lightweight, small, having advanced technological features for administering insulin, and making management of T1DM easier (Nicolucci et al., 2008).

Aberle et al. (2009), in their retrospective study, used Krohne's model of stress and coping as their theoretical framework and discovered that patients who took responsibility for their CSII therapy demonstrated better glycemic measures than those who perceived little control over their CSII therapy. This was an uncontrolled study based on correlational data, so causal relationships between psychological aspects and metabolic control could not be firmly established (Aberle et al., 2009).

Garmo et al. (2013) completed a descriptive cross-sectional qualitative study ($N=16$) and expanded the topic of glycemic control and perceptions of CSII because they refuted previous study conclusions that glycemic control predicted psychological outcomes among CSII users. For example, they explored the everyday experiences of living with CSII and reported that participants had mixed reviews of CSII, referring to it as both a “shackle” and a “lifeline.” The shackle reflected the physical presence of CSII that exists as a physical remainder of T1DM and individuals are made to feel different from others and somewhat stigmatized. The lifeline reflected the positive aspects of living with CSII that had been previously mentioned in this chapter including a sense of freedom and flexibility.

A hermeneutic phenomenological study ($N=9$) by Hood and Duke (2015) explored the meaning of CSII for young adults between the ages of 19-24 years who were transitioning from living at home with family to living on their own. Hood and Duke reported positive and negative aspects of CSII similar to studies by Aberle et al. (2009) and Garmo et al. (2013). Living on their own brought additional challenges for participants living with CSII, including the immediate loss of support networks such as family, who were no longer there to remind them of self-care, and loss of a long-term pediatric healthcare provider. Living in a new area without peer support also contributed to participants’ sense of aloneness and led to concealment of CSII to appear normal to others. Participants stated that life transitions, such as living on their own, forced them to accept responsibility for CSII self-care at a much quicker pace; however, eventually it became part of their lives.

Summary

The DCCT demonstrated that intensive insulin therapy was the best way to prevent, delay or minimize the risk of developing DM-related complications. The DCCT publications quickly

propelled CSII therapy as the predominant choice for T1DM management and served as the foundation for research on CSII. Although current literature on CSII is contradictory, the popularity of CSII continues to rise as the preferred therapy for T1DM management.

Hypoglycemia is often feared more than DM-related complications. The DCCT reported that the incidence of hypoglycemia was three times higher with intensive insulin therapy (The DCCT Research Group, 1993). Researchers have since claimed that CSII reduces mild and severe hypoglycemia and protects against hypoglycemic unconsciousness because it increases hypoglycemic awareness and allows fine tuning of insulin delivery. For these reasons, individuals on CSII therapy report reduced fear of hypoglycemia. Recently, these claims have been treated with skepticism by researchers because of inconsistencies in the definition of hypoglycemia, low numbers of study participants, and variation in the duration and frequency of hypoglycemic events.

The research on the effect CSII has on hyperglycemia and DKA is limited and inconclusive. Although some studies claim CSII reduces early morning hyperglycemia, others have indicated that CSII malfunctioning poses an increased risk for DKA.

Using CSII for more than one year produces a statistically significant reduction in HbA1c favoring CSII over MDI, particularly in those with higher baseline HbA1c levels prior to CSII initiation. A reduction in HbA1c is correlated with improved glycemic control; thus, CSII would present the option for meeting recommended glycemic and HbA1c targets. The improvement in metabolic outcomes with CSII, such as HbA1C and blood glucose levels, have been shown to reduce the risk of microvascular and macrovascular complications.

Although CSII therapy has been found to contribute to increased treatment satisfaction, the burdensome demands of this device cannot be disregarded. The complexity of CSII demands

physical and mental endurance to endure the intense education, continuous follow-up, careful glucose monitoring, carbohydrate counting, and engagement with a multidisciplinary team. It is much more than simply wearing an external device. An individual must be motivated, assume the financial burden, be knowledgeable, and have the physical ability to operate the system. The responsibility and demands of CSII can have a negative impact on an individual's psychological well-being and QOL. While preventing complications and achieving near normal glycemic control is often the goal of healthcare professionals, incorporating psychological support for those living with CSII is important. Understanding the challenges of living with CSII will allow healthcare professionals to recognize the unique needs and concerns of each individual and provide the necessary support.

A gap acknowledged in the literature is the lack of qualitative research of what it means to live with CSII in its everydayness. Further technological advancements of CSII can reduce the demands of managing T1DM and change healthcare professionals' perspectives on how to approach T1DM care with patients and their families. Findings from my hermeneutic phenomenological study will contribute to the literature by providing a rich description of what it means to live with CSII and the associated impacts.

Chapter Three. Methodology

In this chapter I outline the research methodology that guided my study of the lived experiences of eight adults using CSII therapy to manage T1DM. A hermeneutic phenomenological design was employed to explore these lived experiences. Phenomenology is both a philosophy and a research method and the main tenet of hermeneutic phenomenology is that the most basic experiences in the world carry meaning. Hermeneutics is the art of interpreting and understanding that meaningful experience in the context in which it occurred (van Manen, 1997a). Hermeneutic phenomenology enabled me to fulfill my research goal. As I listened and interpreted each narrative account I was able to understand the essence of the everydayness of living with CSII.

Specific topics covered in this chapter are a brief overview of hermeneutic phenomenology, which include van Manen's six research activities, the researcher's pre-understandings of the phenomenon and its influence on the research process, and the specific methods used to carry out the research.

Hermeneutic Phenomenology

To understand the lived experiences of adults using CSII therapy for T1DM management, I aligned with van Manen's (1990) approach to phenomenology. One premise of phenomenology is that individuals have their own reality based on their perceptions of the world. Using phenomenology, the researcher investigates human perceptions of the environment and the interactions humans have with others to understand how participants make sense of experience and bring experience into conscious awareness (Finlay, 2009). The purpose of phenomenological research is to capture the lived experience through rich description and, or, interpretation. The lived experience constitutes an individual's consciousness and can be viewed as structures that

are formulated through interactions with the world. Phenomenologists seek to untangle and describe these structures, and the internal meaning, in order to understand the lived experience (van Manen, 1990).

Hermeneutic phenomenology is the interpretation of the participant's lifeworld, whereby the researcher unveils the subjective world as experienced by participants (Kafle, 2011; Sloan & Bowe, 2014). Through life stories a rich, textural description is produced that can then be interpreted for meaning and participant expression that had been difficult to articulate (Balls, 2009; Sloan & Bowe, 2014). The goal is to highlight and give meaning to (what may seem like) trivial aspects of experience that may be taken for granted in order to achieve a sense of understanding (Kafle, 2011). Using this methodology, the researcher must apply the skill of reading and examining transcripts and textual data and then interpreting spoken accounts of an experience to discover what is telling, meaningful, and thematic (van Manen, 1997b). The lived experience is transformed by the researcher into a written format in a way that challenges normative assumptions whereby the text is made more reflective of what is meaningful (Finlay, 2009; van Manen, 1997a). The themes that are isolated from immersion in the data are the written interpretation of participant experience (Sloan & Bowe, 2014; van Manen, 1997a) and constitute quality data, not opinion and speculation (Sloan & Bowe, 2014). Phenomenologists do not seek to understand the truth, but rather seek to understand perception of the truth (van Manen, 1997a).

Our consciousness is affected by how we perceive our experiences. What we see within the structure of the world is what is produced in our consciousness and is known as *lebenswelt*, or lifeworld (van Manen, 1990). The lifeworld is just there; it is the everyday routine that happens without consciously deliberating it. It is the everyday happenings that are normally

taken for granted and go unnoticed and thus are hidden as phenomena (van Manen, 1990). The perception of consciousness and physicality of the world make up the lived dimensions of an individual's lifeworld identified by van Manen as lived space (spatiality), lived body (corporeality), lived time (temporality), and lived human relations (relationality). These four existentials make up an individual's lifeworld (their lived world) regardless of an individual's personal, social, or cultural situation. The first existential, lived space, is the way individuals know and experience their environment. The space in which we find ourselves affects the way we feel, becoming our lived space (van Manen, 1990). The second existential, lived body, refers to how we are always present in the world and how our bodies reveal or conceal something about us, either consciously or unconsciously; it is how we present ourselves in the environment (van Manen, 1990). The third existential of lived time refers to subjective time, not elapsed time on a clock. Lived time is our past, present and future and how they all influence each other and change over time (van Manen, 1990). Lastly, the fourth existential, known as lived human relation, is how we connect and relate to other human beings. Although these four existentials can be differentiated, they are intertwined and cannot be separated, as they all have an impact on one another (van Manen, 1990). These four existentials impact how individuals experience the world and create meaning.

Methods

A hermeneutic phenomenological method entails both the description and the interpretation of the phenomenon of interest. Using this method, a reflective, exploratory approach was used to enrich one's understanding and depth of each individual's lived experience. This approach was appropriate for my study as my goal was to understand and have greater insight into the lived experience of adults on CSII therapy to manage T1DM.

As a hermeneutic phenomenologist, I chose van Manen's research approach consisting of six research activities: identifying the phenomenon of interest; exploring evidence as it is lived; reflecting on themes; describing the phenomenon through writing; maintaining a connection to the phenomenon; and lastly, considering the parts as a whole. The research activities are discussed below followed by my pre-understanding reflections.

van Manen's Research Activities

A phenomenological question cannot just be written down—the researcher must make the reader wonder about the nature of the phenomenon (van Manen, 1990). Thus, to understand the phenomenon, the researcher must become the question and live the question, not simply ask it (Gadamer, 1975). According to van Manen (1990), the hermeneutic phenomenologist elicits the reader's wonder by conducting six research activities; they are:

1. **Identifying and committing to a phenomenon of interest.** The question of knowledge is always rooted in whom we are, to what we are committed, our lives and our world (van Manen, 1990). I began this research study committed because I live with T1DM and CSII. As aforementioned, I found little research on what it was like to live with this device, thus, I was motivated to explore this research topic. Moreover, as a registered nurse who educates patients and collaborates with healthcare professionals, I wanted to understand the lived experiences of others living with CSII.

2. **Exploring experience as it is lived rather than as it is conceptualized.** Phenomenologists explore participants' everyday stories rather than just their feelings or conceptions of their stories. These stories are descriptions that bring us closer to their everyday realities (van Manen, 1990). The researcher becomes immersed in the experience of the participants to render the full significance of its meaning (Koch, 1998). By listening to their

stories, phenomenologists preserve the concept and allow the meaning of the experiences to be revealed (Benner & Wrubel, 1989).

3. **Reflecting on the essential themes that characterize the phenomenon.** This is a thoughtful, reflective grasping to determine what it is about an individual's experience that gives it significance. I unveiled phenomenological themes that are structures of meaning. They were not simply a notion of what the phenomenon was, but rather a reflective determination and explication of meaning.

4. **Describing the phenomenon through the creative activity of writing and re-writing.** Through reading and re-reading the transcripts, I looked for phrases that were essential. Every line was reviewed, and the meaning carefully questioned. Through writing and re-writing, I reflected and redefined themes to understand the essence of what it means to live with CSII.

5. **Maintaining a strong and effective connection to the phenomenon.** I continuously remained focused on the research question and on the lived experiences of the participants. This demanded maintaining an openness to participants' experiences and not imposing my personal views and remaining aware of pre-conceived notions throughout the process.

6. **Balancing the research context by considering parts as a whole.** While a research plan was important for structure, it was equally important for me to have flexibility, so that phenomenological descriptions were authentic. To do this, it was important that I examined and evaluated each unique participant experience before identifying an overall meaning to the phenomenon of living with CSII.

The Researcher's Pre-Understandings

According to van Manen (1990), the starting point for phenomenological research is our knowledge of a phenomenon. We often know too much about the phenomenon we are

investigating, which can predispose us to interpretations based on our own pre-understandings and assumptions. The role of reflexivity in qualitative research is to remain orientated to the phenomenon, but also to “be reflectively aware of experiential meanings” (van Manen, 1990, p. 57). It is the realization of the idea that the researcher’s own experience could be the experiences of others (van Manen, 1990). My passion for conducting this research study developed from my own experience living with CSII to manage T1DM for most of my life. I began this study knowing that I have my own experiences and pre-understandings of what it is like living with CSII.

Some phenomenologists recommend putting aside our beliefs and knowledge about a phenomenon, known as bracketing; however, van Manen (1997a) considers this idea as nearly impossible to achieve. According to van Manen, if researchers attempt to forget or ignore what they already know about a phenomenon, then eventually their thoughts and experiences about this phenomenon work their way back into their reflections (van Manen, 1997a). Instead, van Manen (1990) suggests that researchers practice critical self-awareness to be aware of their present assumptions, understandings, beliefs, and biases about a phenomenon to ensure the nature of the phenomenon is not interpreted by the researcher before it is explored, otherwise known as reduction (p.185). Furthermore, van Manen believes that bracketing decreases the researcher’s openness to the significance of a phenomenon and a researcher can only obtain a pure description of a participant’s lived experience if a researcher is fully aware of one’s knowledge and beliefs (van Manen, 1997a). Both Gilgun (2010) and Shenton (2004) acknowledge the importance of reflexivity in qualitative research, whereby the quality and accountability of researchers are increased when they identify their own personal and professional meanings of a research topic before, during, and after the research. Through

reflexive dialogue and sharing one's own experiences, researchers develop a deeper level of understanding (Gilgun, 2010; Shenton, 2004).

I did not bracket my own personal experience with CSII, but rather let it guide me throughout the stages of the research. I maintained what Ajjawi and Higgs (2007) and van Manen (1990) refer to as hermeneutic alertness, whereby the researcher steps back to reflect on the meanings rather than accept their own misconceptions at face value. During my initial meeting with my supervisor about my study, I informed her that I have T1DM and currently use CSII therapy. I also shared this information with all my participants with hopes of establishing a unique connection, but not to influence their responses. Throughout my research, I was cognizant that I have my own opinions about CSII and my own personal lived experience. My selection of emerging themes from the data were based on participants' responses and not on my own beliefs. I achieved this by first writing out my own thoughts and feelings so that I could bring them to the forefront. Secondly, I did not verbalize my experience or opinion of CSII prior to participants discussing their stories. Throughout the research and during data analysis, I maintained a conscious effort to continuously reflect on my own experiences with CSII so that I was fully aware of my personal knowledge and beliefs. This did not prove to be a difficult task for me, as I consciously thought about my own feelings with each interview question so that I was aware of my own experience before I analysed the data. Being aware of my own experiences gave me the ability to acknowledge myself within the phenomenon while also being cautious in how I presented and placed myself within the research context. Debriefing with my supervisor throughout the research process helped to validate emerging themes. Shenton (2004) and van Manen (1997a) both attest that discussing research with a colleague or peer may widen a

researcher's vision and probing from the supervisor can help reveal researcher biases or preferences.

Participant Selection

To achieve a rich and meaningful description of what it is like to live with CSII in its everydayness, purposeful sampling was used to recruit eight participants who use CSII therapy to manage T1DM. Phenomenologists use purposeful sampling to select individuals who are knowledgeable of and experienced with the phenomenon of interest. According to Sandelowski (1995), purposeful sampling in phenomenological research often results in variations in sample size because participant selection is based on meeting pre-determined criteria. However, in qualitative research the sample size should ideally remain small, with a minimum of six participants, until conversational redundancy occurs, and a vivid and textured understanding of the lived experience is achieved (Sandelowski, 1995). In my study, participant inclusion criteria were:

1. Able to speak and understand English.
2. Aged 19 years or older.
3. Currently on CSII therapy to manage T1DM.
4. Patients at the diabetes clinic within Eastern Health.
5. Willing to participate in my study.

Participant Recruitment

Participants were recruited with the assistance of a certified diabetes nurse educator at a diabetes clinic on the Avalon Peninsula within Eastern Health, Newfoundland and Labrador. While there were four certified diabetes nurse educators at this location, I had previously developed a professional rapport with one certified diabetes nurse educator and she was chosen

as the primary contact who could relay information to the other certified diabetes nurse educators at the site. In June 2013, I met with her at the local diabetes clinic and provided verbal information and a brief one-page letter (See Appendix A) about the study and asked if she would assist me in recruiting participants (See Appendix B). The role of the certified diabetes nurse educator in recruitment was to present an information letter to other certified diabetes nurse educators and to current patients during their regular scheduled appointment who met the inclusion criteria. The information letter included general information about the study, my contact information, and assurance that confidentiality would be maintained. Individuals were encouraged to contact me, either by telephone or email, if they wished to participate or required further study information.

Recruitment of participants was challenging, and no patients had contacted me between June and September 2013. I was in frequent contact with the certified diabetes nurse educator who advised me that many of the patients at the clinic met the inclusion criteria and had been given an information letter. Although patients had expressed interest to the certified diabetes nurse educator in participating in my study, none of the patients had contacted me after they left the clinic. After consulting with my supervisor in October 2013, recruitment posters were displayed at two diabetes clinics, with the managers' approval, to recruit participants. The recruitment poster described what the study was about, inclusion criteria and contact information (See Appendix C). During the last week of November 2013 and the first week of December 2013, I received three emails from individuals interested in participating in my study. I continued to keep in contact with the certified diabetes nurse educator at the original clinic to ensure letters were still being distributed and I continued to display recruitment posters at both clinics. Over the next several months, I received emails from five more individuals who expressed interest.

Despite my ongoing efforts to recruit participants, the total number of individuals recruited for my study was eight. My recruitment efforts began June 2013 and ended September 2014.

Although recruitment was challenging, the eight individuals provided rich stories about their experiences with CSII.

All eight respondents made initial contact by email. I responded electronically and followed up with a telephone call to each participant. During the telephone call, I provided information about my study including the purpose, their role, the duration of the interview, and I assured confidentiality and anonymity. Participation in my study was voluntary, as no incentive was offered to participate. If the individual was still interested in participating after information was provided, an interview date, time, and location was arranged in consultation with the participant. It was during the telephone call that I also addressed additional questions or concerns about my study or their participation. Participants were assured that their participation was completely voluntary, and this would not, in any way, affect the service and care they receive for their T1DM management. No participants expressed any concerns during the telephone call.

Setting and Context

Individual interviews were conducted at a location comfortable for the participant. I offered the option to come to the participants' homes, to meet in my office at the local hospital, or another location chosen by the participant. Six participants chose to complete the interview in my office, one participant chose their place of work, and one participant was interviewed in his home. There was little noise or distraction during the interviews and confidentiality was maintained. Participant comfort and privacy were assessed at the beginning of the interview and maintained at all interview locations.

Non-leading verbal and non-verbal interview techniques were used to facilitate the discussion of participants' feelings and allowed participants to express their experiences in greater detail. Verbal communication techniques included reflection, probing and clarification. Non-verbal communication techniques included nodding, eye contact, and silence. As well, during the interview, the participant and I sat face-to-face, directly across from one another, about 2.5 to 3.0 feet apart. This distance provided personal space and promoted effective eye contact and overall communication. My clothes were casual and I sat upright in a chair and ensured an open approach by having my hands on my thighs and uncrossed legs. These verbal and non-verbal behaviors create an open and welcoming environment (Preston, 2005; Smith, 2004). Streubert and Carpenter (2011) and Preston (2005) emphasize that in phenomenological research, it is important that the researcher be respectful and genuine during the interview by being an attentive listener and not interrupting and challenging the participant during the interview; using these techniques show support, willingness to listen, empathy, and helps others feel understood.

Informed Consent

Informed consent was reviewed and consent forms were signed with the participant on the day of the interview; this process was reviewed and explained before the audio-recorded interview took place. The consent form detailed the study in layman's terms, in English, and at a reading level of less than grade nine. Details included the purpose of the study; data collection techniques, such as audio recording, confidentiality, anonymity, benefits, and risks; and, information storage. It was reiterated to participants that participation was voluntary, that they could stop the interview at any time, refrain from answering any questions they did not feel comfortable answering, or could choose to withdraw from the study. Participants did not express

any concerns or have any questions. Understanding was evaluated by asking the participants to repeat back to me what they understood. Signing of the consent provided permission by the participant to be interviewed. Participants were provided a copy of the consent form, and to ensure privacy, confidentiality, and to protect participants' identity, signed consent forms remain in a secured and locked drawer in my office (See Appendix D).

Data Collection

Data was collected through in-depth face-to-face semi-structured interviews with all eight participants. Ajjawi and Higgs (2007) state that interviews allow participants to share their own stories in their own words while creating a conversational relationship about the meaning of an experience. Interviews can provide insights when working with smaller sample sizes and are the most suitable approach when seeking rich data that illuminate experiences (Ajjawi & Higgs, 2007). Furthermore, an interview allows direct and personal contact between the interviewer and interviewee promoting expression of emotions, feelings, and opinions (Wilson, 2003). Since the goal of my research was to understand the lived experience of adults on CSII, face-to-face, semi-structured interviews were most beneficial. A semi-structured approach, as opposed to a structured interview, allows participants to freely express their thoughts and feelings without being tied down to specific answers. The standardization of some questions also allows comparison across interviews, offering an advantage over unstructured interviews (Ajjawi and Higgs, 2007).

An interview guide was developed to facilitate the interviews and encourage participants to express their stories (See Appendix E). Interview questions were exploratory in nature and were broad and open-ended, so as not to influence participants' responses. The research question acted as a guide to orientate the conversation to the research purpose. With a phenomenological

conversation, van Manen (1990) highlights that sometimes the researcher can become lost in the dialogue, unsure of how to get back to the original research question (van Manen, 1990).

