The Impact of Technology on the Management of Type 1 Diabetes for Adults in Ireland

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Abstract

Technology for the management of Type 1 Diabetes (T1D) has been available in Ireland for a number of decades. Research has confirmed that continuous subcutaneous insulin infusion (CSII) therapy has the ability to improve glycaemic control of individuals with T1D while enhancing their quality of life. Similarly, the continuous glucose monitor (CGM) removes the need to regularly finger prick in order to test blood glucose. Despite these positive findings, the uptake of both devices is relatively low amongst the T1D adult population in Ireland (Noctor and Firth, 2010, Donaghy, 2016).

This qualitative exploratory research sets out to identify the factors contributing to the uptake of CSII and CGM technologies in Ireland by understanding the impact of both devices on the self- management of T1D for adults living with this chronic illness. The research adopted a qualitative approach by conducting a number of semi-structured interviews with a network sample including both healthcare professionals and Type 1 diabetics in Ireland.

The findings of the research discovered that appropriate patient selection and education are vital to enable successful self-management of T1D using CSII and CGM technology. When used appropriately by suitable candidates, CSII can positively impact T1D in terms of improved health outcomes. A perception of enhanced quality of life through greater flexibility and better real time decision making is also associated with the use of CSII. More evidence based research is required to confirm the connection between the CGM device and health outcome. However, CGM has the ability to impact quality of life both positively and negatively when used to manage T1D. Similar to the insulin pump, the device was found to provide greater flexibility. However, CGM may increase anxiety levels of the user through alerts and alarms along with the constant flow of data which in some cases can lead to information overload.

Keywords: Type 1 Diabetes, self-management, continuous subcutaneous insulin infusion, continuous glucose monitor

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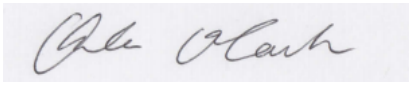
Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

Signed: 

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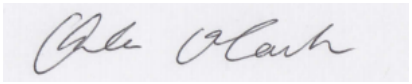
Signed: 

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List of Abbreviations

ADA	American Diabetes Association
CAQDAS	Computer Assisted Qualitative Analysis Software
CGM	Continuous Glucose Monitor
CSII	Continuous Subcutaneous Insulin Infusion
DCCT	Diabetes Control and Complications Trial
DAFNE	Dose Adjustment for Normal Eating
HbA1c	Haemoglobin A1c
HSE	Health Service Executive
MDI	Multiple Daily Injections
NICE	National Institute for Health and Care Excellence
NPH	Neutral Protamine Hagedorn
SAP	Sensor Augmented Pump Therapy
SMBG	Self-monitoring of Blood Glucose
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
TCD	Trinity College Dublin
UK	United Kingdom
WHO	World Health Organisation

1 Introduction

1.1 Context

Technological advances and innovation in healthcare are leading to vast improvements in the industry. This has had an impact on the way in which services are provided to patients, especially those suffering from a chronic illness. Responsibility is shifting from healthcare professionals to the individual, in order to manage their illness more efficiently on a day to day basis. This is true in the case of Type 1 Diabetes (T1D) where it is vital that the patient carefully controls glycaemic levels in order to reduce the risk of diabetes related comorbidities such as microvascular and neurological complications (Skyler, 2004).

Without the use of some degree of technology, the day to day management of T1D would be near impossible. There are many technologies and devices available on the market which can be used to manage T1D such as insulin pens, blood glucose meters, bolus calculators, continuous glucose monitors, insulin pumps and smart phone applications to name a few (Free et al., 2013). This research dissertation relates to the impact of technology on the management of T1D.

1.2 Background

1.2.1 Diabetes in Ireland

According to the World Health Organisation (WHO) (2016) there are approximately 422 million adults over the age of 18 living with diabetes worldwide. An estimated quarter of a million of reported cases reside in Ireland. The number of people living with diabetes in Ireland is increasing and it expected to do so over the next five years, however, the absence of an official national diabetes register makes it difficult to predict demand (Smyth et al., 2017). The prevalence of T1D is on the rise with T1D accounting for approximately between 10% to 15% of the total diabetic population in Ireland (Diabetes Ireland, 2017).

1.2.2 Diabetes Mellitus

T1D occurs as a result of beta cell destruction in the pancreas, these beta cells produce a hormone called insulin which regulates blood glucose levels (Yoon and Jun, 2005). Because endogenous production of insulin is generally absent or in very small quantities in T1D patients, lifelong treatment with insulin therapy is required (American Diabetes Association, 2009). The exact cause of T1D is unknown, however, it is suggested that the illness can arise as a result of genetics and or environmental factors (LeRoith et al., 2004, p. 459).

Self-management

Diabetes demands accurate and continuous self-management (Schilling et al., 2002). The key feature of self-care of any chronic illness is that people participate effectively in managing their own healthcare on a continuous basis (Wilkinson et al., 2014). T1D requires patient engagement and ongoing decision making with regards to glucose monitoring, administering insulin, adjusting dosage, carbohydrate counting and planning required adjustments for physical activity (Alvarado-Martel et al., 2015). Glucose monitoring devices, bolus calculators, insulin pens and pumps are technologies available on the market which can be used to perform these self-monitoring tasks.

A fundamental element of self-management is the monitoring of glycaemic levels to ensure patient specific targets can be met and maintained. The monitoring of overall glycaemic control is clinically assessed to facilitate necessary steps required to respond correctly to changes in glycaemic levels for optimum control (Shrivastava et al., 2013). Self-monitoring delivers current data trends and information on glycaemic levels, which can enable evaluation of therapy guiding necessary adjustments to diet, exercise and medication in order to achieve optimal glycaemic control (Colberg et al., 2010).

Technologies

Technologies for diabetes management, such as continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) systems, have improved remarkably over the last number of decades (Giani et al., 2015). Both technologies contribute to the self-management of T1D. The CSII device delivers insulin to the individual while the CGM monitors glycaemic levels, allowing the user to make an informed decision when responding to their diabetes.