Although phenomenological research is participant-guided, it is important to stay focused on the research question, as deviating away from the purpose can impact the quality of the study. Using an interview guide allowed me to use standard questions for each participant and stay orientated to the research question, but also left room to explore participant responses.

Questions in the interview guide were directed at the participants' experiences and feelings with CSII. I began each interview with an open-ended question allowing participants to set the direction of the interview and define important dimensions of the phenomenon. This also allowed participants to elaborate on what was relevant to them instead of what was relevant to me. As a phenomenological researcher an important question was, "Tell me a story that reveals what a typical day is like for you." Sometimes the things that have the greatest impact on an individual can be considered insignificant by someone not living through it and therefore go unexplored. At times, individuals may not even be aware of the impact until they talk about it. This question allowed participants to examine what living with CSII is like on a day-to-day basis--how it impacts their lives in its everydayness, and to explore the daily challenges of living with CSII. Other questions asked were, "Tell me how wearing an insulin pump [CSII] has affected your self-image." "Your personal relationships." "Your social interactions." "Your attire." Another question specifically assessed how CSII had impacted their lives, "Do you feel that your life has changed since starting the insulin pump [CSII]?"

Follow-up questions explored salient points of discussion to clarify meaning or to gain a deeper understanding of the context. Throughout the interview, participants were given time to share their stories, thoughts, and feelings about CSII and to talk about anything that would help

me understand their experience. Interview times lasted until each participant had exhausted the description of their lived experience with CSII and no new information emerged. I asked participants if they had any further experiences they wanted to share or any other questions about my study. The interviews were recorded with a digital voice recorder.

In qualitative research, participants must feel respected and accepted to develop a sense of trust between the researcher and participant (Demi & Warren, 1995; Jasper, 1994). In addition to my verbal and non-verbal communication techniques, as previously mentioned, I revealed to each participant that I have T1DM and currently use CSII therapy. This facilitated a more personal connection. Moreover, being familiar with the jargon, according to Ajjawi and Higgs (2007), can effectively elicit participant sharing. I did not need to be constantly seeking clarification. During the interview process, participants were actively engaged; felt comfortable; spoke freely about their experiences; and, several expressed that it was nice to talk with someone who could understand the terminology along with the challenges they faced on a daily basis.

Ethical Considerations

My study was guided by the ethical principles on research with human participants set out by the Tri-Council Policy Statement (See Appendix F). Prior to beginning my study, ethical approval was obtained from the Health Research Ethics Authority at Memorial University of Newfoundland in May 2013 (See Appendix G). The Health Research Ethics Authority ensures research is conducted in an ethical manner and there is public awareness of the ethical dimensions involved in health research (Health Research Ethics Authority, 2011). Once Health Research Ethics Authority approval was granted my research proposal was sent to the Research Proposal Approval Committee within Eastern Health. The Research Proposal Approval Committee determines the impact of the research study on the organization, including resource

utilization, and if access to confidential patient information will be required (Eastern Health, 2015). Approval from the Research Proposal Approval Committee was granted in May 2013 with full approval achieved in June 2013 (See Appendix H). An amendment to hire a transcriptionist was approved by the Health Research Ethics Authority in July 2014 (See Appendix I).

All reasonable measures were taken to protect the identity of the participants and to ensure privacy and confidentiality. A transcriptionist was hired and signed consent to an oath of confidentiality. To ensure confidentiality, all data collected and transcribed were anonymized by replacing the participants' names with code numbers in order of the initial interview. Participants' names were not verbalized in the digital audio recording of the interview and all interviews and transcriptions were referred to only by assigned codes throughout the research process. This also ensured no bias or preference was given to respondents during the analysis phase. Access to this information was limited to myself and my thesis supervisor. In keeping with ethical guidelines, participant information and all research documentation will be kept for a period of five years, in a locked cabinet. Participants will not be identified in any way when presenting the study findings.

Data Analysis

The first step in van Manen's approach to data analysis is transcription. However, due to medical issues I was unable to transcribe my data. The physical act of transcribing is the first opportunity to listen to the interview again in detail and I regret not having had that opportunity. When transcribing, attention is paid to every detail, including long pauses, silences, or certain behaviors, such as laughing, when a topic arises. Although I did not transcribe the interviews, I carried out this first step in data analysis by reading the transcripts while comparing them to the

audio recorded interviews without taking notes. This ensured the accuracy of the transcription and allowed me to re-familiarize myself with the words of the participants. Using van Manen's (1990) holistic approach of listening, reading, and re-reading the transcripts numerous times, I was able to immerse myself in each experience and gain greater insight.

The next step in thematic analysis was van Manen's (1990) selective reading and highlighting approach, which contributed to the beginning discovery of significant phrases. Using a line-by-line approach, the text of each transcribed interview was highlighted to select statements or phrases that revealed aspects of the participants' lived experiences with CSII. Subsequently selected statements or phrases were compiled in a Microsoft Word document for further analysis. During this process, I also practiced journaling by taking notes and writing down impressions. Specifically, I wrote down ideas and meanings that were expressed by the participants to identify emerging themes. Examples of notes included:

- "Feels diabetes has been a lonely experience."
- "Feelings of anger and fear about high blood sugar due to pump [CSII] malfunction and complications."
- "Feelings of being normal with the pump [CSII]."
- "Felt betrayed by the marketing of the pump [CSII]."

Next, according to van Manen's approach, I looked for commonalities between my lists of selected statements and phrases. Colored highlighters were used to identify similarities and common threads throughout the lists for each interview and these then became the basis for themes. Next, I re-read the lists to refine the themes that emerged. van Manen (1990) suggests that collaborating with colleagues can strengthen identification of themes by enabling the researcher to see beyond the text and interpret meaning. In collaboration with my supervisor

throughout the analysis, we discussed the themes, moved ideas around, and re-visited our original interpretation. Each of the themes were supported by direct quotations from the participants and captured the lived experience of adults living with CSII to manage T1DM. Based on the themes the essence of the experience was identified.

Trustworthiness

During the qualitative research process, it is critical that the researcher maintains rigor of the study. Rigor can be upheld through trustworthiness that was established by Lincoln and Guba (1985). Trustworthiness is a set of criteria used to evaluate the quality of a research study and is focused on ensuring accurate representation of participant experience. Prior to beginning a qualitative study, it is important to consider the data collection methods, data analysis, the amount of data to be collected, and the methodology to be used. Lincoln and Guba identify several criteria that can be used to establish trustworthiness--credibility, transferability, dependability, and confirmability. Each criterion is discussed below in detail.

Credibility is one of the most important factors in establishing trustworthiness in a qualitative study and thus must be deliberated prior to commencing the research (Shenton, 2004). Credibility is the believability of the study findings and incorporates prolonged engagement, participant freedom, peer debriefing, and methodological congruency. Prolonged engagement involves the researcher spending time with the participant to better understand the phenomenon of interest (Streubert & Carpenter, 2011). I established prolonged engagement by conducting an in-depth interview with each participant. During the interview, I used communication techniques to ensure I understood what the participant was telling me.

According to Shenton (2004), the credibility of the research is enhanced when participants can speak freely and honestly about their experiences without fear. Participants were

ensured that their engagement was voluntary and that they had the opportunity to withdraw from the study at any time, and that there was no “right” or “wrong” answer to questions posed.

Scrutiny of the research study by peers, colleagues and academics also helps to establish credibility. My supervisor, as a phenomenological expert, had successfully completed many qualitative research studies using van Manen’s methodology, and holds a Doctor of Philosophy in Nursing. Shenton (2004) defines peer debriefing as asking a peer to offer feedback and suggest ideas that otherwise may have been missed by the researcher. There were frequent debriefing sessions with my supervisor during which alternative ideas and interpretations were discussed.

Hermeneutic phenomenology is a well-known, respected, and credible method for qualitative research and was well suited to thoroughly explore the lived experience of adults using CSII to manage T1DM. Using van Manen’s (1990) approach it is hoped that each participant will resonate with the reported findings.

Transferability implies that the findings of the study are applicable to other contexts in similar situations or to similar individuals. One way to accomplish this is to have a thick description of the time and context of findings; however, it is other researchers that will determine whether the findings are transferable to another situation (Lincoln & Guba, 1985; Streubert & Carpenter, 2011). Leung (2015) notes that transferability is possible when there are similarities under similar contexts. The context of my study is detailed and thus is transferable. However, it is also important to keep in mind that the goal of phenomenological research is to seek a deeper understanding of the experience of a phenomenon and not generalizability.

Dependability ensures that the findings are consistent and could be repeated (Lincoln and Guba, 1985). Confirmability is the degree of neutrality in the findings, so that the findings are

shaped by the participants' experiences and not the researcher's bias, motivation, or interest (Lincoln & Guba, 1985). According to Streubert and Carpenter (2011), one activity to ensure dependability and confirmability is for the researcher to maintain an audit trail. Throughout this research, I maintained an audit trail. Evidence of the thought process that led to conclusions were documented by maintaining all original transcripts along with each step of data analysis to show how my themes emerged from the data. As aforementioned, I practiced journaling where I made notes of the ideas and meanings that participants revealed to me. I also self-reflect on my own experience of living with CSII so that I was aware of my own thoughts and feelings throughout the study. Collaborating with my supervisor, who also had access to the transcripts, allowed confirmation of the identification of the final themes from the data. These activities provided information to help with data analysis, as well show the decision-making process.

Summary

In this chapter I discussed the choice of van Manen's hermeneutic phenomenological approach to explore the lived experience of adults using CSII therapy to manage T1DM. Participants freely shared their CSII experiences through semi-structured, face-to-face interviews, which was the method of data collection for my study. The recruitment of participants, the setting and context in which the interviews took place were also highlighted. How I conducted the research activities, in particular the steps of data analysis, was also fully addressed and presented in this chapter. Ensuring the ethics and rigor of my study were also highlighted.

Chapter Four. Findings

In this chapter I present the findings of my study that explore the lived experiences of individuals who use CSII to manage T1DM. Before proceeding, it is important to differentiate living with CSII and being an individual diagnosed with T1DM. That is, I became aware during my research that the experiences of CSII and T1DM were not disparate; rather, they were intertwined and together interpreted by the researcher to weave a phenomenological interpretation of what it was like to live with CSII. Below, I commence with a brief description of participant demographics followed by detailed discussion of each of the four themes that emerged in my findings. Themes capture the experiences of each participant and each theme is illustrated by excerpts from narrative accounts. A final synopsis at the end of this chapter adequately reflects the essence of living with CSII.

The Participants

Eight participants shared their stories of living with CSII. Participant demographics are presented in Table 1. All participants were educated at the university or College level. Three participants were single; one was in a relationship; and, four were married. Two out of the four that were married had children.

Table 1.

Participant Demographics

Gender	Male	4
	Female	4
Age (years)	Range	21- 45
	Mean	31
Marital Status	Married	4
	Single/ Not Married	4
Employment Status	Employed full time	6
	Student	2
Duration of T1DM (years)	Range	6 - 34
	Mean	15
Duration of CSII therapy (years)	Range	5 - 14
	Mean	9

Thematic Analysis: The Experience of Living with CSII with T1DM

Four major themes with subthemes related to living with CSII were identified from participant narratives, as presented in Table 2. The major themes and sub-themes provide a rich understanding of what it is like to live with CSII in its everydayness. To reiterate, phenomenology is the study of phenomena or what gives or shows itself in experience or consciousness (van Manen, 1990). It aims to express phenomena in rich language by reoccurring structures of meaning that are embodied in human experience in a text. Naming these experiences allows one to recognize aspects of them and make them real. It is important to note that there are many creative ways to express the meaning of a phenomenon; the writing of this thesis is the most ordinary, down to earth, and common way (van Manen, 1990). I have attempted to write in a way in which meanings resonate with the language and with the names of the themes, where it is recognized that a definition of theme remains elusive (Braun & Clarke, 2013). Themes are tools that researchers use that identify reoccurring patterns that connects the experience into something meaningful. Themes are abstract entities that connect many separate pieces of data and help readers understand the critical and meaningful aspects of the data (Morgan, 2018). The themes and subthemes are not an explanation, but rather a description and interpretation of the phenomenon as it appears in consciousness. To unveil the world as experienced by participants we understand the essence of the phenomenon through their life stories; the essence is what makes something what it is, and without which it could not be what it is (van Manen, 1990). I will discuss the ascendancy of CSII, which is the essence of my study, later in this chapter.

Table 2.

Themes and Subthemes

<p>1. Theme #1: Transitioning: Not a Quick Fix</p> <p>Subthemes:</p> <ul style="list-style-type: none"> Disillusioned, overwhelmed, and unsure Separation of self before and after life with CSII Relinquishing control to CSII: You wear your life Owning it Taking my life back Constantly Vigilant: CSII is a lot of work
<p>2. Theme #2: CSII: Making an Invisible Illness Visible</p> <p>Subthemes:</p> <ul style="list-style-type: none"> Concealing and Accommodating CSII Being Misunderstood
<p>3. Theme #3: The Internal Struggle and Impact on Mental Health</p> <p>Subthemes:</p> <ul style="list-style-type: none"> Striving to meet unrealistic expectations: Blaming self Inner conflict
<p>4. Theme #4: The Impact on Relationships and the Meaning of Support</p> <p>Subthemes:</p> <ul style="list-style-type: none"> Connecting with others who have CSII Re-defining relationships: Bringing in a third party Negative encounters with healthcare professionals: Antithetical to self care The financial burden of CSII

Theme 1. Transitioning: Not a Quick Fix

Although CSII was marketed as a quick fix tool that would lead to a carefree lifestyle, the reality of living with CSII was much different than initially anticipated. Participants felt that the information presented during education sessions was not realistic. They quickly became disillusioned and overwhelmed. Initiating CSII began a period of transitioning in participants' lives whereby they often referred to life before CSII and life after CSII, as if they had established a new identity. Over time the initial stress created by dependence on CSII was replaced with trust and a relinquishing of control, whereby participants began to take ownership of the responsibilities and consequences of using CSII. Although CSII did not fix T1DM, a sense of control emerged where participants felt they had reclaimed their lives. However, CSII was

complex and required a lot of work to reap the benefits; there would always be limitations to their lives. The theme of transitioning illustrates the challenges that participants experienced after initiating CSII therapy. It also highlights the emergence of a different sense of self--a new identity that left participants forever changed. To more clearly present the findings the theme, *transitioning: not a quick fix*, is presented as several subthemes which are: (a) disillusioned, overwhelmed, and unsure, (b) separation of self before and after life with CSII, (c) relinquishing control to CSII: You wear your life, (d) owning it, (e) taking my life back, (f) constantly vigilant: CSII is a lot of work.

Disillusioned, Overwhelmed, and Unsure

The initial education session by the certified diabetes nurse educator, although meant to educate individuals on how to self-manage T1DM with CSII, lasted just a few hours. Once on CSII, the problems began with participants feeling that many important issues were not discussed in the initial education session. Not addressed in the session was; the financial burden of CSII, impact on intimacy and relationships, troubleshooting, the impact on self-image, and the difficulties with concealing the device, and the many accessories such as the continuous glucose monitor. Participants' lack of education about these issues left them feeling unprepared, unsure, overwhelmed, and disillusioned.

Expectations of what CSII could do was antithetical to participants' experiences. Online advertising of CSII shows individuals who are smiling, having fun, and living a carefree life. CSII was promoted as a device that would make individuals happy and perhaps take away some of the difficulties, worries, and uncertainty of managing T1DM. However, participants found this to be very misleading.

When you do some of your own research about the insulin pump [CSII] and you read testimonials online and all that kind a stuff about it. Like these people were, like, lovin' it and they were able to do so much more stuff and there's so much more freedom and I think from, I think from the, the diabetes team I think it was pretty much promoted as it was going to help you. It was a tool. It was kind of, it was kind of marketed and promoted that way to me.

Based on the advertisements, this participant saw CSII as a quick fix that could relieve the burden of T1DM, giving her back control over her life. She believed that she too would be smiling, having fun, forgetting about T1DM, and reclaiming her freedom. Instead, her experience did not mimic the individuals she saw in the advertisements. CSII was not a quick fix; rather, it took time and effort to learn new skills and new practices to self-manage T1DM effectively. She felt disappointed, disillusioned, and betrayed by how CSII was advertised, but also by the educators, whom she perceived failed to present CSII in a more realistic way.

I just think that it needs, everything needs to be more realistic with respect to pump [CSII] education. Because, again, people say oh, we're so glad that you bought our pump [CSII] because for the majority of people, pump [CSII] education, at the beginning, comes from the reps [CSII industry representatives]. Of course, they [industry representatives] want you to buy their product and, of course, [CSII company] would have nothing but great [advertising] testimonials, but in terms of health education and health promotion and all that kind of stuff we need to be real. I think it would have, I think, at the beginning, before I bought it I would have went, 'Oh, wait now.' I would have considered it more. Because I was just like, 'Oh, give me a quick fix.' It's kind a what I thought, I think I would a went, 'Oh no, like, it's going take a year.' I would have

felt better that I wasn't going to be well right away... if it had been more realistic education I think it would have made my transition better.

She continued to elaborate on her experience. "People need to be ready for ups and downs, frustration, you know... To discuss the fact that this is going to be a long road. You're not going to put a pump [CSII] on and have a great A1c [hemoglobin] in 3 months."

For one participant, the exclusion of intimacy from the education sessions left her feeling unsure of what to do with CSII during intimate times. "Nobody has mentioned that [intimacy] to me, ever. In my, all my education sessions, anything I've ever read on it, nobody's mentioned what to do with that [CSII]... The intimacy piece is very important because, like I said, we're all human." To feel a connection and closeness with another individual is a vital aspect of our lives as human beings, yet intimacy was not discussed.

What do you do with your pump [CSII] when having sex? It's hard to know what to do with your pump [CSII] because if you're high, you take it off? Or do you just leave it there beside ya or what do you do? Plus, where the pump [CSII] goes in can be sharp, I think and can injure the other party.

Despite feeling that much had been left out of the initial education session most participants felt that they were unable to process the vast amount of information included in the education session; they felt mentally paralyzed, were unable to ask questions, or anticipate challenges. They did not feel they had sufficient knowledge to troubleshoot issues with CSII nor the readiness to deal with these issues.

I think my training was, there was just so much new information coming at me at once that I didn't have time to ask questions, 'Yeah, oh, ok, so, this is this and that's that.' It

was never, like, ‘What do I do if this happens or that happens?’ because those ideas were so new to me.

In contrast, one man expressed that adding too much information to the initial education session would have been unhelpful and only exacerbated his fears and concerns about his ability to self-manage with CSII. For him, CSII would require a commitment to lifelong learning.

It’s an ongoing thing, you’re always learning, you’re always training...so I don’t think that anything necessarily would have been added because there’s a lot of information at the beginning and you become too overwhelmed...So I don’t think adding any extra information at that time would have made transitioning any different or any easier because there are always things to learn with it. It’s something that you can’t just say ‘okay I know everything about my pump [CSII] now so set me free on the world.’

Separation of Self Before and After Life with CSII

CSII was a reference point in time that created a duality in participants’ lives; whereby, there was a separation of self before CSII and after CSII. Participants felt like they emerged as a different individual with a new identity during the integration and normalization of CSII. “Right away I was able to take advantage of using a pump [CSII] but at the same time I know what life was like before having it [CSII] and the frustration of that and there’s certain times that it hits you.” For one participant the separation became even greater when T1DM and CSII occurred simultaneously. At 28 years old she was married, had a successful career, was living in her own house, and then came the diagnosis of T1DM. Choosing CSII as a management regime was an obvious decision for her with recommendations from healthcare professionals, colleagues and friends who were using the device. However, T1DM and CSII forced her to consider and question everything she did, and this constant awareness was overwhelming and consuming. Life

had now become complex and full of obligations where she grieved her previous self and life. She struggled to make sense of her world and how T1DM and CSII would fit into her life. For her, when she discussed life before and after CSII she was actually discussing CSII and T1DM simultaneously.

The biggest thing for me with being diagnosed with Adult Type I, what I found was you go from not having to worry about anything to having to consider what you eat, ah, you know, take your insulin, your medication, looking at how activity impacts on all of that, counting carbs. I never had to do all that so for me, it was never the insulin, per say, or the medication, or the needles [MDI], or the actual pumping [CSII], type of thing, it was more, when I first started, it was more the regimented, it was more like having to think about these things that I didn't like. If I could just say, if someone could say to me, 'Ok, you take five needles [MDI] a day and your sugars will be perfect from now till you die,' I'd probably would have stayed on needles [MDI]... That's the diabetes pump [CSII], it's, it's just that you're always thinking, it's always there, it's always part of your life. I've lived 28 years of my life that I didn't have to have all these thoughts.

This sense of duality in her life became more pronounced after becoming a mother. Her life was separated into segments of time, where time for her was not measured in seconds, minutes, or days, but rather moments in her life that were significant and life changing.

Having children, like, oh my God when I, when you look at your life, I'm 39 years old. It's like my life before diabetes and then there's after diabetes and then there's also subdivided to before children and after children, so diabetes, so after children is a whole other, like, it's just, it's just so hard sometimes.