CSII

CSII or insulin pumps attempt to carefully imitate the behaviour of the pancreas by providing a continuous level of basal insulin to the body with additional boluses at meal times (Reece and Hamby Williams, 2014). Modern CSII pumps are comprised of a small battery-operated device designed to administer insulin subcutaneously through the abdominal wall (Health Quality Ontario, 2009). The pump is attached to the individual by an infusion set that consists of long flexible tubing with a cannula on one end that is inserted subcutaneously into the patient while the other end of the tubing is attached to a reservoir containing insulin and is placed inside the pump (Forde, 2011). Similar to Multiple Daily Injections (MDI), insulin dose is adjusted in response to measured blood glucose values (Health Quality Ontario, 2009).

CGM

CGM devices measure an individual's interstitial glucose on an ongoing basis (Tamborlane et al., 2008). The technology consists of three components, a glucose sensor, a transmitter and a receiver-monitor (Benhamou et al., 2012):

1. The glucose sensor is inserted subcutaneously using a sensor applicator tool. Sensors can last for up to 7 days before replacement is required.
2. Calibration with blood glucose is required up to 3 times a day due to the physiological lag time between blood and interstitial glucose concentration.
3. A transmitter is connected to the sensor to communicate the signal to a receiver-monitor.

The combination of both CSII and CGM technology is referred to as Sensor-Augmented Pump (SAP) therapy. When used correctly, SAP has been proven to improve metabolic control, reduce glycaemic variability and reduce the rate of hypoglycaemia in adults with T1D when compared with MDI (Tumminia et al., 2015).

1.3 Purpose of research

Diabetes places a significant burden of care on the individual, healthcare professionals and the wider health system (Tracey et al., 2016). At present, €1.35 billion or about 10% of the total annual Irish healthcare budget is spent on diabetes and care for diabetes related complications including blindness, heart disease, kidney failure, and limb amputations (Canavan, 2013).

Continuous improvements and innovations in technology and healthcare can greatly improve the management of chronic illness and reduce long term costs (Hitachi, 2016).

1.3.1 Research problem

Technology for the management of T1D has been available for many years. CSII therapy was first introduced in the late 1970's and has vastly improved since then in terms of mobility, size and ability to improve glycaemic control when compared with insulin injections (Selam, 2010). Despite this, the uptake of such devices is relatively low. In Ireland, it is estimated that 6% of adults with T1D use CSII (Noctor and Firth, 2010). In 2012, the HSE launched 'The Insulin Pump Programme for Children under 5 years of age' with the goal of providing CSII to children under 5 with T1D. However, no such programme was replicated for adults (O'Riordan et al., 2015). Guidelines for pump usage in adult's state that CSII should only be recommended to an adult with T1D experiencing severe hypoglycaemia or those with persisting high levels of Haemoglobin A1c (HbA1c) despite a high standard of care (NICE, 2008).

Similarly, the CGM device was first introduced in 1999 (Gomez and Umpierrez, 2014). CGM is proven to reduce the risk of hypoglycaemia and hyperglycaemia, glycaemic variability and thus enhance the individual's quality of life (Rodbard, 2017). There are no statistics currently available on the number of T1D users of CGM devices in Ireland however, it is estimated that this is only a small minority relative to the diabetic population (Donaghy, 2016).

This research aims to gain an insight into the factors contributing to the uptake of CSII and CGM technologies in Ireland by understanding the impact of both devices on the management of T1D for adults living with this chronic illness.

1.4 Research question

The main goal of this research is to answer the question:

> What is the impact of CSII and CGM technologies on the management of Type 1 Diabetes for adults in Ireland?

The objectives of the research are:

1. Identify the key areas contributing to the use of CSII for T1D self-management by adults in Ireland.

2. Identify the key areas contributing to the use of CGM for T1D self-management by adults in Ireland.
3. Understand the perception of CSII from real life experience.
4. Understand the perception CGM from real life experience.
5. Determine the barriers to uptake (if any) of CSII and CGM.

1.5 Research Rationale

The research topic is an important area of study as the number of people in Ireland with T1D is rising year on year (Diabetes Ireland, 2017). It is anticipated that this increase will result in increased costs to the Health Service Executive (HSE) (Smyth et al., 2017, Diabetes Ireland, 2017).

There is an opportunity to leverage technology to reduce this burden over time, as innovation in healthcare technology has resulted in the availability of more accurate and reliable devices for diabetes management (Forde, 2001). The widespread adoption of CSII and CGM technologies for T1D presents an opportunity to ease cost in the medium to long term by reducing the number of hospital visits for hypoglycaemia, reducing insulin dosage and reducing diabetes related complications as a result of improved glycaemic control (Noctor and Firth, 2010). This will simultaneously improve the patient's quality of life through better management of glycaemic control and increased flexibility day to day (Bode et al., 2017).

CSII and CGM technologies can alter the lives of many people with diabetes through greater freedom to make flexible lifestyle choices, while at the same time improving glycaemic control and recognition of hypoglycaemia (Forde, 2011).

This research provides important insight into the impact of CSII and CGM technologies on T1D management by critically analysing current literature and conducting a primary qualitative investigation using semi-structured interviews.

1.6 Scope

This research focuses specifically on the impact of two devices for the self-management of T1D, these are CSII and CGM. The technologies were chosen simultaneously as they both represent an important stepping stone in achieving a closed loop system for automated diabetes management (Hanaire, 2011, Shulman et al., 2016). The research conducted specifically relates to adults

which are defined as anyone over the age 18 years old. Finally, the location of the study and insight gained is conducted in the Republic of Ireland.

Subjects or topics not included and considered to be limitations of the study are:

- Other technologies for the management of T1D for adults in Ireland for example, bolus calculators, mobile applications, smart watches etc. are deemed to be out of scope for this research.
- Type 2 Diabetes (T2D), the preventable form of diabetes is out of scope and will not be discussed.
- Adolescents and children are excluded from this research.
- As this study relates specifically to T1D in Ireland, all other countries and regions are deemed to be out of scope.

1.7 Beneficiaries

The main beneficiaries of this study have been identified as any individual living with T1D in Ireland. Beneficiaries also span the wider Diabetes community in Ireland including primary and secondary healthcare providers, family members and Diabetes support networks.

The focus of this study is on T1D however, the findings of the research could be relevant to those living with other chronic illnesses such as, T2D or cardiovascular disease, that employ technology for self-management.

The benefits of this research exist through creating a wider awareness of the impact of CSII and CGM technologies on the self-management of T1D. The research intends to focus on this specifically in terms of what factors currently contribute to how these technologies are perceived in terms of quality of life and health outcomes.

To ensure that beneficiaries of the study have an opportunity to access the research, the dissertation will be made available through the Trinity College Dublin (TCD) archive. Following the publication of the research, a copy of the research paper will also be issued to all participants involved in the data collection phase of the study.

1.8 Roadmap of chapters

The research dissertation is broken down into a number of chapters. Below provides a guideline of the structure of the dissertation along with an insight into the contents of each chapter.

Chapter 1: Introduction

The first chapter provides an introduction to the context and background of the research topic. It outlines the rationale for undertaking the study and reason for choosing the research question. The introduction also details the boundaries of the study by describing what is deemed to be in scope for the research and thus providing a recommendation as to whom will benefit from this research.

Chapter 2: Literature Review

The literature review provides a critical analysis of important analogies found in existing literature relevant to the research topic. It cross examines and evaluates existing theories and provides a foundation for the theoretical framework of the research.

Chapter 3: Methodology

This chapter provides a brief overview of the various research philosophies, approaches and methodologies at the forefront of the literature on research methodology process. It also provides justification for selecting the methodology used in this research along with acknowledging the limitations and lessons learned from undertaking the chosen method.

Chapter 4: Findings and Analysis

This penultimate chapter is the most important in answering the research topic. It provides an explanation as to how the data collected was carefully analysed and interpreted and describes what tools were used to perform the analysis. This chapter also states the evidence based findings of the research and what has been discovered as a result of conducting the research.

Chapter 5: Conclusions and Future Work

This is the concluding chapter of the dissertation and provides a summary overview of the details of the research, highlighting the findings and discussing whether the research question has been answered. It also includes recommended future work to be carried out relating to the specific subject.

2 Literature Review

2.1 Introduction

The objective of this chapter is to critically analyse and review important analogies which exist in current literature relevant to the research topic. The literature review cross examines and evaluates existing theories and provides a foundation for the theoretical framework of the research. This is done through the identification of the key themes which have emerged from current studies on in the field of technology for self-management of T1D.

The literature review was conducted using a number of databases accessible through the TCD Library Online portal including PubMed, Science Direct and Wiley Online, to identify journal articles, conference papers, peer reviewed papers and edited volumes pertinent to the subject.

The primary focus of the research is to understand the impact of both CSII and CGM technologies on the management of T1D for adults living in Ireland. Databases were searched using terms such as “type 1 diabetes”, “diabetes management”, and “self-management”, “Insulin Pump” or “CSII” and “CGM” to identify research relevant to the topic.

The literature review critically analyses the selected papers to identify emerging trends and common themes relevant to the impact of CSII and CGM technologies on the self-management of T1D. The themes identified were:

- Patient selection
- Education and Training
- Quality of life
- Health outcomes

This chapter explains each of these themes in more detail, based on the available literature in the field. The first section of the chapter discusses each theme in relation to the CSII device. The second section discusses the literature regarding CGM devices in terms of patient selection, education, health outcomes and quality of life. Thirdly, the use of both devices is discussed and finally a conclusion provides an overview of the findings covered in this chapter.

2.2 Continuous Subcutaneous Insulin Infusion

The aim of diabetes treatment is to achieve tight glucose control to avoid the development of chronic diabetes complications while reducing the frequency of hypoglycaemic episodes (Hanaire, 2011).

CSII or insulin pump therapy was first introduced in the 1970s by research conducted at Guy's Hospital and the University of Yale in the United States of America (Bruttomesso et al., 2009). During that time CSII therapy was proven to provide better metabolic control in place of conventional insulin treatment methods (Brown, 2012).

According to the American Diabetes Association (ADA) (2013) there are many advantages to adopting the use of CSII in place of MDI for administering insulin. These include:

- The elimination of regular injections.
- Improved accuracy of insulin dosage.
- Reduced prospect of fluctuation in glucose levels.
- Less complex administration of bolus.
- Flexibility when adjusting insulin doses to different mealtimes.
- Improved glycaemic control.

Disadvantages highlighted by the ADA (2013) in the same report may include:

- Increased body weight.
- Possibility of ketoacidosis as a result of a catheter slip.
- Increased treatment costs when compared with MDI.
- Issues linked with being attached to the pump 24/7.
- There is a need for long term and repeated education.

Over the past 30 years there have been numerous studies and meta-analyses conducted on CSII (Hanaire, 2011, Krzymien et al., 2016, Shulman et al., 2016). On review of such research it materialises that there are multiple factors contributing to the impact of CSII on the management of T1D, the most prevalent of which are discussed in more detail in Section 1.2.1 to 1.2.4.

2.2.1 Patient Selection

A recurring feature in the literature is the requirement for appropriate patient selection prior to introducing an individual to CSII. Patient selection is extremely important as this ensures the suitability of the device for the individual. Self-management is entirely dependent on the individual and therefore physicians and clinics need to make sure that the technology is a right fit for the patient.

In the United Kingdom (UK), The National Institute for Health and Care Excellence (NICE) have introduced a set of recommended principles and guidelines that should be used by healthcare professionals to assess the suitability of individual T1D patients before proposing the use of CSII as their primary means of insulin delivery (NICE, 2008). At present, there is no equivalent standardised set of guidelines in Ireland. However, NICE recommendations are often adopted by clinics.

CSII is time consuming from both a clinical and individual point of view. This is why effective candidate selection for CSII is vital for safeguarding success (Morrison and Weston, 2013). The success of the device is entirely dependent on the individual's motivation and education in terms of how they use the device. A lack of proper education, diminished motivation, deliberate insulin omission, and behavioural attitude can affect patients' compliance (Giani et al., 2015).

Decisions on appropriate algorithms and adjusting those to the patients' way of life can enable them to achieve their therapeutic goals. While technology may compliment a patient's knowledge of their diabetes it cannot replace education and compliance, as the onus remains on the individual (Krzymien et al., 2016).

According to Krzymien et al. (2016) there is an ongoing debate as to what patients are most suited to using the insulin pump and whether the benefits of using such device are greater than MDI specifically in relation to attaining optimum glycaemic control.

2.2.2 Education and Training

CSII requires engagement from the diabetic to ensure the device is being used appropriately. The importance of education and training regimens is reaffirmed in the literature (Pozzilli et al., 2016).