Relinquishing Control to CSII: You Wear Your Life

The degree of control over T1DM individuals relinquished to CSII was individual to the participant. Yet for most, CSII was understood to be simply a tool and not something that could replace their own knowledge and skill. In the beginning, participants hoped CSII would provide immediate control over T1DM and decrease their fears about DM-related complications. However, there was a duality between expectation and reality, whereby CSII could not guarantee exemption from DM-related complications. The uncertainty and lack of predictability with T1DM is permanent, as is the fear of complications. This fear originated from a place of deep uncertainty and questioning of what the future held. There was a sudden awareness and realization that death could occur, and the risk of complications was still present regardless of the management regime. One participant shared that CSII did not alleviate his fear. "I'm still diabetic, still have all, all the same issues and worries." Fear of developing DM-related complications from blood glucose variability manifested as increased anger and anxiety for another participant. "Being diabetic, having high blood sugar before, I feel I get really tense. It's just almost like anger, I'm just really not comfortable, knowing it's high and thinking about other things, complications." Another participant felt confident that CSII was the best option to reduce the risks to her unborn child, however, the fear of long-term DM-related complications to her own health were still present with CSII.

I am very concerned about the life long effects of having diabetes but right away I was able to kind of take advantage of using a pump [CSII] ... To me, I can 100% say when I was pregnant, you know, that I wore the sensor [continuous glucose monitor], my A1Cs were, like, 5.8, 5.9. Beautiful A1Cs...I was confident that my pregnancy was going to be

healthy and my children were going to be healthy because I had this, you know, piece of technology to benefit.

For another participant, the realization that CSII was “life support” was daunting to accept in the beginning. “It’s life sustaining equipment. Right? So, it was very scary for me and, as I say, I was really, really anxious at the beginning. It’s the realization that you wear your life, like this box is keeping you alive. You sit back, and you think about that, like, you put your life in this box.” Knowing that CSII is life sustaining equipment also aroused fears that it could break, malfunction or be stolen.

If I ever had any worry about the pump [CSII] it wouldn’t be about people noticing or people seeing it, it would be about me hitting it against something or it getting broken in the hallways at university, like, people are crazy so that was one big worry for me.

The fear of having the CSII device stolen restricted one man from participating in certain activities. But despite this the fallback to MDI would be a step backwards in his T1DM management.

...that does drive me nuts. It affects getting into the water. You actually have to take it [CSII] off and lay it there and then if you go for a swim and then there’s always that fear that maybe someone is going to go and grab it [CSII] and what are you going to do if it’s gone, then you’re stuck on syringes [MDI].

One participant described how she missed time from work due to CSII malfunctioning and remembered it as a stressful experience and feared recurrence.

I had some issues with infusion sets... whenever I put it on the left side, on the inside, it seems to leak. It happened at work and I was like, I work over on [road] and I live just

over near the mall and I'm like, 'Oh, I'm going to have to go home now and it's going to take me forty minutes,' like, so, that does stress me out.

Though CSII was cutting-edge technology participants questioned its reliability. Infusion sites with CSII were changed every two to three days and sites were sometimes limited due to practical reasons, such as the location of a waistband or exposed tubing. Scar tissue was also a site restriction that could result in insufficient absorption of insulin and increased blood glucose levels; thus, participants were fearful of blood glucose levels increasing unknowingly due to a lack of insulin absorption. In contrast, MDI offered more site options for insulin administration, thereby reducing scar tissue and variable insulin absorption. "I can tell that after 10 years, like, it's, my sweet spots [infusion sites] aren't so sweet anymore because the insulin doesn't get absorbed properly and with needles [MDI] you've got all those different sites where you can rotate." Another participant was fearful that malfunctioning could result in high blood glucose levels increasing the risk for complications or death. Despite the sophistication of CSII, he would still have to carry syringes as a backup plan for insulin administration.

I've had issues about my infusion sites. You're really relying on them to work and then you realize, 10 or 12 hours later, that your blood sugars have gone through the roof because the infusion set doesn't work, and you still have to fall back on the injection to fix the problem.

Fear of elevated blood glucose because of CSII malfunctioning was such a significant concern for one participant that he reconsidered going back to MDI for his T1DM management regime. "Having trouble with the infusion sets and concerns about blood sugars, I really considered going back." Though he continued with CSII, he acknowledged that manually administering insulin with a syringe would provide more peace of mind and assurance. "You take the injection

and the injection always works.” Participants felt they lacked sufficient knowledge and preparedness to troubleshoot CSII. Feeling unsure of how to calculate insulin dosages, if they had to revert to MDI, had them fearful they would not be able to get this life sustaining medication without CSII as explained by one participant. “That was a fear, like, it [CSII] would fall and break and then I don’t know how to convert to syringes [MDI] in case that ever happened, so that was a big worry.”

The demands of CSII created a sense of imprisonment, making participants feel like a hostage to the responsibilities and obligations of managing T1DM. Administering insulin via MDI gave one participant the feeling that she had more control over T1DM. “Part of it was, for me, not having control because I said I’d never go on a pump [CSII] in the beginning because I didn’t want something else to control. I felt with the needle, I controlled my diabetes.” Adjusting to CSII took time where there was a vulnerability created by depending on a machine. Acceptance and relinquishing control meant overcoming fear, uncertainty, and learning to trust the technology, and this was difficult.

Figure you’re going to put it on and everything is going to be great, but it takes, personally, it took me, I’d say, a year and a half and that’s a long time but to be totally comfortable with my pump [CSII] and my pump’s [CSII] functions and, because it’s, it’s your life, right? Like this is my life.

Participants felt imprisoned by CSII until they accepted the device as part of themselves. Despite their fears they eventually relinquished control. It was as if a relationship developed between the individual and CSII.

I feel like I’ve given some of that control to the pump [CSII]. That was hard at first because I’m such a type A personality and that was really hard for me, at first, to give

some of this control, but it's like the pump [CSII] and I developed this relationship. I've learned to trust it, but it's still a machine. But I still have, I have faith in it that it's going to do its job.

Giving some of the control to CSII was a process of change, whereby trust was necessary for the relationship to work.

At the beginning, when I first went on the pump [CSII], I would hate having to fix those problems or hate not knowing did I get my insulin or not but I think you, like, most people, probably develop a, you got to trust your pump. You develop a relationship with the pump. Well, I mean, it is an inanimate object but you, you have to trust at some point because otherwise you wouldn't be able to wear it.

Feeling competent and confident in troubleshooting and knowing how to administer insulin in the event CSII was not available, was important in reducing fear. One participant eventually accepted that troubleshooting would be something she would have to face to live with CSII.

My fear at the beginning was that it would malfunction and give me way too much insulin. I was afraid I'd go to sleep and it'd bolus me way too much, my basal would be turned off, magically or something. It doesn't have a brain, it's not going to all of a sudden decide to give you way more units than your basal. You know, it's still a machine, there's still that tiny voice of 'wow, what would happen if this breaks' but I'm at the point now that I go, 'Oh, well, I'll just deal with it if it breaks' and when I wear a sensor, too, it makes it a lot easier and more comfortable for me. So, like if my pump [CSII] malfunctioned in the night I would know about it and my sensor would alarm. It is an extra security blanket.

Having other options for insulin administration and feeling knowledgeable how to calculate insulin requirements via a syringe resulted in less worry and less stress for another participant. Knowing that he could still get insulin regardless if he had CSII was comforting and reduced the fear associated with CSII malfunctioning. “It happens but I know what to do with my needles [MDI] if I needed to, so it’s never a huge concern. It rarely ever happens, I find. Ahm, so it’s never really been a massive worry of mine at all.”

Owning It

To live with CSII meant accepting that staying alive depended on self-care and this came with a deep sense of ownership. Because CSII therapy was ultimately the participants’ responsibility, they experienced highs and lows of success and failure and saw their own actions as reasons for success and failure.

There’s such a sense of ownership and control where you feel really good about yourself when you do really well and really bad when you do really poorly. And, if you think about it, sometimes the stress response just elevates your blood sugar. When you go through menopause you don’t feel like that but with the pump [CSII] you definitely take ownership. I know I do, I feel really, really good when things go great.

CSII technology was complex, adding to the pressure of T1DM self-management. Feelings of disappointment and blame were experienced by one participant for not being able to comprehend how to manage T1DM with CSII.

I do have two degrees and, you know, I’m fairly, you know, I’m fairly okay when it comes to reading and understanding stuff and I could not understand why I could not figure this out and I was very upset with myself. But I think as a diabetic anyway we tend to take ownership for our control and sometimes we’re too hard on ourselves either way.

Owning the responsibility of CSII therapy contributed greatly to perpetual self-blame and to some extent almost all participants internalized the guilt.

Getting my A1Cs, you're sitting in the waiting room and I'm like, 'Oh God, I'm the worse diabetic among all these people here.' I'm fine being in the middle group as long as I'm not that one that, 'Oh my God, I really suck.'

Living with CSII was described as a feeling of aloneness. Aloneness was the weight of carrying this burden that could not be alleviated with the presence of family or friends. Feelings of aloneness created a disconnect between themselves and others, whereby others could not understand the burden of being responsible for making life and death decisions. For one participant, who was diagnosed with T1DM and started CSII simultaneously, the feeling of aloneness was distressing.

Diabetes, to me, has been such a lonely experience because I was old and I was living, I had moved out from my Mom and Dad's, you know, I was living with my husband. I was in full management of my own personal health. So, everything was on me, like, I don't even really share that much with my husband. He doesn't really have an understanding of diabetes and, and my poor parents I, I think that's why I don't share anything with them. If I have a good A1C, if I have a bad A1C or if I'm really high, I don't share with them because they don't have the background knowledge... So, it's always been a very lonely experience, ahm, to fault of my own that I haven't shared.

She continued her response.

I keep it so to myself and, like I said, because I was 28, you know, whereas if I had been 11, or whatever age, my parents would have gone through that process with me and they

probably would have been the sole caregiver in terms of my management, so it's always been me.

As participants accepted the responsibility for CSII therapy, the days marched on without much thought to the daily routine of it all. "Day-to-day it just becomes part of your routine. You don't think about having to do it, you just do it." CSII therapy gradually became a natural thing to do, as one participant explained. "Most days I don't really think about being diabetic. It's just something I've had for so long it's, it's like breathing to me now."

In contrast, for another participant, CSII ownership became a source of motivation for T1DM self-management.

This is completely 100% manageable and it's completely 100% self-manageable. Like, if I don't test my sugars that's on me. You know, it's not on anyone else... overall my opinion of the pump [CSII] is that it's fantastic. I'd recommend it to anybody, but you have to be ready to take on that responsibility. You know you have to be willing.

One participant, who had been managing T1DM for over 30 years, believed that positivity was a choice, where each individual had the potential to make the best out of a bad situation. His acceptance of CSII came with much reflection about the changes and advancement that he experienced with T1DM management. CSII was more work than MDI, but he felt there was increased benefit.

It's more work, but, it's more benefit for the work that you do, right? It's just like the more you put into it, the more you're going to get out of it. So, I think that it might, like at first starting off, like anything when you're not used to it, it seems like a lot of work, but as time goes by and you're doing it...like everything, the work becomes easier. I guess, the longer you're doing the same thing over and over. But, you still got to put the effort

into it to get to that level of understanding with it. So, it's still work and it's still a lot a work, but, it, it's more of, I guess, more of a repetitive thing now for me. Because I'm so used to it. It becomes routine and you work it into your schedule.

The work required with CSII was tolerable because he could foresee the benefit of having increased freedom and flexibility. With MDI, he felt he was doing more work than with CSII, but was not able to see any benefits.

For someone who's newly diagnosed now, they don't know what it was 30 years ago right. So, I always, I got that as a comparison. I know what I've had to do as technology has improved over the years. Right now, I know that I'm definitely at a stage where technology is, is helping you to do as little as possible to get the most benefit out of it whereas, before, you were doing a lot more and you don't know what the benefit was that you were getting out of it.

The effectiveness and benefits of CSII were dependent on the amount of work invested into using the device and were not attainable with MDI.

I think you've got to be willing to learn, you got to want to learn about it. You've got to be willing to learn and then you've got to use the information that you learn, to make it work for you right. You're not just going hook it up and suddenly, you're, you're like someone without diabetes anymore right, it doesn't work that way. You got to work at it. It's not just plug in and go on and do whatever you want to do, eat whatever you want to eat, and you're going to be fine.

For this man, CSII required a commitment to lifelong learning, which he perceived as an investment in his health and QOL.

I think that you're always learning something new about it and it's up to you if you want to learn it and how you decide to apply what you learn. So, if you want to do the best that you can for yourself, then you're going to keep learning...It's meant to work on a much higher level than a syringe, so you have to make it work for you.

Taking My Life Back

The subtheme *taking my life back* portrays participants' experiences of CSII as eventually giving them back some decision making and control over their lives and making them feel closer to normal. Although they would never be their pre-undiagnosed self, CSII helped to reclaim freedom, flexibility and blood glucose control. In addition, was the comfort of always having insulin with them.

Many participants expressed that the amount of work to self-manage T1DM made them feel different from others. There was a longing to feel normal and there was hope that a sense of normalcy could be achieved with CSII. One participant expressed that CSII was a tool that made her feel closer to normal or more like everyone else. "It [CSII] gives you way more freedom to be more normal and especially in public, it is more discreet. They don't even realize what's on your side." CSII was like an extension of herself. "You kind of feel a little bit normal. What people have on the inside [pancreas], you have on your outside [CSII] so it's closer to normal."

The diagnosis of T1DM and previous self-management with MDI came with a loss of freedom and flexibility in participants' lives where extensive planning to perform simple tasks and daily activities was necessary. Though CSII was not liberation from T1DM and the results were not immediate, it reclaimed freedom and flexibility from the restrictions and constraints that were inevitable with T1DM.

The pump [CSII] gives you more freedom, flexibility of your schedule. On needles [MDI], it's a little trickier. I could do it but I needed to plan it in advance. Couldn't be just more of the spur of the moment thing, I had to, you know, it required planning in the morning as to what am I going to be doing this evening.

CSII took away some of the restrictions of living with T1DM. "For me, it's always been having to plan, that's the worse part and I think the pump [CSII] took away some of that so that way it made it better for me." Participants had the flexibility and freedom to choose when to eat providing a more spontaneous lifestyle than the strict regime of MDI.

I was on the pump [CSII] for about a week and I realized, I can't imagine not being on the pump [CSII] ...I'd never go back to needles [MDI]. I can't imagine. I don't even know how I did it. I really don't know. I mean, I was fine on needles [MDI]. My A1C was ok but you know, having to eat at strict times – 9 o'clock, 12 o'clock, 3 o'clock, 6 o'clock, 9 o'clock.... I cannot imagine ever going back to that, but life is definitely better on the pump [CSII].

With MDI eating became more of a strain in participants' lives than an enjoyable experience. With CSII, participants felt they did not have to think about T1DM each time they would eat; thus, freedom and flexibility at mealtimes were reclaimed.

The flexibility was, probably, almost immediate. Right, and not being tied to a schedule, that was the big thing, I guess, was not having to do something at a certain time of the day because that's what you do that time every day... if you want to skip a meal I can skip a meal, I don't have to eat breakfast or I don't have to eat lunch or I can go out to supper at 8 or 9 o'clock in the evening. I don't have to have supper at 5 or 6 o'clock so that flexibility was, was right from day one.

One participant, who had lived with T1DM for over 30 years, stated that the freedom and flexibility of CSII gave him back control over his life. He, not T1DM, made the decisions about what he wanted to do and eat; thus, T1DM no longer defined him.

I wouldn't want to go back a step. I wouldn't want to go back to a pen or a syringe or anything like that and be doing that on a schedule basis. The flexibility and the freedom that you got is, you know, you're not tied to any schedule. You make your schedule, you make your own schedule, you have control. It's what you decide to do with it. You are the one that decides which direction you are going, so, you're the master of your own destiny.

CSII offered more than just an unrestricted eating schedule. It also alleviated the need to take MDI, further contributing to increased freedom and flexibility.

Flexibility. Flexibility absolutely...but the ability to eat and to carb count and to eat different amounts, that's definitely a plus. The ability that you only have to change your site every two to three days and, for me, 3 days would have been 18 needles, right, so, that is a total bonus.

For another participant, the freedom and flexibility of CSII allowed for new opportunities in life that their previous regime with MDI did not.

I don't think I could have been a university student on needles [MDI]. When I was in Elementary School, Junior High and High School, the set schedule was much easier but being a university student, your schedule is all out of whack, you know, and different times and I think it would have been a lot harder then to be on needles [MDI]. That flexibility just isn't there for needles [MDI]...I can see, you know, hundreds of things that I do right now that I wouldn't be able to do because I was on needles [MDI].

For others, *taking my life back* was reclaiming blood glucose control. Despite best efforts to maintain consistency with blood glucose, variability is common with T1DM. Blood glucose fluctuations were often unforeseeable, unexplained, and erratic causing social and physical interruptions in participants' lives and their intentions to live a normal life. Although the impact of these fluctuations was difficult to define, the symptoms of hypoglycemia and hyperglycemia were mentally and physically exhausting. Also, distressing was the thought of how blood glucose fluctuations were impacting their long-term health and risk of complications. Persistent difficulty with achieving blood glucose control led one participant to switch from MDI to CSII; thereby, reducing his risk of complications and reclaiming a sense control over his life.

I was, a couple of years there I was trying all kinds of things to get my A1C a little bit lower and I just, just couldn't find a way to get it consistently lower and I think it was that straw kind of thing that I had proven to myself that I couldn't get it to the perfect range unless I was on a pump [CSII] and that's basically why I decided I had to go on a pump [CSII] ... So, I figured, you know, it's either the pump [CSII] or, you know, get sick.

CSII reduced blood glucose variability and reduced the occurrence of hypoglycemia and hyperglycemia compared to MDI. This contributed to participants feeling better mentally and physically.

Better control, less lows, less highs and more in range and just being able to feel better on a daily basis. You don't have the feelings when you're high, that lethargic feeling and groggy feeling, grumpy and contrary because you're high. You can't do anything about it, right?

Another participant elaborated.

You're within range more, you're feeling better, you don't have the, the swings, the mood swings and some things like that that you were probably having on syringes [MDI] when there was a lot more fluctuation between your blood sugars throughout the day. So, you just feel better.

It is worth noting that CSII did not eliminate hypoglycemia or hyperglycemia. However, CSII was viewed positively because, in addition to reducing occurrence, it increased sensitivity to symptoms of hypoglycemia and allowed for earlier intervention.

I don't find, or feel, that it is as much of a concern because the hypers, like I said, I think you can correct that and manage that a lot quicker... where it's just the one insulin you can bring your hypers under control a lot quicker. And the hypos, I guess, there's still a lot of variability with that because of your activity, incorrectly counting your carbs or, or even, I guess, fat contents of a meal, right so, it's probably more of a concern for the hypos than the hypers but those are easier to correct, now, as well. Quicker, easier and I think I became more sensitive to the hypos, too, after I started with the pump [CSII] because it seemed like once you got below a certain blood sugar level you feel it at a higher point than what you would before.

With hypoglycemic events corrected earlier, CSII allowed for more flexibility with food choices.

It leaves more flexibility and not being tied to stuff, not having to make sure that you got a pound of chocolate or candy close by all the time, right? So, you don't have to have as much to treat the hypos and, it's a lot easier to manage and you can correct the highs in a lot shorter period of time.

CSII allowed participants to make frequent changes to insulin delivery during activities, such as exercise, resulting in fewer of the hypoglycemic events that were often experienced with

MDI. This allowed them more freedom and flexibility to participate in activities that were restricted with their previous regimes of MDI.

I felt more pressure to be checking my sugars moreso when I was on syringes [MDI] because the amount can drastically change. And once it's in there, like if you change your morning dose, that will go through for your whole day, like your long acting, like it's there and there's nothing you can do about it.

The continuous glucose monitor, an accessory used with CSII, monitors blood glucose levels continuously. Having quick access to blood glucose readings gave one participant increased freedom and flexibility to participate in activities because he was more aware of his blood glucose levels than with his previous regimes of MDI.

I'm also on the continuous glucose monitor as well, which was a big, a big eye opener. I found I had good A1C's and stuff but I didn't know what was going on for a third of my day, like overnight. Like it's a third of my life and I didn't know what was going on. You have a ballpark idea but sometimes it's a little tough but I got that because I wanted to know what was going on in the middle of the night... that's [continuous glucose monitor] a big help, too, for sports, cause, like, when you're on the bench, or there's a time out, so you can check and see 'okay, what's my sugar now'...I play a lot of different sports and some are aerobic, some are anaerobic, you know, some less physical than others. So, they all wreak havoc on your blood sugars in different ways... on days when I'm not wearing it, I feel lost, because I don't know what's going on every few minutes.

For some participants, CSII provided immediate access to medication and supplies compared to MDI. This resulted in more flexibility, by reducing the need to carry as many supplies; and, reassurance during social outings, knowing that insulin was always with them.

Just versus needles [MDI], the pump [CSII] is just so much easier. Like, before I'd go out and I'd have, like, glucometer and then pens, and pen tops and cartridges. You have to take an extra bag of things. Now, I just go and if I have a problem with the reservoir or the setting I can just fix it myself, like test and see if it's going through and then if it's an issue, like just reinsert. So it's so much easier, like, just going and you don't have to carry so much stuff. You don't have to be worried about, 'Oh, did I take that.'

CSII included all the supplies needed to maintain survival and this was reassuring to participants.

It's just so quick... the pump [CSII], it's all there, it's all connected so you don't have to worry about putting the needle tops back in your purse to properly dispose it, or, you know, whatever. It's just, it's like a little mini pancreas and, it's just, it's always there.