Prior to using an insulin pump the patient must attend a mandatory education programme. Dose Adjustment for Normal Eating (DAFNE) is a structured education course delivered in a five-day intensive skill based education programme to people with T1D. Over the duration of the course, people learn how to adjust their insulin dosage to suit food choices, rather than working their life around insulin doses. DAFNE aims to encourage and equip people with T1D to manage their insulin regimens actively and independently (Forde et al., 2009). In order to use CSII for self-management of T1D and ensure that benefits can be realised, patients must complete the specified education and training programme (Hanaire, 2011). In addition, ongoing professional support is required. Giana et al. (2015) state that "Ensuring long-term follow-up with intensifying education and involving behavioural therapy in training could improve adherence and enhance treatment satisfaction, leading to a better glycaemic control".

Diabetes technologies may improve and reduce the burden of self-management on the day to day life of the diabetic. However, they do not remove the necessity for mandatory patient education and compliance in order to control glucose levels and thus manage their health outcomes (Krzymien et al., 2016).

2.2.3 Health outcome

Diabetes is a disease that can often lead to other health complications. While certain complications cannot be avoided, the initial severity of a number of comorbidities can be reduced through effective and rigorous self-management along with ongoing physician support (ADA, 2013). There are numerous studies for and against the use of CSII in place of MDI to improve the health outcomes of T1D. While improvements are visible in the short term, research has shown that the gap between improvements through CSII and MDI tends to diminish over a longer-term period. The Diabetes Control and Complications Trial (DCCT) found that CSII can reduce the risk of progressive retinopathy and nephropathy for at least four years versus MDI as a result of lower HbA1c levels (Lachin et al., 2000, Bruttomesso et al., 2009).

Hoogma et al.,(2006) conducted a Five Nations Trial with over 270 T1D's, the findings of which demonstrated the superiority of CSII over an Neutral Protamine Hagedorn (NPH) based MDI regimen with respect to HbA1c, reduced blood glucose levels and fluctuations, and a reduction in the incidence of severe as well as minor, episodes of hypoglycaemia.

Research conducted over the last 20 years has increasingly shown that the use of CSII can result in a multiple health benefits and improvements in overall treatment satisfaction (Giani et al., 2015).

Pickup and Sutton (2008) conducted a meta-analysis which found that patients on CSII had less hyperglycaemia and less severe hypoglycaemia as opposed to those using conventional treatment methods. Other meta-analyses showed that the frequency of severe hypoglycaemia was significantly higher with MDI than with CSII therapy. The greatest reduction was seen among patients who had had the highest number of episodes of severe hypoglycaemia while they were receiving MDI therapy (Giani et al., 2015).

Compared with traditional MDI, CSII provides a small but clinically important reduction of HbA1c levels, diminishes blood glucose variability, decreases severe hypoglycaemic episodes and offers a better way to cope with the 'dawn phenomenon' (Bruttomesso et al., 2009). The dawn phenomenon is the elevation of blood glucose from night to morning, before and after breakfast in individuals with T1D (Schmidt et al., 1981).

2.2.4 Quality of Life

CSII is associated with an improved quality of life (Muller-Godeffroy et al., 2009, Alsaleh et al., 2012, Giani et al., 2015). Self-management of T1D requires structure and rigorous planning to ensure optimum glucose levels are attained. This can be time consuming and often an overwhelming task for many individuals (Fritschi and Quinn, 2010). CSII conferred significant advantages to quality of life with improvements in treatment satisfaction, treatment impact, and perception of mental health, flexibility of eating habits and lifestyle, and reduction in diabetes-related worry (Hoogma et al., 2006). Studies have shown a positive or neutral effect of CSII therapy on quality of life, depression and anxiety (Hanaire, 2011).

When compared with MDI, CSII enhances quality of life through allowing greater flexibility with regard to eating habits, lifestyle choices and improved sleep patterns (Hoogma et al., 2006). Barnard et al. (2007) criticises the connection between quality of life and CSII, stating that "Existing literature on quality of life benefits associated with insulin pump use is limited, with conflicting, often ambiguous results and many design or methodological flaws. It is very difficult

to ascertain therefore whether CSII actually contributes to improvements in a person's quality of life".

This was later reinforced by Bruttomesso et al. (2009) who noted, "The impact of CSII on the quality of life remains unclear and poorly defined". In this study, he reviewed 17 articles on the subject between 1988 and 2005 and found the results of these studies to be conflicting, in one instance, in particular he noted 3 out of 5 randomized controlled trials reported mixed results, one reported benefit and one no measurable effect.

Despite these criticisms later studies continue to reinforce previously positive contributions stating that CSII can improve quality of life through decreased fear of hypoglycaemia, increased flexibility in quantity and timing of meals and sleep schedule, improvement in diabetes self-efficacy and independence (Nuboer et al., 2008, Muller-Godeffroy et al., 2009, Giani et al., 2015).

2.2.5 CSII Impact

The findings of the literature suggest that when paired with appropriate patient selection, education and compliance CSII impacts the self-management of T1D through enhancing the health outcomes and quality of life of the individual (Hanaire, 2011). CSII therapy can allow suitable individuals to attain their target glycaemic control and stability (Lachin et al., 2000, Bruttomesso et al., 2009).

The success of self-management through CSII is underpinned by ongoing education and support provided by healthcare professionals to adapt to the needs of the individual (Morrison and Weston, 2013). Effective CSII involves more than wearing a device. It requires a multidisciplinary team, intensive patient education and continuous follow up (Bruttomesso et al., 2009).

When the appropriate measures are followed, CSII has the ability to enhance the self-management of T1D through improved health outcomes of the individual along with enhancing their quality of life through greater flexibility (Linkeschova et al., 2002).

2.3 Continuous Glucose Monitor

CGM systems contain a subcutaneous sensor attached to a transmitter which deliver continuous reporting of glucose levels and trends to the user through a handheld monitor (Lind et al., 2017). CGM represents an important advancement in diabetes technology to facilitate optimal glucose control in T1D (Joubert and Reznik, 2012). The accuracy and usability of CGM has gradually improved over the past decade (Giani et al., 2015). Advantages of CGM include providing continuous feedback on estimated glucose values and illustrating glucose trends (Langendam, 2011).

Further research is required to determine whether the CGM device has an impact on self-management of T1D which correlate to improved health outcomes and enhanced quality of life.

The ADA (2016) published the following set of recommendations with regard to the use of CGM for glucose monitoring and control:

- When used properly in conjunction with intensive insulin regimens CGM can be a useful tool to lower HbA1c in selected T1D adults (aged 25 years or over).
- Success correlates with adherence to ongoing use of the device.
- CGM may be a supplemental tool to self-monitoring blood glucose (SMBG) in those with hypoglycaemia unawareness and or frequent hypoglycaemic episodes.
- Careful selection of patients is required prior to prescribing CGM due to varying adherence.
- Robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use.

Common themes have been identified in the literature with regard to both CSII and CGM technologies enabling the standardisation of results when reviewing the literature. Patient selection, education, health outcomes and quality of life are all deemed important factors in relation to CGM for the self-management of T1D.

2.3.1 Patient Selection

CGM technology is still considered to be relatively new therefore, the distribution of such devices must be managed appropriately for patients with T1D (ADA, 2016). Careful assessment and patient selection is vital to ensure that the device is used correctly and appropriately and can provide the individual with

the information they need in order to make informed decisions about their Diabetes (Block et al., 2008).

The extent to which benefits can be obtained from the use of CGM is dependent on adherence to using the technology and on the interpretation of data to make positive changes in treatment management (Benhamou et al., 2012). Thus, appropriate patient selection is an extremely important factor for the success of CGM.

Joubert and Reznik (2012) confirmed that compliance with the CGM device greater than 6 days per week directly correlated with its effectiveness, stating, “Frequency of sensor usage is a crucial parameter for efficacy of CGM with an additional 0.15% decrease of Hb1Ac for every one day increase of sensor usage per week”. Patient motivation and compliance in wearing the sensor is vital to success of the CGM technologies (Deeb et al., 2015).

Recommendations from previous research along with the ADA advise that CGM should be restricted to users over the age of 25 years old. A number of clinical trials have found a direct correlation between the success of CGM and age (Tamborlane et al., 2008; Deeb et al., 2015; ADA, 2016).

The van Beer et al. (2016) randomised, open-label, crossover trial adds to the findings, acknowledging that while age is a factor, patients with a higher risk of hypoglycaemia experience a greater benefit than patients with less glycaemic variability when CGM is used to monitor glucose in place of SMBG devices.

2.3.2 Education and Training

Appropriate education and training is vital to ensure the benefits of using the CGM device can be realised by the individual. Giani et al. (2015) note, that while new technologies bring promise in terms of positive outcomes, they can often underperform or fail if they are not used correctly or as intended by the manufacturer. For this reason, effective and appropriate training along with patient motivation are vital for success of the CGM.

In order to reap the benefits associated with CGM usage the individual requires two types of training. The first involves a specific educational programme and the second is in the form of ongoing support from a trained nurse specialist or healthcare professional (Benhamou et al., 2012).

Joubert and Reznik (2012) identify three important steps which should be taken by the healthcare professional when providing a patient with the device. These involve:

1. Determine the needs, expectations and goals of the individual from the CGM.
2. Provide the appropriate education adapted to the needs and requirements of the individual.
3. Provide ongoing support as required to ensure success.

Technical training on CGM is essential to optimise the reliability of results and safety of use. This training should include how to insert the sensor, the overall functioning of the system, the minimal handling of the receiver and the provision of blood glucose measurement for calibration of the system (Joubert and Reznik, 2012).

2.3.3 Health outcome

The use of CGM is associated with improvement in metabolic control in T1D, with significant short and long-term reductions in HbA1c and reduction in the duration of periods of hypoglycaemia and hyperglycaemia versus SMBG (Floyd et al., 2012).

A study from Garg et al. (2006) showed that CGM use resulted in a 23% decrease in the incidence of postprandial hyperglycaemia (Joubert and Reznik, 2012). Further research indicates that CGM may enhance the self-management of T1D in adults who have the motivation to use this technology and the capability to incorporate it into their own daily diabetes management (Tamborlane et al., 2008).

Intensive insulin therapy resulting in good glycaemic control has been shown to prevent and reduce the progression of diabetes related complications in patients with T1D. When used by patients with inadequately controlled T1D treated with MDI, the use of CGM compared with conventional treatment for 26 weeks resulted in lower HbA1c (Lind et al., 2017). Furthermore, in a randomised, open-label, crossover trial conducted by van Beer et al. (2016) of T1Ds with increased risk of severe hypoglycaemia it was found that CGM reduced the prevalence of severe hypoglycaemia when compared with SMBG.

More accurate evaluation of interstitial glucose levels during hypoglycaemic events are necessary as CGM performs poorly in the hypoglycaemic range, and the lag time between interstitial glucose and blood glucose, increased sensor sensitivity and inappropriate calibration require improvement (Damiano et al., 2013).

A meta-analysis suggests that, compared with SMBG, CGM is associated with short-term HbA1c lowering of 0.26% (Yeh et al., 2012). The long-term effectiveness of CGM needs to be determined. This technology may be particularly useful in those with hypoglycaemia unawareness and or frequent hypoglycaemic episodes, although studies have not shown consistent reductions in severe hypoglycaemia (Choudhary et al., 2013).

2.3.4 Quality of Life

CGM devices have the ability to impact quality of life of T1D individuals both positively and negatively. As a result, patient selection and education are important predecessors of using such device (Block et al., 2008). While research has identified a perception of enhanced quality of life in certain circumstances there is further investigations required over a longer period of time and a larger scale to prove this hypothesis.

Improvement of glucose control and stability or a reduction in hypoglycaemia events can be positive effects of CGM in terms of quality of life and satisfaction (Benhamou et al., 2012). In study conducted by Joubert and Reznik (2012) CGM users reported a feeling of improved efficiency and a greater satisfaction with the device while quality of life parameters were not significantly affected by the use of CGM. Lind et al. (2017) highlight that when used correctly, CGM has the ability to reduce glycaemic variability and as a result increases subjective well-being, treatment satisfaction.

Additionally, it should be noted that permanent use of the device, the triggering of sometimes false alarms and the constant viewing of glucose variations can have a negative impact on some individuals and lead to increased levels of anxiety (Benhamou et al., 2012).