CSII could not take away T1DM, but it did provide a less restrictive and controlling lifestyle. Over time, participants adjusted their expectations of CSII and eventually established a "new normal" in their lives. Participants were able to do or achieve anything, but at the same time, they recognized that there would always be limitations when managing T1DM. Living with CSII would never match the expectation of leading a normal life because participants still had T1DM. "I think there's always a little bit of a limit, like, being on a pump [CSII], even with all these things, there are some things you can't do. You can't just because you're on a pump [CSII], just pretend you're 100% healthy."

Regardless of all the benefits of CSII, participants shared that T1DM affected their ability to do the things they loved. Imminent obligations and an overwhelming responsibility to always be engaged with the device contributed to a sense of feeling restricted. "It's always going to be limits and, I mean, that could lead to some depression and some mental health issues. The fact that I am not, that I can't do everything that I want to do." T1DM was still an ever-present

responsibility that required attention in individuals' lives; thus, participants had to live their lives, but accept that there would always be restrictions and limitations, despite having CSII.

I've got an insulin pump [CSII] ... you just got to live your life as if you don't have diabetes, even though you do, you got to know your limits right?...It doesn't stop me. Just makes me aware of what I need to do to be able to do it.

Constantly Vigilant: CSII is a Lot of Work

The paradoxical nature of CSII was that it offered freedom and flexibility, but it was a manually-operated device with infinite obligations and never-ending responsibilities and required constant vigilance. "It's been easier to incorporate into a lifestyle but at the same time, you still got to do the infusion changes, rotations, you still have to test your sugars, you still have to bolus, like manually do it." Many participants expressed that the features and complexities of CSII required more vigilance to manage T1DM than MDI. "It was a lot more work than needles [MDI], especially first starting off because your carb counting has to be pretty spot on, because you have no long acting [insulin] now, right."

The public often mistakenly believed CSII was automatic and self-regulating, even though it actually required more care and vigilance than MDI. It was extra work and extra responsibility in addition to managing T1DM. "You have to be intelligent to be on the pump [CSII]. There is so much math involved in it and trying to figure out to use it appropriately and to be on top of it and to use this great technology to the best benefit, it requires a lot of work." CSII required constant attention in every aspect of their lives. It was a harsh realization of the amount of vigilance required to reap the benefits, yet these benefits were not instantaneous.

You don't realize how much work and it's marketed that it's going to make you so much better and for me it felt like it was going to take away some of the hardship with diabetes,

that it was going to relieve me of some of that, some of that work that I had to do, that it would make me a little bit “back to normal.” But, in actual fact, what had happened, it almost made it a little bit worse for the short term when you’re first getting used to the pump [CSII]. And I had a hard time and I wondered for even up to a year if it was worth it, if I should go back [to MDI]. To be honest with you, I was really over anxious about it. I wouldn’t change it now for the world but one thing that people really need to know is that it’s not instantaneous and it takes a lot of work.

Being constantly vigilant meant incorporating a multitude of overwhelming responsibilities and considerations into their lives. For some, vigilance was having to be aware of CSII’s presence and location. As one participant described: “It did take me a while to get used to it. I mean you kind of got this thing stuck to you pretty much everywhere you go and anything you do you have this on your side.” Another stated,

Well, just the fact that you’ve got it [CSII] with you and on you all the time. You got to be careful. Sometimes you don’t even realize that you got it there, but you got to be aware that you got it there all the time. You forget that it’s there and all of a sudden you get a reminder because you hook your tubing in something and it pulls you back or your pump [CSII] flies out of your pocket.

Constant vigilance also meant always having to think about CSII. The necessary level of thought and care required for every action, every activity, and every decision was consuming at times. “It’s always there but you always have to be conscious that it’s there--every little alarm or every little beep.” One participant described her experience as a “catch 22” where the freedom she acquired with CSII came at the price of having to be constantly vigilant.

There is no spontaneity that's a whole Catch 22, too, cause the pump [CSII] is supposed to allow spontaneity to be able to turn down your basal rates if you're going to go for a walk. It's just more diabetes overall, that, you know, there's always that internal voice that, 'Hey, okay, if we go for a walk or go for a bike ride with the boys, okay, how long am I going to be gone, how much active insulin?' You just can't get up and go.

It was necessary for participants to consider how everything would affect CSII therapy. For some, it was a point of contention, as CSII was supposed to take away some of the onerous work of managing T1DM, not increasing it.

Sometimes, with the freedom that you have with the pump [CSII] it's a little bit of a curse. With needles [MDI]... you had your meal plan and you matched your insulin to that and, you know, you didn't deviate from it. So, now, when you have more freedom, trying to figure out, like, how much fat content and should I do like a dual wave [bolus], there's just that much more to think about that I find frustrating.

Similarly, another participant thought about reverting to MDI. 'Having to always think about it is so frustrating...I just, I don't know anything about life without it and sometimes I think I'd like to go back on needles [MDI] because it [CSII] requires so much work.'

Theme 2. CSII: Making an Invisible Illness Visible

Participants began the interviews with stories of how wearing an external device brought visibility to an otherwise invisible illness; CSII was symbolic that something was wrong. This had a significant impact on how they believed they were viewed by others and how they viewed themselves. It is the participants' beliefs that others underestimated the amount of work involved and vigilance required to operate the CSII device. Participants wanted to hide CSII; hide the illness; and hide the scarring, fearing they would be misunderstood and stigmatized by the

public. They also did not want to be reminded that they had an incurable disease. Subthemes included (a) concealing and accommodating CSII, (b) being misunderstood.

Concealing and Accommodating CSII

CSII was a physical reminder to participants that they had T1DM, and for many this was the most unappealing aspect of the device. It revealed that something was broken in their body and that something was wrong with them. “So, when you put a pump [CSII] on you, you have an external reminder that your pancreas sucks.” Although T1DM was invisible, CSII involved auditory reminders to check blood glucose levels or to take insulin. Although this was meant to improve the management of T1DM, the auditory alarms also externalized the illness to the participant and the public. This was frustrating to participants. “I have alarms that go off a lot of times...it’s not only a visual reminder, it’s also an auditory reminder, too, that you have this disease.” Many participants did not want CSII because it exacerbated feelings of being different, as one participant shared.

I was resistant to that [CSII] for a couple of years. Well, I already had diabetes and I didn’t want another thing [CSII]. I was 15, 14, years old, like, obviously there’s a little bit of a stigma associated with it. You’re just a kid, you just want to be normal and you don’t want to wear an extra thing. So, I was very resistant at that age, not because I didn’t think it was going to help, just because I didn’t want to wear something else on my body.

The visibility of CSII changed individuals’ sense of being in the world and the relationships they had with themselves and others leading to the desire for concealment and/or accommodation. The effort put into concealing CSII reflected participants’ self-awareness of how they presented themselves to the world and how they were perceived by others, where CSII brought criticism and judgement. “Some people, when they found out I was diabetic, treated me

a little more, at least treated me a little more delicately and I was, like, ‘Listen it’s perfectly fine, it [CSII] can’t break.’” The physical presence of CSII often created an opportunity to use T1DM as a punchline for jokes, making social situations difficult, further amplifying participants’ feelings that they were different from others.

Friends jokingly tease you about being diabetic. You know some of it was all playful, but I do find people, again people who don’t know what a pump [CSII] is and don’t know how it works, are always worried that if they touch it they’re going to break it or they’re really delicate about it. You got to try to explain to people that it’s set up so that it’s foolproof, people just don’t understand what it can withstand, and they are always, and people are always concerned... having to explain that to people is a little, like they don’t always understand it so I find that people don’t understand what kind of physical response it can take.

Thus, participants revealed to me their desire to conceal CSII to eliminate the constant physical reminder that they had an incurable chronic illness and to avoid talking about CSII or T1DM with strangers or acquaintances; thus, they took active measures to conceal the device to render it “invisible” to themselves and to others. “I cover it up, just because I don’t care for the extra questions, ‘What is that? What does that do?’ I’m not bothered by them, I just can do without everyone asking, everyone looking. So, I just cover it up.”

For other participants, concealment of scars, caused from infusion sets, was important because they felt self-conscious, ashamed, or embarrassed about their body image. “I would still never be able to wear a bikini, or it’s always a full cover-up of my stomach because of the scar tissue that I have.” Another participant expressed similar worries and concerns when it came to the visibility of scar tissue and infusion sets. “If I’m at the beach in the summertime, I’m always

very self-conscious of like the little mark on my stomach from the scar tissue.” For one man, having CSII also meant sometimes having to make changes to his body affecting his body image in negative way.

The only thing that I find, which kids and women wouldn’t find, I have to shave places to put my infusion set so, you’re there without a shirt on at a water park and you got two big bare spots going across your stomach whereas the rest of your body has hair, so, just something like that is, that might be a little bit of image thing.

For some participants, accommodation of CSII was for practicality and comfort, while for others it was finding a place on their body to store it. Accommodation of CSII was a daily challenge for participants, especially choosing the right attire. “It definitely impacts on, on what you wear and sometimes your activities because I’ve tore it out, like, just running from room to room getting dressed.” Accommodation was a reoccurring problem to be solved as participants reinvented ways to accommodate CSII, as explained by one participant:

My Graduation Day, I’m like, ‘Where am I going to put this?’ and then you put it on the side of your underwear and it’s so heavy and it starts to drag everything down. So, then you got to get inventive, you’re like, ‘Maybe I’ll wear shorts.’

For another, CSII was not a big deal most of the time. However, it was apparent throughout the discussion that increased body awareness and re-inventing ways to accommodate CSII was challenging at times.

I’ve never had a concern about what I am going to wear or how am I going to hide it. I do, though, when I wear a suit. I don’t like that. That one was always an issue. I got, I got a seamstress to sew these little pouches inside of, my underwear and my shorts... cause on a suit the big thing hanging out and the tubing, it just doesn’t look very formal.

Finding ways to accommodate CSII had one participant considering going back to MDI. “If that technology wasn’t available I would seriously consider going back on needles [MDI], at times. It’s not having something, it’s finding where to poke it [CSII].”

Accommodation for some participants was about comfort and safety. One participant described her hesitation about using CSII, fearing it would result in pain, discomfort, and disruptions during sleep. “I was hesitant at first [initiating CSII]. I did not like the idea of something always being in me. Like I, I’m a stomach sleeper.... I said that would be so painful.” For another, accommodating CSII was about safety and preventing it from falling off her body.

It definitely would impact on what I wear because I probably would wear more of a, more coverage bikini type of thing. What I mean is kind a like a Tankini or something that so I can clip my pump [CSII] on moreso. In the meantime, I’m almost 40 years old. I’m not wearing any skimpy stuff anyway now, but, if I wanted to I really couldn’t. I, I feel like I couldn’t because I need somewhere to put my pump [CSII] and it’s not because I don’t want people to see it. For me, it’s not that point, it’s I don’t want my pump [CSII] to fall off.

Being Misunderstood

A common perception among all participants was that there was a lack of knowledge and understanding from the public about CSII and T1DM. For example, as a visible device CSII was often confused with electronic devices, such as a MP3 player. Participants often resented having to constantly educate the public.

I was never ashamed to be diabetic, but I didn’t announce it to the world either... I don’t think there’s a disadvantage to wearing the pump [CSII], but I think there’s a general lack of understanding from the population as to what a pump [CSII] is, what diabetes is. A

bunch of my teachers in junior high thought it [CSII] was an MP3 player. So, it happened a bunch of times where I was using it in class and they were, like, 'Pay attention.' It's a negative. It's a lot of questions that you don't want to have to answer, that you don't want to be bothered with.

One participant was embarrassed and fearful that others would misinterpret CSII as something used by an illicit drug user. "There's always that fear that someone sees you taking out the pump [CSII] and injecting insulin and saying, 'Look at that guy doing drugs.'" Others frequently offered their opinion to participants on how to manage T1DM based on assumptions and their interpretation of CSII and T1DM.

You show that you have diabetes and some of the, the research, especially now, going into the Diabetes Charter of Canada, is showing a lot of people want to hide the fact that they're diabetics because they end up getting a lot of stigma and discrimination.

Participants resented these encounters and felt stigmatized. They felt that with MDI, they could hide T1DM and perhaps avoid some of these comments and judgements.

I think for me when I talk about it [CSII] as visual it's not a self-esteem type of thing but a concern with people thinking they can say whatever to you. I personally feel that people think it's okay to comment on diabetes to people that have it. So, people might think it's all right to come up and say things about what you should and shouldn't do based on their interpretation of what's right and wrong 'quote, unquote' for diabetes.

Encounters with the public often led to warnings and advice about T1DM. Participants disliked the constant, not so subtle, cautionary messages about what they should be eating or how "bad" their T1DM was because they had CSII. Seemingly harmless advice from the public undermined

participant knowledge of T1DM and the work they put into living with CSII and further reflected the lack of public knowledge, leaving participants having to defend their choices.

You're just so frustrated that, like, 'Oh you can't be having that, sure you're diabetic.' And you don't want to get into it with everybody and you know, the poor old dear is 70 odd years old and I wasn't getting into fat content and absorption, like carbohydrates, with her. I just, I just kind of nodded. So, other people, I will educate them more and tell them 'no, actually, you know, I'm better off having this versus a piece of white bread, you know', in terms of your blood sugar and they'll kind of get it. Ahm, but, you know, that just comes with it I guess. Not everybody has the understanding of what it is or people find out that you're a Type 1 or have Juvenile or whatever or for older people that don't really have an understanding, that find out that I'm on needles [MDI], 'Oh, my God, your diabetes must have been bad then, to go on a needle, on a pump [CSII]'...it's not something that really bothers me. I mean there's points that it's frustrating.

Some participants displayed an indifferent attitude towards public perceptions about CSII. One participant admitted that he allowed the public to think what they wanted just to avoid getting into lengthy conversations about CSII.

It's too much to have to explain to someone, to get them to understand how to use it so, you just let them think what they want to think. That's what I do. I don't want to waste my time with that [educating the public] so as long as I know what I'm doing, and I know that I'm doing the best for me then other people's perceptions are exactly that.

Public perception of CSII was irrelevant for two participants. For them, the public would never truly comprehend their experience of living with CSII because they could not put themselves in the situation.

They don't even know so I don't care what other people's perceptions are because I'm the one that's got to live with it right. Unless you live it, you don't know... they don't know what it would be like to have to do that or to just kind of be aware of everything you put in your mouth when you do it.

He continued to elaborate. "Other people's perceptions, until they walk a mile in my shoes, I don't really, not that I don't value their opinion or their perception but their perception of it would be a lot different than, than mine." For another, the acceptance and appreciation of the role CSII played in sustaining her life overshadowed any significance of public perception. "It is what it is. I have this thing if I don't give insulin, I'm going to get sick so I don't care if you don't want to see it, don't look. You know? It's my life and you don't watch, if you don't like it you don't have to watch but it's something I have to do."

Theme 3. The Internal Struggle and Impact on Mental Health

T1DM is a self-managed chronic illness that involves making frequent life-altering decisions. It is the individual with T1DM, not the physician or diabetes educator that is responsible for the daily management of this disease. CSII therapy was a constant and often overwhelming responsibility, permeating every part of participants' lives. Endless responsibilities and demands were often met with unrealistic expectations from healthcare professionals that left participants experiencing guilt and self-blame. There was a punishing reality of losing oneself--losing time with children, losing energy to socialize or care for oneself, and losing opportunities to do everyday tasks. Inner conflict was often present from the opposing demands and responsibilities of CSII. The fourth theme, *the internal struggle and the impact on mental health*, emerged as the mental health implications of managing T1DM with CSII was

illuminated. Subthemes included (a) striving to meet unrealistic expectations: blaming self, (b) inner conflict.

Striving to Meet Unrealistic Expectations: Blaming Self

There was an expectation from healthcare professionals that participants would adhere to a prescribed treatment plan of: maintaining blood glucose and HbA1c levels within target range; counting carbohydrates; exercising regularly; assessing and making frequent changes to CSII settings, all the while maintaining a balance within their home, work, family and social life. Participants perceived that other individuals were not held to the same standard of living such a rigid and controlled life. Although participants strived to meet these expectations with CSII they often struggled to do so.

The perceived cookie-cutter set of expectations of healthcare professionals was unrealistic to apply to all individuals with CSII. Healthcare professionals failed to take into consideration variables in participants' busy, non-routine lives; what may have been achievable for one individual was not necessarily achievable for another. This was particularly challenging for one man, who worked hard to self-manage with CSII yet felt that these expectations were not achievable and was lost as to how he would even reach these goals. "I've never had an A1C of six. I don't know how I would get there, I mean, they don't want you to have lows but I really don't know how I would get to that point."

The terms "good" and "bad" were often used interchangeably by healthcare professionals during interactions with participants and typically referred to controlled and uncontrolled blood glucose levels, respectively. Participants described the use of such terms as a consistent reminder of the inherent goal of keeping blood glucose levels within "normal" limits. It also perpetuated the idea that maintaining target blood glucose levels was behaving well and having blood

glucose levels outside the target was behaving badly. They felt judged for not meeting expectations that were sometimes out of their control due to the unpredictability of T1DM causing them to feel frustrated and discouraged.

I mean, I'm a person, I exercise every day, at least an hour a day and I've been doing it for years and so it's hard when you're not quite sure what you're eating because it's still all a guessing game when it comes to carbohydrate counting.

The challenge of infertility was difficult for one participant and trying to reach glycemic goals to be approved for in-vitro fertilization proved to be even more challenging. Though she was aware of the risks of poor glycemic control, achieving the necessary blood glucose target to be approved for in-vitro fertilization seemed like an unreachable task. She felt that healthcare professionals treated her as being non-compliant; however, her experience was that their expectations were unrealistic. She felt a disparity in terms of approval criteria. Healthcare professionals readily granted in-vitro fertilization approval to those without T1DM, whereas in her case, because she had T1DM, approval meant meeting expectations of a perfect life. This left her with feelings of personal blame for not being able to get approval for in-vitro fertilization or conceive, and she felt unfairly judged by healthcare professionals.

Dr. X wouldn't sign off on me going away [for in-vitro fertilization]. There's lots of people that get pregnant if they're Type 1; they make that choice, but I didn't have a choice. It was between Dr. X and Dr. Y. Ah, they would have a conversation whether or not I could go and try to get pregnant. It was a really bizarre, really bizarre experience with that and, and people almost making a judgement on me that, 'Why do you have that high sugar?' 'What are you going to do to correct that?' We had waited so long to get accepted to Calgary, to be able to go through in-vitro fertilization, there could have been

somebody wherever that had a totally crappy A1C, and got pregnant on twins, you know that's it.

This participant understood that having HbA1c and blood glucose levels within the target range were important for a healthy baby. However, the lack of approval for in-vitro fertilization was like punishment for doing something wrong, where her efforts were just not good enough, and she was not good enough. Not only did healthcare professionals let her down, but she shared feelings of self-betrayal due to the fact that she could not meet the targets and she believed her body was defective. Ultimately, the reality of having another child was out of reach.

If I didn't have diabetes, I would have had another child... diabetes has prevented me from having another child, and that's the frustrating part... my A1C hasn't been good enough to go away [for in-vitro fertilization] ...I know that if I didn't have diabetes, I probably would have gone away again, you know. It's very upsetting to think about that.

Inner Conflict

It was a struggle to live a balanced life with CSII. Participants were often torn between making decisions, such as spending time with family or attending to CSII or choosing to eat a treat knowing it would increase blood glucose levels. Participants faced inner conflict on a daily basis when making choices that were potentially life-altering. This back and forth inner dialogue of discussion, negotiation, and arguments eventually became an automatic, natural part of thinking. Constantly having these thoughts left participants feeling submersed in a life that was dominated by CSII. One participant shared her experience of the inner conflict she experienced.

Your mind is always racing. There's always an internal voice... you can't just enjoy it [food] for the sake of 'ok, I'm going to have something that tastes really good. There's always in the back of your mind, like, 'Should I really be having this?' you have such a

love, hate relationship with food... now it's, like, 'Ohhh, why did I do that?' My sugars are through the roof and I'm doing, like, all this correction bolus to bring it back. I shouldn't have had that so it's again that internal like I'm a shitty diabetic...you do feel like a failure, because the internal thought.

Her inner conflict was cycling through a process of acceptance and forgiveness, accepting what she was able to achieve and forgiving herself for the decisions she made.

You beat yourself down and then, then the other voice is, like, saying 'you got to give yourself a break. Diabetes is a chronic disease that is very difficult to deal with and you have to cut yourself a break. And you know, you're not defined by that, tomorrow is another day. You know, so you have this internal back and forth that, that you're always, like, trying to calm yourself down and trying to talk yourself into doing this.

Self-blame and guilt riddled the participants' narratives and further emphasized their inner conflict. They did not always make the best decisions about self-care, but they took responsibility for the consequences, often leaving them feeling bad about themselves and their choices. Guilt manifested itself in many ways--guilt for not being there for their children, guilt for not taking care of themselves, and guilt for how well they were managing T1DM; thus, guilt played a large part in the participants' experience with CSII. Balancing guilt and satisfaction revealed the incessant tide of emotions that compounded their exhaustion.

When you end up getting that excellent A1C, or like yesterday, I went for a run and my sugars were beautiful the entire day and then you feel so good about yourself, you know, so, at the same time, you know you shouldn't judge yourself based on what that number is, but you can't help but, it is, it's kind of like school, like, 'Ok, today, I passed today' because I got this excellent blood sugar and I managed my diabetes really well and then

other days, well, 'I suck because I did this.' There's so much emotion and self-worth and self-esteem just attached to these numbers that it's hard.