2.3.5 CGM Impact

CGM has the ability to impact the self-management of adults living with T1D in a number of ways. Patient selection and education is vital to the initial use of the device to ensure adherence and compliance. Subsequently, ongoing support is also required for the individual to allow them to meet their therapeutic goals. Research has found that individuals aged 25 and over are more likely to benefit from the use of the CGM, this is reinforced by the recommendations of the ADA (2016).

While the CGM has been proven to improve glycaemic control for patients using such device there is a reliance on the individual to comply with the guidelines and instructions provided during the training programme.

In addition to these positive impacts, there are also negative outcomes associated with the use of the device. CGM can lead to increased anxiety triggered by built in alarms or the requirement to constantly check glucose levels (Benhamou et al., 2012). This can have a negative impact on quality of life which is why patient selection is extremely important to reduce possibility of negative outcomes as a result of using such device. As the literature suggests, there is further research required to determine the impact of CGM devices on T1D (Lind et al., 2017).

2.4 CSII and CGM usage

SAP therapy combines CSII with real-time CGM and has been shown to improve metabolic control while reducing the rate of hypoglycaemia in adults with T1D compared to MDI or standard CSII (Tumminia et al., 2015). Figure 1 shows the real-time CGM sensor on the surface of the skin with adjoining pin measuring interstitial glucose levels. The glucose value is then transmitted through a radio frequency to the insulin pump device.

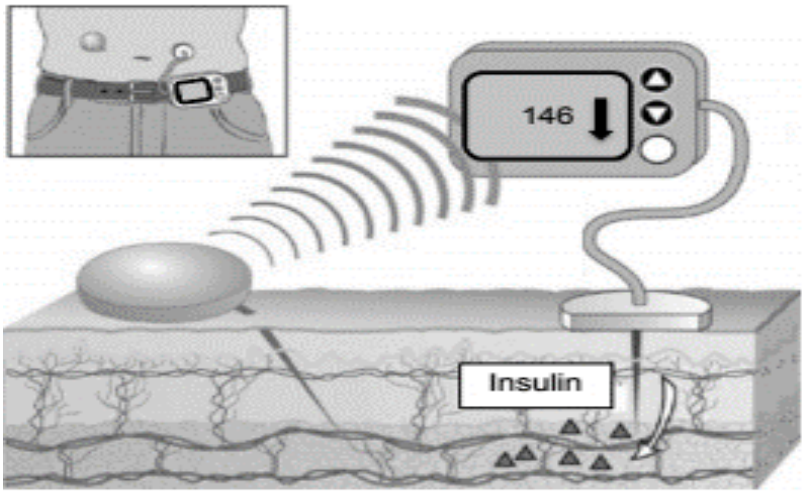

Figure 1 Sensor Augmented Pump Therapy (Tumminia et al., 2015)

Tumminia et al. (2015) identify a number of factors which contribute to the success of SAP therapy. Similar to those relevant to CSII and CGM, they include:

- Patient motivation to adopt the correct behaviours for successful self-management of T1D.
- Ensure frequent use of the CGM sensor (recommended at least 65% of total time).
- Understand and correct interpretation of data trends.
- Awareness of lag-time period.
- Suitable patient selection by the healthcare provider.
- Appropriate training on diabetes management and technical device.

A number of studies have evaluated the impact of SAP on health outcomes. When replaced with MDI, SAP therapy was found to be effective at lowering HbA1c levels in patients (Slover et al., 2012). Conversely, studies investigating the effectiveness of SAP in patients already using the insulin pump showed conflicting results, ranging from no significant benefit to significantly improved glycaemic control (McNally et al., 2010).

SAP therapy is associated with decreased time spent in hypoglycaemia compared to MDI or CSII, but few significant results were found in the rate of severe hyperglycaemic events (Giani et al., 2015).

There are a number of benefits to be achieved when using SAP therapy to manage T1D, however the technology requires hands on maintenance and control in order to work effectively and realise benefits in terms of enhanced

health outcomes and quality of life. As this concept is relatively new, further work is required in the field to determine the benefits long term.

2.5 Conclusion

There are a number of contributing factors identified in the literature which add to the success of CSII and CGM technologies. These include:

- Patient selection
- Education and training
- Health Outcomes
- Quality of Life

Each theme must be taken into consideration when assessing the impact of a CSII and CGM technology on the self-management of T1D for an individual. Appropriate patient selection emphasised in a number of studies as vital to ensure patient suitability (Block et al., 2008, Benhamou et al., 2012). Patients are required to show motivation and commitment to comply with the technology and engage effectively with the device in order to achieve their goals and ultimately improve their quality of life.

It is important to note that while technology can bring perceived benefits they may not be proportional to the time and effort required. In a qualitative study conducted by Shulman et al. (2016) to determine how physicians value insulin pumps, it was found that while technologies for T1D treatment come with high expectations, they often come with marginal benefits at increased costs.

3 Methodology

3.1 Introduction

A dynamic, well established research approach encompassing interpretive, qualitative epistemology is required to investigate the impact of CSII and CGM technology on the self-management of T1D and answer the research question. Selecting a qualitative approach ensures that participants to the study are given an opportunity to present their subjective insights and opinions on the topic while enabling objectivity through the appropriate research principles and mechanisms of epistemology.

3.2 Purpose of the Research

This research aims to gain an insight into the factors contributing to the uptake of CSII and CGM technologies in Ireland by understanding the impact of both devices on the self-management of T1D for adults living with this chronic illness. The primary goal of this exploratory research is to answer the question:

> What is the impact of CSII and CGM technologies on the self-management of Type 1 Diabetes for adults in Ireland?

The corresponding objectives of the research are to:

1. Identify the key areas contributing to the use of CSII for T1D self-management by adults in Ireland.
2. Identify the key areas contributing to the use of CGM for T1D self-management by adults in Ireland.
3. Understand the perception of CSII from real life experience.
4. Understand the perception CGM from real life experience.
5. Determine the barriers to uptake (if any) of CSII and CGM.

3.3 Research and Design

3.3.1 What is research?

Research is something that is undertaken to discover things in a systematic way and to increase knowledge (Saunders et al., 2009, p. 5). A systematic approach is adopted to ensure appropriate mechanisms are in place to define, explain, understand, criticise and analyse the research in order to validate reliability (Ghauri and Grønhaug, 2005, p. 5, Saunders et al., 2009). This approach is identified through research design.