The demands of both motherhood and CSII appeared to have transformed one participant's perspective of her responsibility to both. Motherhood was filled with obligations and tasks and was a struggle to manage at times without the added responsibility and demands of CSII. She alluded to the competing demands for her attention both as a mother and as an individual managing T1DM with CSII. "Diabetes and having children is a whole other ballgame in terms of trying to manage it effectively and take time for yourself." For her, this was a heartbreak like no other because as a parent she wanted to seem invincible and never show weakness to her children. T1DM and CSII, however, took this away and she often experienced a heavy sense of failure--failure to her family for taking time for her health and failure to herself for not taking the time to manage T1DM with CSII. Taking the necessary self-care moments to use CSII caused significant inner conflict. Choosing her own health over spending time with her family left her feeling selfish and guilty, as she felt she was putting herself ahead of her children.

You should take that time, right at that moment to go change your reservoir, change your site, do this, do that. You know, it is only three to five minutes, max but, you're so caught up with playing street hockey with the boys and enjoying that time, I put it off because I am choosing my children over my own health, if it comes down to it. Those are the real life experiences and that's probably one of the most difficult, the most challenging, you know, taking the time for yourself. Trying to find the time to use the technology, what it supposed to be doing is what I find the most difficult for sure. I know you need to take that time for yourself and for your health, but it's just an ongoing battle.

She went on to add.

As you know, a mother of two twins and, you know, young children, sometimes it's really hard to put yourself first, to realize, like ok I have to take this time away that even though I find my sugar has been ok, they haven't been great, but they certainly aren't crazy, out of control. I've certainly had better but to that frustrating point that I realize, ok, I need to take time away from my children to be the best, in the best health for me.

Inner conflict persisted throughout the participants' experiences, leading to feelings of depression. Some days, managing T1DM with CSII overwhelmed their coping strategies, and participants felt utterly defeated. The inability to break away mentally was a struggle described by one participant.

I can see how the strict schedule and just not being able to kind of do what you want more or less can definitely lead to a lot of depression. You always have good days and bad days when you're a diabetic and some days you feel like you can't get it right, you got a bunch of low blood sugars and you have a situation with your pump [CSII] and you just feel like I just can't do this today and sometimes that can build up.

He continued to say:

I always hear them talking about cures for type 2 diabetes but for type 1 we don't have anything and I think that becomes a little bit depressing sometimes for diabetics, the fact that I didn't do anything to deserve this but yet I still got it and there's nothing we can really do about it and I think you can go down some pretty dark paths if you dwell on that. I know I struggled with it a little bit too.

An important point he highlighted was that although an individual may not have a clinical diagnosis of depression, the effects on mental health can be debilitating. "It's well known that having diabetes has been linked with increased bouts of depression and I know some diabetics

who are not, you know, clinically diagnosed but you know definitely have mental health issues.” He went on to reflect.

So this idea that even though you’re not clinically diagnosed with depression on a DSM [Diagnostics and Statistical Manual of Mental Disorders] IV level that you can still have poor mental health and that even low levels of mental health without being diagnosed with depression can lead to as many problems as being diagnosed with depression.

Theme 4. The Impact on Relationships and the Meaning of Support

The importance of support in helping participants manage and cope with CSII was prevalent within each of the participant’s interviews. Support was sought from a variety of sources including informal support, such as other individuals with CSII, family members and significant others. Formal support was sought from healthcare professionals such as physicians, registered nurses, certified diabetes educators and registered dietitians. Financial support was also identified as important. Participants acknowledged that informal support networks enhanced their coping skills. Formal support networks, such as certified diabetes nurse educators, were praised by participants for their availability, knowledge, and helpfulness. However, formal support from physicians and certified diabetes educators from disciplines other than nursing often left them disappointed and frustrated, limiting the resourcefulness of such support networks. These various forms of support are deliberated below under the sub-themes of: (a) connecting with others who have CSII, (b) re-defining relationships: bringing in a third party, (c) negative encounters with healthcare professionals: antithetical to self-care, (d) the financial burden of CSII.

Connecting with Others who Have CSII

Individuals are not self-contained units, but rather are part of a community where they are continuously affected by others who shape the way they see themselves, see others and perceive an experience to give it meaning. An individual always exists in the world anchored in time, place, body and social relations. Living with CSII often came with a sense of aloneness until participants connected with individuals who were also living with CSII.

Many participants described a distinct connection with other individuals with CSII. This connection with others who were experiencing something similar helped ease the burden of managing the disease and living with CSII. There was a uniqueness to the relationship, a comradery, where there was an automatic sense of understanding, a sense of knowing and acceptance that could not be found with individuals who were not using CSII. One participant described this connection as a break from having to explain what it is you are experiencing, a break from judgement and not having to worry that the other individual would not understand. This connection provided a comforting and reassuring support, a different kind of support, even for those who had strong support from family and friends.

The majority of people that I have met with an insulin pump [CSII] it's like this connection or something or this comradery that it doesn't matter who you are or if you've ever seen them before in your life, it's, like, when you pull out that pump [CSII] you're automatically in that club and that person actually knows what you're talking about. Participants expressed that other individuals with CSII "got it," referring to shared feelings of acceptance and a feeling of something that could not be described. It was being able to relate to each other's experiences. "It's good to have people to talk to about these things because sometimes people who aren't diabetic, like, they just don't get it, they just don't understand..."

it's something that's always on my mind but they just don't realize it." One participant shared his experience of resisting CSII until he connected with an individual who was living with the device. Though he appreciated advice from healthcare professionals, those living with CSII provided an insider's point of view.

I think that's what got me resistant [to initiating CSII] was that they [healthcare professionals] don't know, they don't know what it's like to wear it all the time, they think it's going to be a good idea but they don't have to wear it every day. I think, what would have been a big help for me, instead of getting a lot of educators and doctors and nurses who weren't diabetic and just telling me you should do it would have been, it wasn't until I met with people who are on the pump [CSII] and I met with one of my educators up on [road], she's diabetic and she wears a pump [CSII]. That kind of swayed me in the right direction. I know it sounds silly but I think you appreciate the opinion of a fellow diabetic, I don't say a little more but a little differently. It's an insider opinion and as much as anyone else researches, they just don't know what it's like to wear it all the time, what it feels like.

Connecting with other individuals on CSII through an online network of support groups helped dissipate one participant's feelings of isolation and aloneness. Belonging to a community where other individuals were experiencing similar challenges and struggles with CSII, she felt understood, knowing they could put themselves in her situation.

I found this a tremendous support [Facebook group] knowing that it does get better and just knowing that other people share that same experience 'That alright, okay, I know that today is not a good day but tomorrow we'll try it again.' I find that on a social group people are responding, and everybody knows you're not giving medical advice to

somebody else, but I've experienced the same things. Yeah, it's [living with CSII] super frustrating and it's just, you're putting it out there so that it's not just you that's trying to figure this out in your head.

Connecting with others online provided validation that it was okay to struggle with CSII, without the fear of being judged. "So this Facebook group, has been so helpful to me, 'Oh, my God, okay, you have the same, you're going through the exact same thing I'm going through, you know.' I have found it so beneficial. Like, really, really beneficial." Online videos showing how other individuals coped with some of the challenges with CSII was supportive and encouraging to another participant.

I wear compression shorts when I play a lot of sports. I saw a bunch of videos of football players online who would tuck it into their compression shorts or sew a little pouch into their leg and tuck it in there and I was, like, if they can do it I don't see why I can't either.

Face-to-face connections with friends or family on CSII were undeniably a source of support for one participant. Being around her sister, who also had CSII, made her feel not alone in her challenges. "I've gotten used to it and my older sister also has it [CSII] so I'm not the only person at the beach who has an insulin pump [CSII], like, a site on their stomach." Seeking out advice by connecting with friends also living with CSII was a positive form of support for another participant.

I don't want to say clothes goes around the pump [CSII] but, I don't usually run into problems and if it is something I'm like 'ok, who can I ask that's been in this situation before?' So, I have, you know, I have some friends that are on pumps [CSII] and I'm, like, 'where do you put it, what do you do?' It helps to have, ah, friends in the same situation.

Re-Defining Relationships: Bringing in a Third Party

Starting on CSII was a significant life change for participants, their family members and loved ones. Interactions within relationships were altered and would never be the same as they were before. CSII required substantial thought and action and was constantly present. The subtheme *re-defining relationships: bringing in a third party* emerged as participants, family members and significant others all felt that having CSII was like bringing another person into their relationships.

CSII was perceived by one participant's husband as a more intensive therapy than her previous regime of MDI, whereby her starting on CSII was indicative of the decline and progression of T1DM. Initially, he struggled to accept CSII as part of who she was and as part of their relationship. "I think he was just more worried for me having to wear this all the time and I think he felt that because I had gone on the pump [CSII], my diabetes was getting worse." CSII was a tangible object in their relationship. It was always with them, creating fear and concern for her husband; fear that CSII would cause more harm than T1DM alone; or fear that he would break the device, injuring or causing death to his wife. Before CSII, T1DM was vague; however, CSII was reflective of the disease. "I think he was afraid of it at first. He was afraid he was going to break it and I was going to die in the bed."

Participants stated that CSII presented an awkwardness in their relationship due to having to explain the device or adapting to its presence, while others found that it simply got in the way during intimate moments. For one participant, this was particularly challenging for her and her husband. "My husband said to me, when I was thinking about getting the pump [CSII], it's like, 'Sure, do you have to wear that on you all the time, hanging away from ya?' He was appalled." There was a need for maintaining togetherness with her husband, yet the ways of relating to each

other had changed and become complex as CSII was now the third party. Intimacy was challenging and difficult for both partners as they moved forward in their relationship with each other and CSII. “I think it does impact, not so much sex, but just cuddling in at night when you’re going to sleep...we’ve had to learn, we’ve had to learn together about what we can do with it and how it impacts us.” The way they interacted and communicated with each other changed with the presence of CSII. Humour was a positive strategy they used that helped lighten the burden that CSII had on intimacy.

I think for us, we make a joke out of it and I’ll say, ‘Excuse me, I have to take off my life support here now’ but it depends on what my sugar would be because if I’m high, I’m not taking my pump [CSII] off cause I don’t want to go that amount of time, without it.

Considering when and how to reveal CSII to significant others was an individualized experience for participants. CSII brought the opportunity to alter relationships. While some participants expressed that they were open to others about T1DM and the CSII device early in the relationship, others preferred not to expose their diagnosis or the device, initially. The integration and normalization of CSII into the relationship early was discussed by one participant who viewed CSII as an extension of herself.

I’m not going to be the type of person to hide it [CSII]. I’d be like, it’s just my pump [CSII]... Do I tell this person, do I not but I’m pretty straightforward you know, I believe our first date we went out for supper and I was sitting there testing my sugars. He’s, like, ‘Oh, you’re a diabetic’ and I’m, like, ‘yep, have been for the last 15 years.’ So, I’m pretty open about that, like, I don’t, I might as well talk about it.

Another participant was honest about his hesitation about disclosing CSII in a relationship.

However, the physical presence of CSII and visibility of the tubing would often raise questions

and facilitate the conversation. The discreetness of MDI gave him more control over disclosure, allowing him to withhold that information until he was ready to talk about it.

It comes up inevitably but that's it. You know, it's just a topic of conversation that has to be broached at some point. If, if anything, I'd say that, that the pump [CSII] helps that conversation to start... they're probably not that likely to see you just take a needle so, you know, you got a little tube poking out your pants.

In contrast, for one participant the importance for the decision to initiate CSII was about wanting to lessen his parents' worries. Understanding the risks of complications with T1DM created a sense of uneasiness and fear that was relieved when their son began using CSII.

I just started the pump [CSII] and then I was planning to go away for university, like, it just seemed like a good thing to do and it seemed like it gave my parents more peace of mind. Knowing that, you know, this [CSII] was a little bit more flexible... you're not going to be on such a strict routine as you did before.

Negative Encounters with Healthcare Professionals: Antithetical to Self-Care

Encounters with healthcare professionals were often a negative experience. Multiple factors contributed to this negativity, such as healthcare professionals' lack of knowledge, lack of insight and lack of consistency. Participants often left encounters feeling frustrated and disappointed rather than feeling supported. Participants hoped to have a relationship with healthcare professionals that offered support, guidance, knowledge, consistency, and the ability to work together as a team. Negative interactions were antithetical to the capacity to achieve successful CSII self-care.

Participants were encouraged to pursue CSII self-care; however, at times they were given few resources. They felt lost and frustrated within a system that failed at providing care and

support.

I went to see, I believe it was an endocrinologist. He specializes in Type II... and he called me to his office and he just kind of said, like, 'I don't know anything about this and I don't even know where to start with Type I' and, so, it was basically a, 'I'm sorry, that you were referred to me but I can't help you type of thing.'

The financial burden of CSII was often not understood by healthcare professionals. Participant decisions based on financial constraints were often misinterpreted and judged as being non-compliant. Feelings of guilt and shame progressed to frustration and resentment at being misunderstood by those meant to provide support. As stated by one participant,

When I went to the Grand Rounds thing, I'm sitting there and I'm listening, and I don't know anything about Dr.X. She was mentioning about patients on pumps [CSII] and how they should have a backup pump [CSII]. I was, like, 'Oh, get real' because they are so expensive. It's just those things that non-diabetics just don't think about. I know that they realize that there is a price but sometimes I feel nurses are just, 'Oh, did you swap out your site, did you do this, did you do that?' and I'm, like, 'I did' but I felt bad because now I'm on two pump [CSII] sites when I should only have been on one so that's going to affect me and I'm going to be short [infusion set].

Healthcare professionals lacked insight into the realm of responsibility with having CSII as a management regime and this was frustrating to participants. CSII was recognized by healthcare professionals as a valuable tool to manage T1DM; however, the tremendous responsibility of CSII was not clearly understood. They often failed to recognize that CSII was a complicated piece of equipment that was manually operated by the participant and that it would not be suitable for everyone. "At the Grand Rounds thing they talked about Type IIs going on the pump

[CSII] and I'm, like, 'they don't understand that that's a huge responsibility.' I feel, like, sometimes they push, and they don't really understand the aftermath."

A lack of continuity with healthcare professionals was also experienced as a negative encounter. Participants acknowledged that consistent healthcare professionals inspired confidence in the healthcare system and their ability to manage with CSII. Having the same healthcare professionals helped established a connection with someone who knew them, knew about their T1DM and CSII and how these factors intertwined to influence their lives. Encounters with different healthcare professionals often resulted in a disconnect in their care. One man described the difficulty he had with getting to see a healthcare professional after transitioning to an adult facility from a children's hospital. The frustration and disappointment were apparent, as he felt the healthcare system had failed him by not making care accessible.

When I was going to university I sort of fell through the cracks. I was seeing this one specialist for a while and then I didn't see her anymore for an unknown reason and that was, then trying to get to see another one, is a very arduous task. That was a year and a half ago, or more, and I still haven't seen one... they're trying to get me in, you know, to see someone [endocrinologist], but it's taking forever.

The need to connect with a healthcare professional was important in providing a sense of comfort, encouragement and up-to-date information on CSII management. A lack of continuity resulted in participants receiving mixed messages about CSII management. This did not facilitate a trusting rapport or provide the holistic care one participant was hoping for.

For the longest time I actually saw a dietician, a dietician that was a certified diabetic educator, and I got to tell you, I think we need nurse educators because, and nothing against dieticians. I do know is that the nurses that I've had are far more holistic. But,

what I found when I started was I was kind a bounced around in the beginning from one nurse to another nurse to whatever. So I found I was getting all this mixed information.

Interactions with physicians were often one-sided, where participants did not feel like an active partner in their own care. One man experienced being left out of the conversation and described it as disrespectful and he was left feeling insignificant.

I found that any time I had any sort of information session or just an appointment with a doctor that they just kind of assumed that you're a kid and you really don't want to know anything so they kind of talked to Mom but she's not scientifically minded.

The limited availability and lack of accessibility of a physician was a deterrent to starting CSII for one participant, as it contributed to him feeling alone in his management with CSII.

I was so used to the clinic at the [hospital] was every three months, and you saw a team of, like, eight people. I was so used to having these people I could bounce ideas off, have questions with. I was worried 'well, I'm only going to see a Doctor every six months now, but what do I do for daily problems because he doesn't have time to just pick up the phone and, you know, talk to me for half an hour, you know, every couple months when I got a question.' But, that's the benefit of having this team. I think, they really helped me to turn a corner on wearing the pump [CSII].

Appointments with physicians left participants feeling rushed with little time to ask questions, or few opportunities for them to get to know each other. All participants noted that certified diabetes nurse educators made themselves available and took the time to discuss patient care. For one participant, having a consistent team of certified diabetes nurse educators that knew his history alleviated the need for him to explain himself at each appointment.

It's nice because I've had the same two people [diabetes educators] now, for seven or eight years. So, we've built, like, a good rapport or they know my lifestyle. They probably know more about my lifestyle than my parents do. I can't imagine, like, seeing new people every three months, having to explain my situation, to re-explain my lifestyle because our meetings still go an hour, an hour and a half. They know that already so we don't have to waste time, each time, doing that, but I find with my doctors I almost have to re-explain my situation because they are constantly switching or moving to different clinics or gone away for six months so, it's really nice having that, like, consistent team.

Participants found comfort and reassurance in connecting with a certified diabetes nurse educator who was understanding, knowledgeable and available at a moments notice. It was comforting knowing someone cared and would be available outside regular working hours. "So the nurse, it was actually on a weekend and she said, like, 'just come to my house', you know, so, like, whatever wasn't mentioned, they were definitely there. Like, if I ever needed them I knew I could call." Another related to the availability of the diabetes nurse educators.

That's one thing with the diabetes team. Now, I haven't spoken to [diabetes educator] in a while, my pump [CSII] nurse, I know I should, but I know tomorrow, if I want her to review my sugars, she will, you know. I'll e-mail her and she will be there.

It is worth noting that one participant identified support from the industry supplying CSII devices as important. Support included troubleshooting CSII and CSII replacement.

I'm with [company]. They have been great. They have been very supportive. The first pump [CSII] I had, I had for about 4.5 years and I had changed the battery and I lost all my settings. Just the pump [CSII] just reset so I called [company] and they couriered me out a new one and I got it later that day.

The Financial Burden of CSII

CSII cost substantially more compared to insulin administration with a syringe, thus the financial burden of CSII was identified as a major stressor by participants. It was a financial struggle to cover the costs of using the device, even with health insurance, and many participants feared having to return to MDI to manage their T1DM, as this was seen as a step backwards. Thus, the financial implications of using CSII was a major consideration.

Moving home I'm quitting my job I had, I didn't know if I was on my boyfriend's insurance or not and I know that there's a provincial drug coverage but it won't cover pump [CSII] supplies so I'm, like, 'that's \$150.00 out of my own pocket that I have to pay a month' and I was really worried about that and just, like, financial worries would be my main issue with the pump [CSII]. I've just come so far now that going back to syringes [MDI] is like a dozen steps backwards.

CSII was not a feasible option without health insurance, and subsequently, participants would be forced to use MDI for insulin administration. "If there was no insurance I don't know if I'd be able to have the pump [CSII] or if I'd still be on syringes [MDI]. "The financial burden of CSII was still substantial even with insurance coverage, and out-of-pocket costs for CSII were significant.

I spend, even with my insurance, a couple hundred bucks a month so if you look at it, that's, like, between \$200 and \$250 a month times 12. So, I'm definitely looking at about, \$2800, \$3000 out of my pocket a year for supplies.

Part of participants' financial income had to be dedicated to CSII and supplies, money they could have used elsewhere. "The financial cost, it can be a stressor. I've been fortunate in that I can afford my supplies that my insurance doesn't cover but I could use the money elsewhere."

Two participants accepted the financial costs of CSII, as the device was viewed as a necessary component of T1DM management. “Financially myself and my husband do ok. I’ve never had to make that decision of, like, ‘my health care versus finances’. We’ve just always done it and it’s just always been a part of this.” For another participant CSII was viewed as a treatment for a serious disease, much like an individual would view treatment for cancer. CSII was necessary for her to stay alive; therefore, financing for CSII was incorporated and accepted as part of her treatment costs.

If you had, if you had cancer, nobody would say ‘well I’m not getting that drug because it’s going to cost me.’ You find ways. I just chalk it up to this is what it is to live with this particular disease and that’s it, you know. Like I said, nobody, if you had something else you’d say ‘oh well, I don’t know,’ you’d figure out a way, right?

Essence: The Ascendancy of CSII Over T1DM

The lived experience of CSII is not well understood and is an area requiring further research. In the literature, CSII has been referred to as a “lifeline” due to the many biomedical benefits this device brings to participants’ lives. However, the term “shackle” has also been used to describe the experience of living with CSII. This term has a negative connotation and reflects the many constraints of self-managing with this device (Garmo et al., 2013).

CSII devices are highly specialized, complex computerized technology that have become a popular choice for T1DM management because like a pancreas they can control the amount of insulin released in the body. However, CSII therapy is not self-maintaining, but a programmable device that is manually operated making it only as effective as the person wearing it. Using CSII requires participants to use cognitive thinking for dosage calculations, carbohydrate counting as well as technical skills for dose administration, changing the infusion set and programming

settings that are uniquely personalized. CSII was meant to improve the lives of those living with T1DM, however the paradox was that having the device required the individuals to know more about T1DM, assume new skills and responsibilities and required unwavering attention day and night. Participants had to bear the responsibility of operating this device, as their lives were dependent on it. Eventually, CSII established ascendancy over T1DM in participants' lives. CSII ascendancy over T1DM was the never-ending thought process where the demands and obligations that were necessary to live with this device produced a myriad of intense exhaustion, fear, guilt, frustration, and depression.

As CSII was incorporated into participants' lives it took precedence over T1DM because it required the participant to be constantly engaged. They could no longer take a set amount of insulin with a syringe and forget about T1DM. Now participants had calculations to do, correction factors to determine, carbohydrates to count, and make frequent changes to settings, as well as, troubleshooting the device. They also had to decide how much insulin to administer based on the active insulin currently in their body and whether to administer the insulin with a standard bolus, dual-wave bolus, or square-wave bolus. It was incumbent that participants check blood glucose levels several times a day: before meals, after meals and during the middle of the night. Auditory alarms and reminders that were supposed to be beneficial now became the focus of their attention and were an added burden to their lives. CSII was attached to their body 24 hours a day reminding the participant and others that they had T1DM often encountering unwanted attention and comments. The amount of effort it took to wear the device in a discreet manner to avoid public scrutiny and feeling the need to educate the public were significant. Thus, features of CSII and its requirements that were intended to be beneficial had unintended consequences of making participants constantly engaged and constantly immersed in a life that

was dominated by T1DM. The responsibilities and obligations and constant inner thought required to use CSII eventually took ascendancy over T1DM. A device meant to provide freedom and flexibility now dominated their lives more than the chronic illness.

Summary

My study findings revealed that participants seemed to have, an almost, love-hate relationship with CSII as the daily struggles and victories with CSII were illuminated. Transitioning to CSII was challenging because expectations of CSII did not match the reality of the challenges integrating and normalizing the device within their lives. Education sessions lacked information on these day-to-day challenges, such as intimacy—participants felt unprepared, unknowledgeable, and unsure. Participants also highlighted that false advertising of CSII also contributed to unmet expectations. Advertisers did not include the significant amount of work and vigilance required to live with CSII. Another negative aspect of CSII was the visibility of the device that was a physical reminder of T1DM often bringing unwanted questions and judgment from the public. Thus, participants sought to conceal CSII to avoid these conversations and to avoid embarrassment and shame.

Acceptance and relinquishing control were gradual because feelings of uncertainty and fear persisted—fear that it would be broken; fear that it would be stolen; and fear that it would malfunction. Developing DM-related complications was also a significant fear. Eventually, participants had to learn to live with CSII therapy and were able to acknowledge the many benefits CSII offered such as freedom and flexibility. However, they still recognized that there would always be limitations in their life even with this advanced insulin delivery system.

Support was important for overall well-being and coping strategies. Peer support was deemed critically important. This was a bond unlike any other that promoted understanding and

acceptance. Support from family and significant others was important but did not come without challenges as both partners had to adjust to living with this device. Interactions with physicians were often negative. Participants preferred more of a partnership relationship with healthcare professionals something that was only possible with certified diabetes nurse educators. The endless struggle to be understood by their care providers left some participants feeling guilty blaming themselves for unmet expectations.

There was no break from the physical or mental efforts required. Many participants expressed overwhelming feelings of exhaustion. Participants spoke of persistent thoughts of CSII and despite the negative aspects of living with CSII, participants claimed that CSII was the best therapy for managing T1DM and their best chance at reducing morbidity and mortality.

Chapter Five. Discussion

The lived experience of individuals with CSII to manage T1DM is more than the metabolic experience or even the psychological impact of glycemic control or perception of CSII on well-being and QOL. Phenomenology is the study of a phenomenon in its everydayness within the lifeworld or the world as it is presented before thought or reflection. This lifeworld is comprised of four existential pillars originating from Merleau-Ponty's work and include 'lived space,' 'lived time,' 'lived body,' and 'lived human relation' (van Manen, 1990). Lived space grounds the person in a location (van Manen, 1990), and is that the space in which we are located (for example, the size and type of building and how it affects us). There is a difference in how we feel in the space that is our home compared with a more impersonal space of work or business. 'Lived time' refers to subjective time, as opposed to objective, clock time (van Manen, 1990). Lived time can seem to speed up when we are busy or enjoying ourselves or slow down when we are bored or waiting for something. The way in which we interpret or ascribe meaning to events that occur at a particular time in our lives may influence understanding or perceptions; positive experiences of education or the healthcare system can positively influence our approach to these services. 'Lived body' is the concept of embodiment that we are always in our body (van Manen, 1990). When we meet people, they and we reveal and conceal things about ourselves consciously and unconsciously. Van Manen (1990) states that body language can change because of an encounter with another. 'Lived human relation is relation we maintain with others in the interpersonal space that we share with them (van Manen, 1990). This includes how we communally experience the world. Throughout relationships with each other, we influence and are influenced by others.

In this chapter I discuss the results of my study of the lived experience of individuals with CSII for T1DM. This discussion, as with most theses, will reflect past literature on CSII. However, most importantly I present a view into the lifeworld of eight individuals with CSII in relation to the four existential pillars. For sake of convenience and clarity, this discussion will align with the four themes outlined in chapter four. Each of the following sections will begin with a brief overview of the theme followed by a discussion of the particulars.

Transitioning: Not a Quick Fix

The term transitioning implies an evolution of sorts; evolution by nature takes time. Transitioning with CSII was a gradual process. Participants initiated CSII with false expectations that it would immediately relieve the burden of managing T1DM. It was not made explicit to participants that CSII would present new challenges that would take time to assimilate. CSII was complex and demanding leaving participants overwhelmed and unsure if they could incorporate this device into their lives. Their stories were of how they felt that they had developed a new identity where they separated their lives into before CSII and after CSII. Fear and uncertainty with CSII dominated participants lives initially, as they struggled to relinquish some of the control of management to CSII. Acceptance and relinquishing control were gradual because feelings of uncertainty and fear persisted—fear that it would be broken, fear that it would be stolen, and fear that it would malfunction. Developing DM-related complications was also a significant fear. Eventually, participants had to learn to live with CSII therapy and were able to acknowledge the many benefits CSII offered such as freedom and flexibility. However, they recognized that there would always be limitations in their life even with this advanced technology and the amount of work required to live with CSII would not diminish over time.

One finding not in the literature was the unfulfilled expectations of how CSII would improve the lives of those managing T1DM. Participants expected CSII would take away some of the burden of T1DM and make them feel normal again. Instead, CSII demanded specialized skills, enhanced knowledge, and a need to adopt new practices to make full use of its potential and this was both tedious and challenging. Researchers acknowledge the importance of discussing expectations of CSII with patients prior to initiation (Reidy, Bracher, Foster, Vassilev & Rogers, 2018). However, consistent with previous studies, (Hayes et al., 2011; Reidy et al., 2018), my study findings illustrated that advertisements and education sessions about CSII were misleading. Participants shared that online marketing and healthcare professionals recommending the device did not indicate the amount of time and training that would be necessary to operate CSII effectively. Participants struggled to adjust to the new demands of CSII therapy and were unsure how to use and manipulate this complicated piece of technology. False expectations left them feeling disillusioned and overwhelmed with the burden of CSII.

Researchers report that CSII can decrease the risk of DM-related complications, which remain a significant cause of morbidity and mortality, compared with MDI (Bruttomesso et al., 2009; Chatterjee & Davies, 2015); Giménez et al., 2007; Hammond et al., 2006). Participants in my study had incessant fear about developing DM-related complications and death, despite CSII therapy. The persistent fear my study participants experienced after initiating CSII is a new contribution to the research literature. Fear, existentially, affected participants corporally (lived body), spatially (lived space), and temporally (lived time). Spatially and corporally, persistent fears dominated their thoughts and temporally, the future remained uncertain. They realized that they were not invincible even with CSII.

Consistent with findings from Trief et al. (2013), whereby participants described hypoglycemia as “the worst feeling” and “life and energy draining,” participants in my study feared hypoglycemia so much so that they would do anything to avoid it, including maintaining a state of hyperglycemia. Symptoms of hypoglycemia were experienced corporally through confusion, trembling, sweating and rapid heartbeat (Cummins et al., 2010) and were described by participants in my study as “physically and mentally exhausting.” Hypoglycemia was so psychologically distressing that the thought of having these symptoms was anxiety provoking before they even occurred. Temporally, both the present and future were stressful, whereby participants recognized that death could occur if hypoglycemia was not urgently treated and then they spent hours thereafter trying to bring blood glucose levels back within normal range. Like previously reported, CSII increased participants’ sensitivity to the symptoms of hypoglycemia, allowing them to intervene earlier resulting in less frequent and less severe hypoglycemic events (Bernard & Skinner, 2007; Bruttomesso et al., 2009; Nicolucci et al., 2008; Rasmussen et al., 2011; Todres et al., 2010). A salient finding from my study was that participants continued to fear the long-term effects hypoglycemia and hyperglycemia would have on the development of complications and possibly death, even with CSII. Lived space was perceived as a threatening environment full of anxiety, fear, and distress.

Consistent with previous research, participants in my study also feared that CSII would malfunction, break, or be stolen. Research on the safety and efficacy of CSII is limited (Heinemann et al., 2015), yet malfunctioning remains a frequent occurrence accounting for 40% of DKA cases (Bruttomesso et al., 2009; Heinemann et al., 2015; Thabit & Hovorka, 2016). Fears are compounded living with CSII because individuals need to know how to calculate

insulin dosages for MDI to be prepared at all times for the anticipated breakdown of their life-supporting CSII device.

Congruent with Rasmussen et al. (2011) and Ritholz et al. (2007) participants described transitioning to CSII as a life altering event that was more significant than being diagnosed with T1DM. From a spatial lifeworld dimension, participants shared that, initially, they felt “imprisoned” by CSII--the “walls were closing in.” Eventually, they reached a point of acceptance given there was no cure and no freedom from T1DM and so the only course of action would be to learn to live with CSII. As integration and normalization of CSII occurred, participants had to find a new sense of purpose and meaning. They were the same people before CSII, yet they were transformed, as if they had established a new identity after initiating CSII whereby they separated their lives into pre- and post-CSII identities.

Researchers examining kidney transplant recipients describes the paradoxical nature of a medical intervention, whereby the individual emerges from the experience as forever changed. That is, medical interventions neither render an individual as completely healthy nor shed the status of being sick. Individuals depend on an intervention to stay alive, yet this intervention allows them to feel closer to normal, though they will never emerge as completely healthy. This in-between state is described by researchers as the “transliminal self” (Kerr, Souliere, & Bell, 2018). The individual eventually emerges from this in-between state, like a snake shedding its skin, and takes on a new identity. Researchers refer to this acceptance of their new self as the “liminal state” (Kerr et al., 2018). The same concept can be applied to participants in my study, whereby learning to live with CSII was experienced corporally and temporally. Corporally, participants took on a new identity in the world. They had to go beyond the identity of being someone with T1DM to an individual living with CSII. Although CSII made them feel closer to

normal it was still a reminder that they had a chronic illness. Temporally, there was a duality of participants' lives, whereby they had a past identity without CSII and a present identity with CSII. Eventually, participants "shed their skin" and took on the identity of someone living with CSII. Similar to Reidy et al. (2018), as my study participants learned to master the technology, the initial feelings of stress and vulnerability created by depending on CSII were replaced with feeling autonomous, whereby eventually they described CSII as "an extension of myself."

Participants felt burdened by CSII because they could never take time off from T1DM self-management. This finding was similar to Garmo et al. (2013) who reported that having to be constantly aware of CSII and remembering to take equipment with them contributed to feelings of burden. More recently, Hood and Duke (2015) reported that participants found the freedom with CSII came at a cost of immense responsibility of having to plan ahead; have backup supplies available; checking blood glucose; ensuring there was enough insulin in the reservoir; and, enough battery life. In my study, participants further elaborated by describing burden as having no choice but to be constantly vigilant. Days and nights were filled with thoughts and considerations of CSII and eventually these thoughts and actions became automatic. There were times when they wanted a break from having to think about CSII, however, this was not an option; CSII was necessary for life. Within the Corporal body, there was an ongoing battle between the malfunctioning body and the will of the participants to stay alive. Eventually living with CSII took ascendancy over living with T1DM. Temporally, the idea of time was immeasurable. Lived time was not measured in seconds, minutes, or days, but rather a collection of moments dominated by CSII. Time was constant, always there, just like their thoughts and obligations with CSII. In my study, lived time was experienced by participants as a state of

perpetual readiness where days seemed to be a continuous loop of assessing, making decisions, and having to be constantly engaged with CSII.

Despite the noted challenges of living with CSII, participants in my study reported several benefits that contributed to high levels of treatment satisfaction. Benefits were consistent with the published literature including flexibility and freedom without having to carry as many supplies, less restricted eating schedules, improved glycemic control, reduced rates of hypoglycemia, the ability to correct blood glucose levels quicker, readily available insulin, and eliminating the burden of having to perform daily injections (Bruttomesso et al., 2009; Franklin, 2016; Heinemann et al., 2015; Misso et al., 2010; Todres et al., 2010; Trief et al., 2013; Weissberg-Benchell et al., 2003).

The benefit of improved QOL with CSII has been controversial in the literature due to poor assessment measures, and as such previous studies have assumed an increase in QOL without sufficient supporting evidence. Barnard and Skinner (2007) claimed that assessment of QOL is flawed for two reasons; one is the lack of an all-inclusive definition of QOL capturing the subjective experience of those living with CSII; and, the other is that quantitative methods predominantly used to assess QOL cannot truly capture what QOL means to an individual using CSII. QOL has largely been evaluated based on improvements in metabolic control; that is, it has been assumed that improvements in glycemic control improves QOL (Barnard et al., 2007; Cummins et al., 2010; Nicolucci et al., 2008; Trief et al., 2013; Valenzuela et al., 2006) and improves indicators of overall happiness. My study findings revealed that participants who were meeting glycemic targets still had daily struggles with CSII. For this reason, assessment of improvements in QOL with CSII must go beyond metabolic outcomes. Evaluation and

consideration of the psychological effects of living with CSII would better target the ability to cope and adjust to living with the device.

Initially, because of T1DM, participants experienced a loss of control due to lack of freedom and independence. Similar to previous findings by Barnard and Skinner (2007, 2008), the aforementioned benefits of CSII worked together to enable participants to re-establish control and normalcy in their lives. Instead of T1DM controlling them, they had control over their disease. My participants claimed that this was the most positive aspect of CSII, as they felt like they were getting their lives back. Of course, participants already had a life; they were not literally taking life back in the true sense of the word of having a life. Rather, they meant taking their life back as they knew it, before CSII, where regaining control and flexibility and reduction of blood glucose variability meant a new normal. They talked about CSII as an extension of themselves, making them feel more normal. Their sense of lived body was closer to what they perceived as normal.

Making an Invisible Illness Visible

CSII was a personal, individual experience for the participants in this study, however, much of living with CSII was experienced socially with others in their world. T1DM was made more visible to the participants and to others. CSII was an appendage with bells and whistles, and required attention to operate. CSII required accommodation within the lives of the bearer. To the public it symbolized that something was different or maybe not normal. Public misconceptions about CSII led to participants frequently having to explain the device or the decisions they made about their management. It was evident that this experience became frustrating and tiring. To avoid these negative interactions participants sought to conceal CSII from others.

It has been well documented in the literature that CSII heightened body awareness and self-consciousness (Barnard & Skinner, 2007; Garmo et al., 2013; Hayes et al., 2011; Heinemann & Krinelke, 2012; Kay, Davies, Gamsu, & Jarman, 2009; Ritholz et al., 2007; Saarinen, Fernstrom, Brorsson, & Olinder, 2014). With T1DM came a disruption of the smooth non-reflective functioning of the taken-for-granted; the body had broken down. One does not normally have to attend to the pancreas. Now, however, participants had to pay attention. Maintaining the lived body now had to be a consideration. CSII imposed upon this smooth non-reflective way of previously being-in-the-world. The internal disease was now externalized with CSII making participants question what they looked like to the world. CSII drew attention to themselves and their body. Sartre (1956) describes consciousness as the relation of the body to the world where both consciousness and body are both the person as a presence to the world. In health, we do not take notice of our corporeal being, thus the body is often neglected or “passed over in silence.” When an individual’s well-being is disturbed one can no longer live in a self-forgetful, passed over relation to the body and sense of self and body is changed. The body is the consciousness that becomes the self-consciousness. The self-conscious body knows itself as being looked at with curiosity or aversion and this can be confirming or criticizing (Sartre, 1956).

I was able to capture the social implications of living with CSII whereby the public’s lack of knowledge about CSII and T1DM resulted in participants’ negative interactions with others. My study findings revealed that the public viewed CSII as an effortless, self-maintaining management tool for T1DM and did not understand the significant demands required to use the device. They also viewed CSII as an indicator of decline or having the “bad kind” of T1DM that was self-inflicted from eating too much sugar, being overweight or lack of exercise, and

participants felt stigmatized. Liu et al. (2017) defines DM stigma as identifiable characteristics related to DM, such as insulin administration or blood glucose monitoring, which differs from culturally defined norms resulting in a punitive response. My participants claimed that the CSII device as an identifiable characteristic of T1DM and for them this was stigmatizing. Interactions with the public became constant warnings of what participants were doing wrong and the consequences of being a “bad diabetic.” Conversations often led to stories of someone who experienced DM-related complications, unsolicited advice on how to control T1DM, or a quick-fix antidote that would cure it. Consistently educating the public and constantly defending their choices became a tiring and frustrating experience for participants where they felt the amount of work they invested into CSII therapy was discredited. In contrast, findings from Ritholz et al. (2007) and Saarinen et al. (2014) found the public was interested and curious to know more about CSII contributing to positive interactions.

CSII became a source of embarrassment leading to stressful interactions, so to avoid conversing with and educating the public about CSII participants sought to conceal the device, consistent with findings from Kay et al. (2009). Clothing was used by all participants to hide CSII and required extensive thought and planning. Participants struggled to find “a good place to hide it” in a comfortable and stylish manner because it was constantly attached to their body and so they often made alterations to their clothing. As with previous studies by Hayes et al. (2011) and Ritholz et al. (2007), discreetly wearing CSII became so challenging that participants often avoided wearing bathing suits and dresses. Stigma related to CSII had such a significant impact on participants that some thought about discontinuing CSII and reverting to their previous management regime of MDI where they felt T1DM could be easily hidden (Franklin, 2016; Hayes et al., 2011).

Most participants struggled with the decision to disclose T1DM because they recognized it could significantly impact others' perceptions of them. According to Dovey-Pearce, Doherty, and May (2007), having control over disclosing T1DM to others is important. However, it was revealed to me that because CSII was visible it took away participants control to disclose T1DM. CSII often started the conversation without intention, making participants feel exposed. While the impact of T1DM on public perception is noted in the literature, the impact that CSII has on public perception has not been clearly identified and is a new finding from my study.

The Internal Struggle and Impact on Mental Health

Living with CSII brought expectations to meet stringent guidelines, devote time to self-management, and attend to everyday aspects of life, such as work and family. Participants struggled with balancing these obligations and sacrificed time for self-care and time with family. Failing to succeed in meeting these expectations came with a sense of guilt and blame. Thus, inner conflict was experienced on a daily basis by participants as they tried to devote time to aspects of their home life and with CSII self-management.

There is little insight into the psychological implications of CSII although psychological variables play a significant role in managing stress, adapting coping skills, and predicting metabolic control and adherence to management regimes (Aberle et al., 2009; Robinson, Coons, Haensel, Vallis, & Vale, 2018). Drawing from my study findings, I add to the literature by describing adverse psychological effects of living with CSII, including fear, guilt, and constant vigilance.

Findings from my research illustrated the negative emotions associated with CSII therapy. DM distress is a symptom of depression and a term that refers to the negative emotions and burden of self-management. DM distress is the emotional turmoil related to continual self-

monitoring, concerns about complications, and the frustration and psychological impact of self-management (Balfe et al., 2013; Robinson et al., 2018). Participants in my study described experiencing DM distress that was exacerbated when living with CSII, unlike findings reported by Barnard and Skinner (2008). They indicated that individuals with CSII had less DM distress and fewer emotional problems compared with their previous regime of MDI.

Previous studies, using quantitative methodology, identified the presence of DM distress with CSII and other negative emotions, but did not identify the underlying factors. My study participants spoke about several stressors; in particular, taking ownership for CSII therapy. They were uncertain asking themselves, “Am I doing it right or not doing it right?” Also, they asked, “Am I doing everything that I can be doing?” Participants blamed themselves when they did not meet metabolic targets. In addition, while participants recognized and accepted that self-management of T1DM with CSII was their responsibility and they had to deal with it themselves, consistent with findings from Todres et al. (2010), it was not uncommon for my study participants to experience the burden of dealing with the device, alone. Relationally, there was a disconnect between participants and others because others could not understand the challenges associated with CSII therapy. As days marched on into weeks and months, temporally participants realized there would never be a definite end to these feelings of loneliness.