3.3.2 Research design

Research design defines the strategic plan for the study or investigation (Creswell, 2008). It is a blueprint for conducting research with maximum governance over any influences that could hinder the legitimacy of the findings (Grove et al., 2003, p. 195). A well-structured research design provides a strategic framework for action by connecting the research question with the implementation of the research strategy (Blanche et al., 2004, p. 29).

The purpose of appropriately designing research is to ensure that the research is conducted in a logical, comprehensive manner to ensure that the results are valid, reliable and credible based on the process undertaken by the research investigator.

3.4 Research Method

When conducting research, it is important to use an approach that is fit for purpose. This is done by establishing a method best suited to the purpose of the research and thus enables the research question to be answered (Bryman and Bell, 2015).

The 'Research Onion' approach by Saunders et al. (2009, p. 108) was employed in order to select the most suitable research design and method for this study. This technique systematically determines the most appropriate mechanism for research based on a number of different layers, each of which are discussed in more detail in Section 3.5 to 3.10.

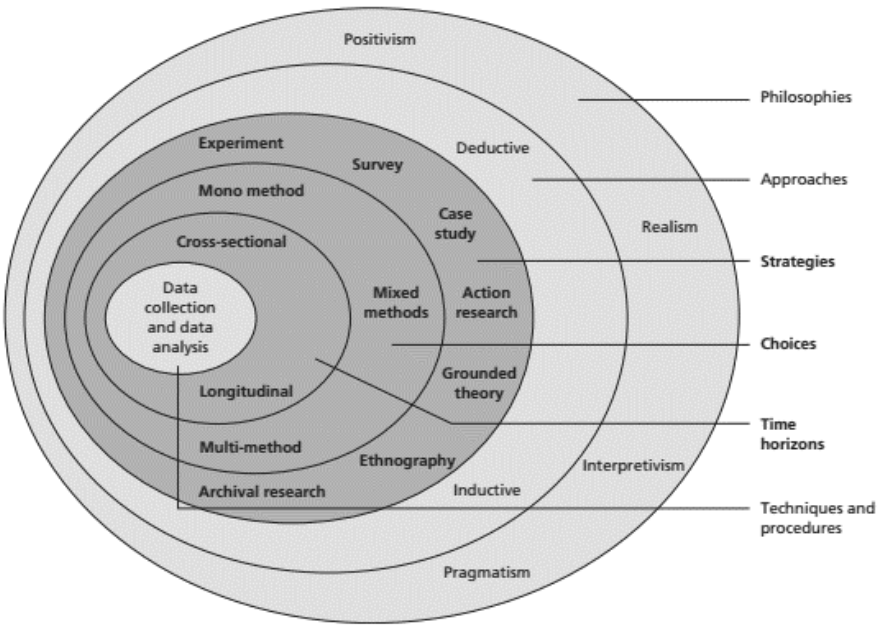

Figure 2 Research Onion by Saunders et al. 2009 p. 108

3.5 Research Philosophy

Research philosophy is the outer layer of the Research Onion and relates to the assumptions of the research based on generalisation of the world and includes assumptions based on the mind, matter, reality, reason, truth, nature of knowledge, and proofs of knowledge (Hughes, 1994).

The research philosophy is underpinned by the chosen research approach and strategy. Cognisance of the philosophical commitments made through the choice of research strategy is essential as this will have a significant impact on what is done and also in understanding what the research is investigating (Saunders et al., 2009, p. 180).

Easterby-Smith et al. (2004) highlights three reasons why the exploration of philosophy is important for research methodology. These are:

1. To refine the methods to be used in the research and simplifies the overall strategy.
2. To evaluate different methods and avoid inappropriate use or unnecessary work by identifying restrictions of the particular approaches.
3. Finally, to encourage creativity in selection of methods adopted.

Assumptions made about research are informed by ontology and epistemology. Ontology relates to the nature of reality and can be deemed objective or subjective based on those assumptions (Saunders et al., 2009, p. 110). Epistemology is a general set of assumptions about what constitutes acceptable knowledge in a particular field of study (Easterby-Smith et al., 2004, p. 31). Epistemology guides the research through the appropriate design and methodologies that distinguish between the findings and opinions of the research by informed decision making.

Saunders et al. (2009, p. 108) identifies four main philosophies associated with research. These are positivism, realism, interpretivism and pragmatism.

1. *Positivism* relies on observation and reason as a way of understanding behaviour, explanation proceeds by way of scientific description (Cohen et al., 2013, p. 7). It applies natural science methods to the study of social reality (Bryman and Bell, 2015).
2. *Realism* acknowledges that humans are affected by social forces and processes and therefore cannot be studied in the same manner as natural sciences. It takes the view that there is an external independent

reality, separate from individuals' perceptions (Bryman and Bell, 2015). Realists use a scientific approach for the collection, analysis and development of data but view their findings as evidence-based probabilities (Guest et al., 2012).

3. *Interpretivism* believes that situations are fluid and changing rather than fixed and static, events and behaviour evolve over time and are affected by context, events and individuals are unique and largely non-generalisable (Cohen et al., 2013, p. 31).
4. *Pragmatism* centrally places the research question and applies all approaches to understanding the question (Creswell, 2012). Pragmatists use a mixed method approach and work with both quantitative and qualitative data collection, using different analysis techniques (Saunders et al., 2009, p. 109).

This research adopts an interpretivist philosophical approach. This is deemed the most appropriate philosophy as it is important to understand context and not generalise when interpreting the findings of the research due to the nature of T1D. Shulman et al. (2016) highlight concern that certain diabetes management technologies are valued for their status as novel devices without providing improved outcomes in relation to the individuals' diabetes. This research aims address this issue by understanding the unique reasons behind the subjective views of those partaking in the study to determine the impact of CSII and CGM technologies on T1D.

3.6 Research Approach

Research is approached in a deductive or inductive manner (Saunders et al., 2009, Bryman and Bell, 2015). The contrast between these approaches is seen by the differing steps implemented when applied to the research process which can be either open or narrow (Bryman and Bell, 2015).

3.6.1 Deductive

The deductive approach begins by framing a hypothesis that will then form a theory (Matthews and Ross, 2014). Following the definition of the hypothesis data collection and analysis will commence with the objective of confirming the developed theory (Gray, 2013).