Self-management of T1DM with CSII was emotionally difficult for participants. It often meant choosing between self-care with CSII and daily activities of their normal lives, such as spending time with family. Inner conflict was the dilemma about daily decisions that was happening inside participants’ minds to self-manage with CSII and a daily process of accepting and forgiving themselves for what could and could not be achieved. Everyone experiences inner conflict; however, it was revealed to me that for participants with CSII it was much more than

just fighting an urge because the results and consequences would have long-term effects on their lives. Hood and Duke (2015) discovered that individuals often forgot CSII self-care at times because their busy lives became a distraction. Balfe et al. (2013) found that management of T1DM with CSII therapy often resulted in other areas of participants' lives being overlooked, whereby feelings of guilt became part of the daily routine. More recently, Robinson et al. (2018), described the emotional turmoil of T1DM self-management with CSII leading to a higher incidence of mental illness. The realization that lack of self-care could have serious consequences left one participant feeling "horrible." Time was measured in accordance with the missed moments with children or family and considerations, whereby other aspects of their lives were often neglected resulting in inner conflict and guilt. Occasionally, participants intentionally made life choices knowing it would result in unfavorable consequences, such as increased blood glucose. These decisions were made to promote their mental health by living even for a short period of time, without adherence to a strict set of rules.

The Impact of Relationships and the Meaning of Support

Relationally, participants needed to feel connected and supported by others to self-manage with CSII. Participants sought support from other individuals living with CSII. Having CSII meant relationships had to be re-defined at home with family and significant others. Support from healthcare providers was also significant, as well the financial implications of living with CSII. Support enabled participants to face the daily demands of self-managing a chronic illness with a complex device. Without these connections and support participants felt disconnected from others. Human beings are always relating to other people and things in the world. The way we are in the world is not a spatial relation but is an existential relation with other entities in the world (Dreyfus, 1991). Therefore, people that we encounter in our daily

activities are not experienced as detached objects, but rather are meaningful and significant (lived human relation). Thus, the experience of CSII has meaning, not because meaning is added on, but because of the relationships, practices, and language that is around us.

Of particular note in my research was the integral role of peer support in the lives of individuals living with CSII. Participants shared that they sought others living with CSII, either face to face or through online support groups. Peer interactions were positive and uplifting and thus the greatest source of support. Embuldeniva et al. (2013) concluded that peer support in the lives of adults with T1DM, enhances feelings of connectivity, which have shown to improve confidence, coping skills, health outcomes, and the ability to find meaning, while reducing feelings of isolation. Similarly, my participants felt a sense of comradery and the instant connection made them feel understood, validated, reassured, and accepted. Moreover, there was no fear of judgement or criticism, so participants felt comfortable sharing stories and venting.

In my study, the introduction of CSII was stressful, altering participant relationships with family members and significant others. Golics, Khurshid, Basra, Salek, and Finlay (2013) reported that chronic illness negatively affects 69% of relationships by increasing stress, tension, and arguments. Participants felt that significant others and family members showed concern, but they lacked understanding and involvement in their management of T1DM with CSII. Consistent with findings from Golics et al. (2013), family members and significant others perceived CSII as an indicator of disease progression and a decline in body and social functioning creating fear about the development of complications and that their loved one would die. Congruent with Rintala, Pasvilainen, and Astedt-Kurki (2013), increased fear with CSII for family members and significant others stemmed from uncertainty; lack of knowledge about the device; and, uncertainty how to respond to an emergency, such as hypoglycemia.

Another important point documented in the literature is the lack of inclusion of family members and significant others in CSII education sessions and appointments. Rintala et al. (2013) claimed that lack of involvement of family members and significant others in education sessions leave them feeling like outsiders, external to the management of T1DM. Subsequently, they undervalue their role and try to stay in the background by not posing questions or comments. Participants in my study were frustrated, disappointed, and felt disconnected because family members and significant others did not get involved. However, participants also blamed themselves for not directly involving family members and significant others in their care.

Reidy et al. (2018) identified that it was awkward explaining CSII to a partner, but beyond that there is little exploration of the challenges of CSII during intimacy in the extant literature. It was made explicit in my study that CSII had a significant impact on intimacy that went beyond awkwardness; it was as if a third party had been brought into the relationship. Intimacy with CSII became stressful for both partners due to uncertainty of what to do with CSII during intimate moments. Considerations during intimacy included avoiding wrapping the tubing around their partner or themselves and remembering to reconnect CSII afterwards. Participants in my study revealed that the use of humour helped both partners re-establish a connection in their relationship. Humour as documented by Kuiper (2012) enhances personal relationships during stressful and traumatic periods. Humour reduces stress, promotes emotional resiliency, and reduces depression and anxiety levels.

The desire to build a positive relationship with healthcare professionals was evident in participants' stories and not new to the literature. However, there is a paucity in the literature on interactions between healthcare professionals and adults using CSII therapy. It was revealed to me that quality of professional support had a significant impact on how well participants adapted

to and embraced living with CSII. Relationally, support from healthcare professionals was lacking; lack of emotional support in providing a non-judgmental environment; lack of physical support in terms of availability; and, knowledgeable support about CSII was inadequate, resulting in unmet healthcare needs. As aforementioned, Barnard and Skinner (2007) found that healthcare professionals lacked knowledge about the device. In my study, lack of knowledge from healthcare professionals referred to not understanding what it means to live with CSII because their knowledge of CSII was learned knowledge and not experienced knowledge. Participants wanted healthcare professionals to recognize the individuality of living with CSII, whereby CSII was experienced in different ways. Participants revealed that healthcare professionals often failed to consider the consequences of CSII, such as the financial implications, or would recommend the device to patients with low literacy levels and who were computer illiterate. Self-management within a system that was lacking in support made it difficult to achieve recommended targets and achieve optimal outcomes.

A disconnect with physicians was created by long wait times, a lack of continuity, and physician turnover. Furthermore, the diminished physician contact led to lower CSII knowledge and understanding and limited opportunity for therapeutic intervention and counselling. Moreover, each provider would have different recommendations negating the advice of the previous provider. These experiences precipitated in mistrust in the provider and overall healthcare system. Consistent with findings from Balfe et al. (2013), my participants shared that brief physician encounters left little time for them to ask questions. Although physicians seemed to care and had good intentions, they did not have the time to get to know participants and therefore were not able to monitor them effectively and provide the support they needed.

Participants in my study sought recognition for their personal expertise, knowledge, and experience during encounters with healthcare professionals. Vahdat, Hamzehgardeshi, Hessam, and Hamzehgardeshi (2014) revealed that patient participation in decision making improved outcomes. However, I discovered that relationally, encounters with physicians were one-sided where they positioned themselves as expert leaving participants out of the decision-making process and having little involvement in their care. This contrasted with previous findings from Todres et al. (2010) who indicated that CSII therapy was conducive to increased collaboration and partnerships with healthcare professionals.

In contrast to comments about other disciplines, participants described certified diabetes nurse educators as knowledgeable, compassionate, and readily available. These characteristics contributed positively to participant coping strategies, confidence level, and acceptance of CSII. It is interesting that even the certified diabetes educator was not deemed as helpful as the certified diabetes nurse educator.

According to the Canadian Diabetes Association (2011), 57% of Canadians are unable to follow recommended therapy because of the heavy financial burden and stress with out-of-pocket expenses for DM medications and CSII devices. Newfoundland and Labrador is one of three provinces that has the highest costs of DM supplies. Participants in my study viewed CSII as a life-sustaining device used to treat a serious illness, but even with health insurance, they struggled with the high costs and feared they would have to revert to using MDI. Participants revealed that without insurance coverage CSII would not be a viable option due to the significant financial implications. However, for participants in my study the financial burden was worth taking on due to the perceived benefits of CSII.

Summary

In the last few decades there have been many advancements made to the CSII device. It is smaller, more user friendly and is easier to adjust, making it a sought-after choice and recommendation for T1DM management. However, compared with other electronic advancements, CSII devices still remain a bulky, cumbersome, and a complicated piece of equipment creating many challenges for wearers. In this chapter I discussed unrealistic expectations, in particular the ease of adjusting to CSII because in reality the learning curve was daunting. Establishing a new identity draws attention to how participants separated their life into pre- and post-CSII as they attempted to integrate and normalize the device. The burden of self-management described the inner conflict and distress of continuous self-monitoring. Adverse psychological effects covered three important aspects including the fear of complications and hypoglycemia; the guilt of balancing CSII and family life; and, being constantly vigilant, referring to the endless thoughts and considerations about CSII. There is a lack of understanding and stigma experienced from the public. CSII was related to stress within relationships with family members and significant others due to misunderstandings about the device and uncertainty with how to navigate intimacy with the device. Quality of provider care draws attention to the lack of support participants received from physicians and positive and respectful relationships they developed with certified diabetes nurse educators. Another insightful finding was that peer support helped participants find meaning and purpose with their new normal where sharing their experiences made them feel connected and understood without fear of judgement.

The findings from this study shed some light on the meaning of CSII for T1DM management. CSII was experienced through the body. One's primary relation to the world is a matter not of reflective thought, but rather practical involvement (Merleau-Ponty, 1945/1962).

“The body is the vehicle of being in the world, and having a body is, for a living creature, to be involved in a definite environment (Merleau-Ponty, 1945/1962, p. 82). Time is more than a discrete past, present, and future. The events in our lives are meaningful because time is connected. For individual’s with CSII missed time was not clock time, but rather time lost with family and friends. Lived space was perceived as a threatening environment full of anxiety, fear, and distress. Lived body speaks of the development of a new identity, visibility of the device, and stigma from the public. Lived relation referred to the support and challenges with family, significant others, healthcare providers and peers.

Chapter Six. Implications

In this final chapter I outline the implications of my study findings for practice, health professional education, research, and, for policy and administration. Pertinent to practice are my study findings that I have designated as developing partnerships, reducing stigma, psychological implications, recognizing uniqueness, patient and public education, peer mentoring, and professional development. Under health professional education I discuss important considerations for undergraduate and graduate programs. Below, I also make recommendations for further research in the area of living with CSII to self-manage T1DM. Finally, I suggest changes to policy and administration to improve the QOL for individuals living with the challenges of CSII technology before I conclude my thesis with study limitations and closing remarks.

Implications

CSII has become an increasingly popular choice of treatment for T1DM. As CSII becomes more prevalent, nurses and other healthcare professionals will encounter more patients who are using this device and thus providers need to understand the complications of living with CSII beyond metabolic data to incorporate a holistic plan of care. Moreover, providers can have a positive impact on those living with CSII if they are aware of the daily challenges and psychological impacts, which are essential to understanding their lived world.

Dissemination of my study findings will inform clinical practice, enabling nurses and other healthcare professionals to provide better care and support that will enrich patients' lives and improve QOL. In addition, the new insights from the experiences of individuals living with CSII have several implications for education, research, policy and administration. Each is explicated below.

Practice

Developing partnerships. The findings of my study have implications for multidisciplinary practice, including registered nurses, physicians, registered dietitians, and social workers, given that the care of adults living with CSII involves interacting and collaborating with professionals from diverse disciplines. In addition to the desire for glycemic control, I discovered that nurses and healthcare professionals must be aware that this patient population seeks control over their lives. Participants in my study shared that they needed to feel in control of their care and wanted to be recognized as expert and knowledgeable during interactions. The opportunity to partner with nurses and other healthcare professionals to actively participate in decisions regarding their own health and self-management with CSII, is one way to promote a sense of control. A partnership role with nurses and healthcare professionals can provide patients with access to support, referrals, resources and empower them to feel in control of their self-care. As detailed in chapter four, Todres et al. (2010) informed that patients want a collaborative relationship with healthcare professionals because they want to take control and responsibility for self-care. Collaborative relationships not only provide a sense of control, but also contribute to patient problem solving and seeking solutions autonomously.

Reducing stigma. Healthcare professionals can reduce stigma through non-verbal and verbal communication during patient interactions that conveys acceptance and support. Words and actions that are non-judgemental create a non-stigmatizing environment. Alternatively, the stigma associated with living with CSII is perpetuated by verbal moral judgements, such as “good” and “bad” comments about an individual’s ability to manage T1DM with CSII. Also, conveying interest through active listening enables a healthcare professional’s ability to establish

rapport. Healthcare professionals need to display an attitude of caring and respect during all encounters with both patients and family members.

Psychological implications. According to Kamilowicz (2011), when faced with a significant life event, self-identity is often the subject of greatest change forcing individuals to assess and re-assess their life. This identity shift can cause psychological vulnerability and loss of personal power as the individual grapples with the changes in the sense of self-concept and body image. Participants experienced a loss of who they were before CSII and a loss of hope for normalcy and the carefree lifestyle they were longing for. They had to adjust and accept a new identity as an individual living with CSII. Corporally, their body had become a source of pain and trouble, a manipulated object that was experienced as alien while undeniably still themselves.

Adjustment to CSII has been characterized by feelings of frustration, sadness, feeling overwhelmed, uncertainty and fear. Associations between distress and DM have been found in the literature, however, depression and other mental health illnesses are often undiagnosed due to the overlap of symptoms with hyperglycemia. The presence of CSII is a physical reminder of the disease, increases attention to an individual's body, and forces the individual to be constantly engaged with the device. During interviews, participants acknowledged that the burden of CSII was felt by the excessive thinking and the inner conflict and guilt of trying to make the "right" decision to constantly achieve targets and maintain control. The self-blame that is experienced when targets are not achieved along with healthcare professional's unrealistic expectations contribute to further psychological turmoil.

Participants perceived encounters with healthcare professionals were focused on glycemic goals, reducing risk factors, and visits with specialists to screen for complications

(Aberle et al., 2009; Robinson et al., 2018). It is often assumed that risk reduction in an individual's life is more important than quality; however, humanistic discussion must be included as well as medical innovation (Kerr et al., 2018). According to Lupton (2016), when patients become a quantifiable digital patient they question, existentially, "Who am I without these numbers." It was explicit in my research that focusing entirely on the metabolic aspects of meeting targets provided little insight into the challenges participants encountered in their efforts to reach these targets with CSII. Participants began to question their decisions, choices, and ability to manage with CSII while also living their life with meaning and purpose. Given these findings, holistic clinical care should incorporate a psychological component that regularly assesses the emotional well-being of patients. Psychological complications often coincide with poor adherence to treatment goals, thus, a proactive approach in preventing these complications from occurring should be taken by beginning a psychological assessment when CSII is initiated to minimize effects on overall health and QOL. As well, it is critical that healthcare professionals normalize these emotions and encourage patients to express how they are feeling.

Recognizing uniqueness. Though many similar experiences exist among patients living with CSII it is important that healthcare professionals recognize the uniqueness that sets each patient apart. Healthcare professionals should be asking questions such as "How has adjusting to CSII been like for you?" Active listening will communicate the healthcare professional's desire to learn more about each individual patient as opposed to one of the many consumers. Focusing on the unique subjective experience enables identification of patient needs, strengths, and challenges more accurately, allowing a more tailored, comprehensive plan of care.

Patient education. Participants in my study felt overwhelmed adjusting to CSII in the beginning because of unrealistic expectations. Participants felt they learned the basics from the

education session on CSII, but many of the day-to-day challenges were not discussed. As well, the complexity of the device and the vast amount of information were overwhelming.

Participants were left with more questions than answers and were uncertain of what to do in situations or who to ask for advice. I recommend nurses and healthcare professionals, during patient education sessions, discuss the following:

- discuss realistic expectations, including the time, effort and knowledge required to operate the CSII device;
- provide realistic timelines to achieve blood glucose targets;
- acknowledge that feelings of fear and uncertainty are a “normal” part of adjustment;
- carefully review a backup plan for insulin demonstration with MDI, as well as, hypoglycemia preparedness;
- discuss the challenges of intimacy with CSII and explore possible solutions;
- provide follow-up sessions shortly after initiating CSII. This would allow patients to process information provided in the first session, to experience life with CSII, and to enable healthcare professionals to provide the support needed for any challenges, concerns, and questions;
- provide follow up sessions with participants after starting CSII;
- include family members and significant others in education sessions whenever possible and to assess their coping mechanisms;
- assess for literacy levels to ensure that patients are ready to take on the responsibility of operating complex, technological equipment.

Peer mentoring. It is not uncommon for patients living with CSII to feel a sense of loneliness. Participants in my study who connected with peers, reflected on CSII and their daily lives more positively. Participants stated peers were easy to relate to, allowed expression of frustrations without judgement, and normalized their experiences. Patients would benefit from a peer mentoring program offered in diabetes clinics facilitated by healthcare professionals.

Public education. Participants were frustrated with a lack of public knowledge about CSII and the judgemental and stigmatizing attitudes. Healthcare professionals should invest in public education to enhance CSII knowledge and place emphasis on the fact that CSII is not a “quick fix” or cure for T1DM. In addition, the public should be made aware that CSII requires incredible effort and individuals living with CSII should be respectfully commended and not be made to feel embarrassed or ashamed. For example, pamphlets and posters could be placed in hospital environments with waiting areas, such as emergency departments and clinics.

Professional development. Healthcare facilities should facilitate and support initiative from Certified diabetes nurse educators in frequently keeping abreast of new research in CSII therapy. Healthcare facilities should offer in-services or classes to nurses and other healthcare professionals to learn more about CSII therapy. Education about CSII is required for all areas of practice because of the widespread occurrence of T1DM and the increasingly popular choice to use CSII as a management regime. This would produce a more supportive and knowledgeable healthcare team.

Health Professional Education

Health professional undergraduate and graduate programs could benefit from increased content specific to CSII. It is important that upcoming healthcare professionals understand the psychological implications of living with CSII. Furthermore, students should understand that

CSII is not self-maintaining and involves endless considerations beyond lifestyle alterations and administering insulin. Incorporation of interdisciplinary case studies and education into the curriculum, specifically about CSII, would foster team building by encouraging various healthcare disciplines to work together. Also, engaging in critical evaluation of the psychological impacts on an individual living with CSII would illuminate behaviors that impart blame, stigma, and judgement. Interdisciplinary case studies with a focus on psychological aspects of CSII would also encourage students to consider the patient as a person first, beyond the medical model, within which the focus of interactions is often the diagnosis and medical intervention. I am also recommending that clinical placements for healthcare professionals include diabetes clinics where they would get in-depth education and experience working with individuals with CSII and T1DM.

Research

There are several implications for nursing research. My study findings serve as a foundation for further qualitative research to advance understanding of the immense psychological effects of CSII. For example, research focused on the transitioning process is warranted. The transitional process of adjusting to CSII is a significant life event with substantial psychological effects not only on the individual, but on family and significant others. Such exploration during this transitioning process will equip healthcare professionals how to better support individuals through the challenges that arise to promote better adoption and adjustment.

All participants in my study were using a Medtronic Minimed CSII device, which delivers insulin through a tube that is attached to the CSII device and the device is attached to the wearer. However, in Canada another type of CSII device is available, known as the Omnipod, that delivers insulin wirelessly and tube free. That is, the Omnipod CSII device is not attached to

the wearer, only the infusion set. Further research exploring patients' experiences using this particular CSII device would be interesting because the device is less visible and one would anticipate there are fewer concerns with body image and concealment.

Certified diabetes nurse educators had a positive impact on participants. Research examining the practice approach and principles that set certified diabetes nurse educators apart from other diabetes educators should be conducted. The views of certified diabetes nurse educators along with patient perspectives would provide insights how to best interact with and support individuals living with CSII. The support of healthcare professionals is an important topic for both patients, family members, and significant others. The research goals could also include collecting feedback and input from family members and significant others about available supports.

Policy and Administration

My research study highlights the critical role of the certified diabetes nurse educator in the care of patients living with CSII. If policies were changed to increase the number of certified diabetes nurse educators, I believe we would witness patients feeling more supported, understood, and empowered to manage T1DM. Hiring additional certified diabetes nurse educators may come at a cost, but advancing patient self-management reduces healthcare system expenditures in the long-term. As presented in chapter two, researchers have provided evidence that using CSII therapy decreases the risk of DM-related complications by improving glycemic control and HbA1c values. These improved metabolic outcomes may decrease hospital admissions, and thus serve to justify the additional funding.

Along the same vein, there should be government legislation to improve financial assistance for CSII users. In Newfoundland and Labrador, individuals under the age of 25 years

are subsidized for all CSII equipment and supplies. However, the financial burden and challenges for those beyond the age of 25 years are immense given policies do not exist for government funded programming. Participants in my study living with CSII and older than 25 years of age shared how they must find their own means to finance their CSII device and this only detracted from their efforts at T1DM self-management.

I plan to disseminate my study findings through peer reviewed journals and professional newsletters in hardcopy and online. I will discuss my findings through professional development sessions and during conferences to reach certified diabetes educators and other healthcare professionals. Websites including the Canadian Diabetes Association of Newfoundland and Labrador will be another important venue for dissemination. Posters in local and provincial healthcare facilities will also be used to illustrate important findings.

Limitations

I described and interpreted the lived experiences of adults using CSII to manage T1DM. The aim of phenomenological research is not to generalize the findings to the larger population but represent the experiences of study participants. Participants in my study were diverse; there were four female participants and four male participants; four participants were married and four were not married and two participants had children. Participant ages ranged from 21-45 years; length of time living with T1DM ranged from 6-34 years; and, length of time living with CSII ranged from 5-14 years.

However, there were similarities among participant sample characteristics that may have been a study limitation. All participants were Caucasian, educated at the college or university level, and resided in an urban location. Thus, a similar study that included participants that were non-Caucasian, had less education, and living in a rural location may have revealed different

experiences with CSII. Participants living in urban areas may have had increased access to healthcare and supportive services than those living in rural locations, while those living in a smaller community may have developed more of a rapport with healthcare professionals. Participants in my study were using CSII for at least five years. In the literature, metabolic benefits are not typically seen until after one year (Bruttomesso et al., 2009). Hence, CSII experiences before the one-year period may have been different than those who participated in my study. As well, a lower HbA1c level is associated with a more positive view of CSII (Ritholz et al., 2007). Since my study focused on the lived experience, metabolic data were not collected from participants. Differences in metabolic data may have been an influential factor on participants' perceptions of CSII. Another issue related to homogeneity was that, as previously mentioned, all participants were using the same type of CSII device. If there were participants using a tubeless CSII device different experiences may have been reported (e.g., there would have been no concerns regarding visibility and intimacy).

My personal experiences living with CSII, as aforementioned, may have had both advantages and disadvantages. I had to be conscientious and self-reflective throughout my study to identify those experiences that were my own and ensure that they were separate from those of my participants. Journaling throughout the data analysis and verifying developing themes and subthemes with my supervisor ensured authenticity of my study findings.

Concluding Remarks

After conducting this phenomenological study of the experience and meaning of living with CSII using van Manen's (1990) hermeneutic approach, I believe that I have thoroughly addressed my research question: What is the meaning of the lived experience for adults who are on CSII for the treatment of T1DM? I was able to uncover the transitional process and the

psychological implications for eight individuals' experience of CSII through four substantive themes with supporting subthemes.

This journey began as I sought to understand the lived experience of CSII both for personal reasons, as an individual living with T1DM and considering CSII therapy, and for professional reasons with intent to enhance practice and future research. Van Manen (1990) does not believe we can bracket out experiences, but ultimately it is what we know about a subject that initiates our interest. My experiences shaped the way I interpreted the data and described participants' experiences, although I frequently reaffirmed my findings with my supervisor to ensure themes and subthemes were reflective of participant experiences and not my own. As revealed in my study, participants appreciate experienced knowledge differently than learned knowledge. Having experienced knowledge gave me an advantage because it allowed me to have an unparalleled dedication and a deeper understanding of the phenomena of interest and a deeper connection with participants whereby they saw me as a peer and not as a researcher. Participants felt safe sharing their stories with me, knowing that I would understand as someone who was also living with CSII.

My study findings revealed that CSII therapy brought many benefits to participants' lives giving them freedom and flexibility, improved glycemic control, and making them feel closer to normal. However, these benefits came at a cost where the burden of the responsibility and psychological implications of CSII took ascendancy over T1DM. Participants had to be excessively engaged with the device resulting in feelings of loneliness, distress, frustration, self-blame, and guilt. I discovered that the psychological implications of living with CSII are not screened on a routine basis and are often overlooked by healthcare professionals in favor of achieving metabolic targets. However, my research showed that living with CSII impacts the

psychological well-being of individuals who have good metabolic control so healthcare professionals focusing solely on metabolic data could overlook the unidentified psychological complications lurking beneath. My study highlights that psychological complications are as important to assess as physical and metabolic complications. Through regular assessment these complications can be prevented or at least treated at an earlier stage and allow healthcare professionals to provide a more comprehensive plan of care for patients improving their overall QOL.

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Appendix A – Letter for Diabetes Educator to Give to Participants

8 Rattling Brook Rd.
Torbay, NL A1K 0C4

(Date)

Dear Participant

My name is Renee Fagan and I am a student in the Master of Nursing Program at Memorial University of Newfoundland. As part of that program I am required to do a research study. My proposed study is the lived experience of adults, over the age of 19 years, who have Type I Diabetes Mellitus that are currently receiving treatment via an insulin pump. This research will be conducted under the supervision of Dr. Karen Parsons. Presently, there is little research completed in this area. The results from this study will give greater insight and a deeper understanding of what it means to live day-to-day with an insulin pump. I have a strong passion for this topic because I have had type I diabetes over 29 years and have been using an insulin pump for the last seven years. Because you are a current insulin pump user your opinions are important to this study. I would like to tell you more about this study and what your involvement would be should you decide to participate.

I would like for you to participate in a face-to-face audio-taped interview with myself. Completion of the interview is expected to take about 1-2 hours of your time. You may omit any question you prefer not to answer, and you can withdraw from the study at any point in time, however, information collected up to that time will continue to be used for the purpose of this research project. There are no known or anticipated risks to participation in this study. Participation is voluntary and all information you provide will be considered confidential and no names will be mentioned in any writings or presentations made. The data collected through this study will be kept for a period of five years in a locked office at Memorial University of Newfoundland with access limited only to the researchers involved in the study. After five years all data will be destroyed by shredding all documents and destroying all audio material.

If after receiving this letter, you are interested in participating in this study or you have any questions or would like additional information about this study to assist you in reaching a decision about participation, please contact myself, Renee Fagan at 709-233-0094 or 709-764-1665 or via email at renee.fagan@mun.ca.

This study has received ethics approval through the Health Research Ethics Authority of Newfoundland and Labrador and the Research Proposal Approval Committee within Eastern

health. Your time and consideration are greatly appreciated, and I thank you in advance for your interest in this study.

Yours sincerely,

Renee Fagan, B.Sc., ADFS, RN, BN

Appendix B - Letter to Diabetes Educator at the Diabetes Clinic on Major's Path

8 Rattling Brook Rd.
Torbay, NL
A1K 0C4

(Date)

(Name of Contact Person), Diabetes Educator
(Address)

Dear (Name of Contact Person)

My name is Renee Fagan and I am a student in the Master of Nursing Program at Memorial University of Newfoundland. As part of that program I am required to do a research study. My proposed study is the lived experience of adults, over the age of 19 years, who have Type I Diabetes Mellitus that are currently receiving treatment via an insulin pump. This research will be conducted under the supervision of Dr. Karen Parsons. Presently, there is little research completed in this area. The results from this study will give greater insight and a deeper understanding of what it means to live day-to-day with an insulin pump. I have a strong passion for this topic because I have had type I diabetes over 29 years and have been using an insulin pump for the last seven years.

I am requesting your assistance in the recruitment of 8-10 suitable participants for this study. The requirements for participants are English speaking adults with Type I Diabetes Mellitus over the age of 19 years old currently receiving insulin therapy via an insulin pump and are patient's at the Diabetes clinic on Major's Path. The time commitment anticipated for you is minimal. Your requirement would be to inform patients that I am conducting this study and give them a letter that I will provide you outlining the purpose of the study (attached). You will then ask for permission to release their contact information to me. You will then record their name and telephone number if they are willing to be contacted for further information. I will be responsible for contacting patients for further explanation of the study and to determine their willingness to participate once they have agreed that you can give their contact information to me. You will not be required to answer any questions about the study. No medical files or records will be required. Participation from you is voluntary and all information you provide will be considered confidential and no names will be mentioned in any writings or presentations made. Informed consent will be obtained, and participants will be informed that they can withdraw from the study at any time.

This study has received ethics approval through the Health Research Ethics Authority of Newfoundland and Labrador and through the Research Proposal Approval Committee

within Eastern Health. If you have any questions about this study or would like additional information to assist you in reaching a decision, please feel free to contact myself, Renee Fagan at 709-777-7335 or 709-764-1665 or via email at renee.fagan@mun.ca. Your time and consideration are greatly appreciated, and I thank you in advance for your interest in this study.

Yours sincerely,

Renee Fagan, B.Sc., ADFS, RN, BN

Appendix C - Recruitment Poster

Memorial University of Newfoundland Research Study



Do you have Type I Diabetes?

Are you on an Insulin Pump?

Are you over the age of 19?

If so, then I would love to hear about your experience as an adult with Type I Diabetes using an Insulin Pump. A research study is currently underway as part of Memorial University Master in Nursing program. Taking part in this study is completely voluntary and will take very little of your time.

This research needs YOUR help!

For further information please contact Renee at

709-231-2196 or 709-764-1665

or email: renee.fagan@mun.ca

Appendix D - Health Research Ethics Authority Consent

Memorial University of Newfoundland
School Of Nursing
St. John's, NL

Consent to Take Part in Research

TITLE: The Lived Experience for Adults on an Insulin Pump Living With Type I Diabetes

INVESTIGATOR: Renee Fagan, B.Sc., ADFS, RN, BN

SUPERVISOR: Dr. Karen Parsons

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your usual health care/ normal treatment.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

1. Introduction/Background:

There is not much research about day-to-day living for adults with Type I diabetes that are using insulin pumps. There is a lack of knowledge to health care providers, educators, and insulin pump manufacturers. By participating in this study, you will be providing valuable information that may change how education is provided about the insulin pump to new and existing users, giving them greater understanding of what issues are important to insulin pump users. Lastly, it will provide insight into the commitment and dedication it takes for someone with Type 1 Diabetes to live on an insulin pump.

2. Purpose of study:

To understand what it means for adults with Type I Diabetes Mellitus to live with an insulin pump on a day-to-day basis.

3. Description of the study procedures:

You are being asked to take part in an interview that will be conducted at a location and time convenient for you. This session will be audio recorded. The interview will last approximately 1-2 hours or until you feel you have fully explained to me what it means to live with an insulin pump. The investigator will request a brief follow up interview or contact you by telephone after the interview to confirm that the description taken from the interview is representative of your experience. Findings of the study will be presented at Memorial University of Newfoundland by the principle investigator and you are invited to attend this presentation. No names will be mentioned in any written or verbal material. Your participation will remain anonymous and you may withdraw from the study at any time.

4. Length of time:

Your participation will include one face to face interview lasting approximately 1-2 hours. The investigator will request a brief follow up interview or contact you by telephone after the interview to clarify any information and ensure it is representative of your experience. The second interview or telephone call will last approximately 30 minutes – 1 hour.

5. Possible risks and discomforts:

There are no physical or social risks involved in this study. You may feel uncomfortable discussing certain issues related to wearing an insulin pump, however, you can omit any question that you do not feel comfortable answering and/or stop or delay the interview at any time.

6. Benefits:

It is not known whether this study will benefit you.

7. Liability statement:

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

8. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records.

When you sign this consent form you give us permission to

- Collect information from you
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The members of the research team will see study records that identify you by name. Other people may need to look at the study records that identify you by name. This might include the research ethics board. You may ask to see the list of these people. They can look at your records only when supervised by a member of the research team.

Use of your study information

The research team will collect and use only the information they need for this research study.

This information will include your

- date of birth
- sex
- medical conditions
- medications
- information from study interviews

Your name and contact information will be kept secure by the research team in Newfoundland and Labrador. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will be kept for a period of five years.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. It may not be removed. This information will only be used for the purposes of this study

Information collected and used by the research team will be stored by Memorial University of Newfoundland in St. John's, NL. Renee Fagan *B.Sc., ADFS, RN, BN* is the person responsible for keeping it secure.

Your access to records

You may ask the researcher, Renee Fagan, to see the information that has been collected about you.

9. Questions or problems:

If you have any questions about taking part in this study, you can meet with the investigator who is in charge of the study at this institution. That person is:

**Renee Fagan B.Sc., ADFS, RN, BN.
Telephone: 709-231-2196 or 709-764-1665.**

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through:

Ethics Office

Health Research Ethics Authority

709-777-6974 or by email at info@hrea.ca

After signing this consent you will be given a copy.

Signature Page

Study title: The Lived Experience for Adults with Type I Diabetes Mellitus on an Insulin Pump

Name of principal investigator: Renee Fagan, B.Sc., ADFS, BN,
RN

To be filled out and signed by the participant:

Please check as appropriate:

I have read the consent Yes { } No { }

I have had the opportunity to ask questions/to discuss this study. Yes { } No { }

I have received satisfactory answers to all of my questions.

Yes { } No { }

I have received enough information about the study.

Yes { } No { }

I have spoken to Renee Fagan and she has answered my questions Yes { } No { }

I understand that I am free to withdraw from the study Yes { } No { }

- at any time
- without having to give a reason
- without affecting my future care

I understand that it is my choice to be in the study and that I may not benefit.

Yes { } No { }

I agree to be audio taped Yes { } No { }

I agree to take part in this study. Yes { } No { }

Signature of participant

Name printed

Year Month Day

Signature of person authorized as

Name printed

Year Month Day

Substitute decision maker, if applicable _____

To be signed by the investigator or person obtaining consent

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

Signature of investigator

Name printed

Year Month Day

Telephone number: _____

Appendix E - Semi-Structured Interview Guide

Interview script to initiate the interview:

Thank you for agreeing to take part in my study on how having an insulin pump affects your life. I am interested in what it is like for you to live your life with an insulin pump and how it affects your day-to-day living and experiences. If you could tell me how having an insulin pump has affected your life this would help me to understand this better. You can start wherever you feel comfortable. You are free to withdraw from the study at any time and you may omit any question that you do not want to answer.

Interview guide to be used include:

1. Tell me a story that reveals what a typical day is like for you?
2. What are some of your thoughts and feelings about your experience with an insulin pump?
3. Do you feel your life has changed since you started wearing an insulin pump? If yes, how so?
4. Tell me about how wearing an insulin pump has affected your self-image?
5. Tell me about how wearing an insulin pump has affected your personal relationships?
6. Tell me about how wearing an insulin pump has affected your social interactions?
7. Tell me about how wearing an insulin pump has affected your attire at home, work, or in social situations?
8. Tell me about a positive experience with using an insulin pump? Tell me about a negative experience with using an insulin pump?

9. What are some things that you would like to see included in training sessions about insulin pumps that you feel would have been beneficial to you?
10. Are there any other comments or thoughts that you would like to share with me about your experience with using an insulin pump?

Appendix F – Tri-Council Policy Statement Certificate

PANEL ON
RESEARCH ETHICS

Navigating the ethics of human research

TCPS 2: CORE

Certificate of Completion

This document certifies that

Renee Fagan

*has completed the Tri-Council Policy Statement:
Ethical Conduct for Research Involving Humans
Course on Research Ethics (TCPS 2: CORE)*

Date of Issue: 12 November, 2011

Appendix G - Health Research Ethics Authority Approval



Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

May 6, 2013

Ms. Renee Fagan
 8 Rattling Brook Road
 Torbay, NL A1K 0C4

Dear Ms. Fagan:

Reference # 13.103

RE: The Lived Experience of Adults with Type 1 Diabetes Mellitus who are on Continuous Subcutaneous Insulin Infusion

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Board. **Full board approval** of this research study is granted for one year effective **May 2, 2013**.

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- ❖ Revised Letter for Diabetes Educator to Give to Participants dated May 3, 2013, approved
- ❖ Letter to Diabetes Educator at the Diabetes Clinic on Major's Path dated April 22, 2013, approved
- ❖ Interview Guide for First Interview, Semi-Structured Interview Guide, dated April 22, 2013, approved
- ❖ Interview Guide for Follow up Interview or Telephone Call, Un-structures Interview Guide dated April 22, 2013, approved
- ❖ Consent Form dated April 22, 2013, approved
- ❖ Research Proposal dated April 2013, approved

MARK THE DATE

This approval will lapse on **May 2, 2014**. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date. *The information provided in this form must be current to the time of submission and submitted to HREB not less than 30 nor more than 45 days of the anniversary of your approval date.* The Ethics Renewal form can be downloaded from the HREB website <http://www.hrea.ca>.

email: info@hrea.ca

Phone: 777-8949

FAX: 777-8776

Ms. Fagan
Reference # 13.103
May 6, 2013

Page 2

The Health Research Ethics Board advises THAT IF YOU DO NOT return the completed Ethics Renewal form prior to date of renewal:

- Your ethics approval will lapse
- You will be required to stop research activity immediately
- You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again

Lapse in ethics approval may result in interruption or termination of funding

It is **your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate.**

Modifications of the protocol/consent are not permitted without prior approval from the Health Research Ethics Board. Implementing changes in the protocol/consent without HREB approval may result in the approval of your research study being revoked, necessitating cessation of all related research activity. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREB website) and submitted to the HREB for review.

This research ethics board (the HREB) has reviewed and approved the research protocol and documentation as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; ICH Guidance E6: Good Clinical Practice* and applicable laws and regulations. The membership of this research ethics board is constituted in compliance with the membership requirements for research ethics boards as defined by *Health Canada Food and Drug Regulations Division 5; Part C.*

Notwithstanding the approval of the HREB, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you every success with your study.

Sincerely,



Dr. Fern Brunger, Chair, Non-Clinical Trials
Mrs Patricia Grainger, Vice-Chair, Non-Clinical Trials
Health Research Ethics Board

C C VP Research c/o Office of Research, MUN
VP Research c/o Patient Research Centre, Eastern Health
HREB meeting date: May 16, 2013

email: info@hrea.ca

Phone: 777-8949

FAX: 777-8776

Appendix H – Research Proposal Approval Committee Approval



**Department of Research
5th Floor, Janevay Hostel
Health Sciences Centre
300 Prince Philip Drive
St. John's, NL A1B 3V6
Tel: (709) 752-1636 Fax (709) 752-3591**

May 13, 2013

Ms. Renee Fagan
8 Rattling Brook Rd.
Torbay, NL A1K 0C4

Dear Ms. Fagan:

Your research proposal HREA # 13.103: "*The lived experience of adults with type 1 Diabetes mellitus who are on continuous subcutaneous insulin infusion*", was reviewed by the Sub-Committee of the Research Proposals Approval Committee (RPAC) of Eastern Health and *Interim Approval* has been granted as of May 13, 2013. This decision will be brought to the RPAC Committee for ratification at the next meeting, scheduled for June 11, 2013.

The approval of this project is subject to the following conditions:

- The project is conducted as outlined in the HREA approved protocol;
- Adequate funding is secured to support the project;
- In the case of Health Records, efforts will be made to accommodate requests based upon available resources. If you require access to records that cannot be accommodated, then additional fees may be levied to cover the cost;
- A progress report being provided upon request.

If you have any questions or comments, please contact Donna Bruce, Manager of the Patient Research Centre at 777-7283.

Sincerely,

Mike Doyle, PhD
Director of Research
Chair, RPAC

MD/jmps

cc: Ms. Donna Bruce, Manager Patient Research Centre
Ms. R. Fagan (renee.fagan@mun.ca)



**Department of Research
5th Floor, Janeway Hostel
Health Sciences Centre
300 Prince Philip Drive
St. John's, NL A1B 3V0
Tel: (709) 752-1636 Fax (709) 752-3591**

June 11, 2013

Ms. Renee Fagan
8 Rattling Brook Rd.
Torbay, NL A1K 0C4

Dear Ms. Fagan:

Your research proposal *HREA Reference # 13.103: "The lived experience of adults with Type 1 Diabetes Mellitus who are on continuous subcutaneous insulin infusion"*, was reviewed by the Research Proposals Approval Committee (RPAC) of Eastern Health at a meeting dated: June 11, 2013, and we are pleased to inform you that the proposal has been granted full approval.

The approval of this project is subject to the following conditions:

- The project is conducted as outlined in the HREA approved protocol;
- Adequate funding is secured to support the project;
- In the case of Health Records, efforts will be made to accommodate requests based upon available resources. If you require access to records that cannot be accommodated, then additional fees may be levied to cover the cost;
- A progress report being provided upon request.

If you have any questions or comments, please contact Donna Bruce, Manager of the Patient Research Centre at 777-7283.

Sincerely,

Mike Doyle, PhD
Director of Research
Chair, RPAC

cc: Ms. Donna Bruce, Manager Patient Research Centre
Ms. Renee Fagan (renee.fagan@mun.ca)

MD/jmps

Appendix I - Health Research Ethics Authority Amendment Approval

Health Research Ethics Board
 777-6974 (Phone)
 777-8776 (Fax)

Version June 2013

RECEIVED JUL 24 2014

Request for Amendment to an Approved Application

HREB #: 2013.103

Current Date: July 23rd, 2014

Title of study: Include protocol number, if any.

The Lived Experience of Adults with Type 1 Diabetes Mellitus who are on Continuous Subcutaneous Insulin Infusion

Amendment Date: July 23rd, 2014 Version # (if applicable):

Are these changes editorial and/or administrative?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Will there be any increase in risk, discomfort or inconvenience to the participants?	Yes (Specify below)	<input checked="" type="radio"/> No
Are there changes to inclusion or exclusion criteria?	Yes (Specify below)	<input checked="" type="radio"/> No
Is a modification to the consent form required?	Yes (Append form)	<input checked="" type="radio"/> No

Summarize the significant changes being requested. It is not necessary to itemize editorial, administrative and similar changes.

I am requesting to have audio recorded interviews with participants transcribed. The transcriptionist would be required to complete a confidentiality agreement. No identifying information, including names, is mentioned in the audio recordings during the interviews.

What is the rationale for the amendment(s)?

Recently I've had some unexpected serious medical issues with my eyes making it difficult to use the computer for prolonged periods of time. I am unable to transcribe the completed interviews myself due to these medical issues. I would like to continue with my research and having these interviews transcribed would make this possible. If additional information is required regarding these medical issues please contact me.

Other pertinent information – List documents, _____, to be reviewed:

Renée Fagan Renée Fagan July 23/14
 Printed Name of Principal Investigator Signature of Principal Investigator Date

Health Research Ethics Board
777-8974 (Phone)
777-8776 (Fax)

Version June 2013

This Health Research Ethics Board (the HREB) has reviewed the amendment as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified study site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to Tri-Council Policy Statement (TCPS2) and applicable laws and regulations. The membership of this research ethics board complies with the membership requirements for research ethics boards defined in TCPS2.

Full Board Review and Approval granted at _____ Meeting

Signature Chair (Dr. Fern Brunger) Date

Signature Vice-Chair (Patricia Grainger) Date

Reported to Full Committee at Aug 21, 2014 Meeting

Approved by:

Signature Chair (Dr. Fern Brunger) Date

APPROVED JUL 25 2014 ⇨ *Patricia Grainger*
Signature Vice-Chair (Patricia Grainger) Date

*Attach additional documentation if necessary

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