3.6.2 Inductive

In contrast, the inductive approach begins by collecting data which subsequently leads to a theory (Gray, 2013). The inductive approach presents

many possibilities for the research and allows considerable room for exploration of theories and related concepts (Silverman, 2013).

The main objective of this research is to determine the impact of technologies on T1D self-management for individuals in Ireland. A qualitative analysis approach is adopted in order to answer the research question by critically analysing current literature in the field and collecting primary data on the subject matter through semi-structured interviews. The selected approach for this research was inductive due to the interpretive nature of the topic, the exploratory approach to data collection and the longevity of the research.

3.7 Research Strategy

According to Saunders et al. (2009, p. 108) there are 7 approaches to research strategy, experiment, survey, case study, action research, grounded theory, ethnography and archival research.

Grounded theory encourages the discovery of theory from data through the general method of comparative analysis which involves linking findings across previous literature to assess similarities and variances in order to discover the generalizability and boundary conditions of a concept (Johnson, 2015). Grounded theory methodology is designed to enable the discovery of inductive theory and develops a theoretical justification of the general features of a topic while simultaneously grounding the account in empirical data (Wiesche et al., 2017).

The research adopts a grounded theory strategy as this method compliments the interpretive, inductive approach to qualitative research. Grounded theory focuses on the broad areas and themes of research which have been identified to make connections and reaffirm findings. This approach is adopted during the analysis of qualitative semi-structured interviews along with insight gathered from the critical analysis of existing literature specifically focused on the impact of CSII and CGM technologies on self-management of T1D.

3.8 Research Choice

The research choice relates to the method chosen to conduct the research investigation and can be mono, multi or mixed method. Saunders (2009, p. 151) highlight that mono quantitative and qualitative practices do not exist in isolation. A qualitative mono method research choice is adopted in this research as semi-structured interviews were used for the mono source of primary data collection. This choice was adopted due to the type of information and insight required.

Opinions and perceptions of technology were of great importance to this study and therefore a quantitative method was deemed insufficient for data collection. Previous literature and secondary data play an important role in forming the basis for the research and in validating the reliability of the findings.

3.9 Time Horizon

This study is cross-sectional as it focuses on the impact of technology on T1D during a given time frame, over the duration of the research. Longevity research which observes a hypothesis over time was ruled out due to the time allowance of the undertaken research. This research was conducted over an 8-month period from 1st January 2017 to 31st August 2017 during this time frame both secondary and primary data research was employed.

3.10 Techniques and Procedures

This final layer of the research onion is the core of the research and relates to data collection and analysis. This is an extremely important step as it employs techniques to safeguard the credibility of the study by emphasising procedures for the reliability and validity of the study.

3.10.1 Reliability

Reliability relates to the consistency of the findings through correct data collection and analysis techniques. Qualitative research reliability is viewed as the trustworthiness of the procedures undertaken and the data generated(Stiles, 1993). It relates to the extent of which the results of a study are repeatable in differing conditions (Bryman and Bell, 2015).

The findings of the primary research are consistent with that of the literature in terms of the impact of CSII and CGM technologies for T1D self-management in adult patients. Auditability and traceability is an important element in proving the reliability of this research (Roberts et al., 2006). Transparency is provided throughout the research by disclosing the detailed approach to research including the methodology and design. The transcribing of interviews also adds to the reliability of findings by providing traceability to the reader.

The use of computerised data analysis software packages increases reliability by applying predetermined rules for coding and categorisation built into the programme (Roberts and Woods, 2000). Coding and categorisation was used in the data analysis phase of this research and is detailed in Section 4.4. Reliability of the research is observed through transparency, coding used to

analyse data along with the consistency of findings observed from the critical analysis of previous literature.

3.10.2 Validity

Validity relates to the consistency of the findings in that they are what they appear to be about (Saunders et al., 2009, p. 157). A potential difficulty in achieving validity in qualitative research is researcher bias, which can arise from selective collection and recording of data, or from interpretation based on personal perspectives (Johnson, 1997). The impact of this on validity can be avoided through transparency of the research process allowing the reader to trace key decisions made in relation to the philosophy, context, and strategy and method of the research (Roberts et al., 2006).

This research upholds validity of the study through the use of reliable sources when conducting secondary data investigations as recommended through the TCD library database. Transparency of the primary research process is also provided in section 4 of the research which documents the data collection, interpretation and analysis phase of the study. The risk of bias was reduced as there was no previous experience with the subject matter and similarly did not know the participants prior to taking part in the study. Triangulation has been employed during the research process.

3.10.3 Triangulation

Triangulation is a qualitative research strategy which adopts multiple approaches to data gathering techniques in one study in order to develop a comprehensive understanding of the findings (Patton, 1999; Saunders et al., 2009, p. 146). Triangulation reaffirms reliability and validity of the research and contributes to the consistency, comprehensiveness and robustness of the study (Roberts, 2006).

Data triangulation refers to the use of different data sources like interview data or observational data. By means of various sampling strategies, data is collected at different times, in different social situations and on a variety of people (Carter et al., 2014).

This research employs the process of data source triangulation by adopting a qualitative approach to primary data collection and reaffirming the findings through the use of secondary data and previous published literature relating to the research topic. This approach to triangulation was taken in order to verify

the findings of the research against previous literature. Triangulation reaffirms the credibility of the findings. This was particularly important during for the research as a result of the sample size.

3.10.4 Population and Sample

In the absence of an official diabetes register it is estimated that there are approximately 16,000 people living with T1D in Ireland (Diabetes Ireland, 2017).

A total of six interviewees partook in the study. These involved both healthcare professionals and individuals living with T1D in Ireland:

1. Diabetes Regional Development Officer
2. Type 1 Diabetic
3. Type 1 Diabetes Nurse Specialist
4. Type 1 Diabetes Dietician
5. Type 1 Diabetic
6. Type 1 Diabetic

This approach to sampling is referred to as Network Sampling. Network sampling involves taking a sample size from a larger segment of a community or group tied together by a common relationship (Salganik and Heckathorn, 2004, Trotter, 2012). The varying profiles of participants, including both adults with T1D and healthcare professionals was strategically chosen with the objective to strengthen the validity and reliability of the data collated by providing a more rounded view of opinions and perceptions.

3.10.5 Data Collection

Primary data collected for the purpose of this research was conducted using interviews. Interviews are the optimum approach to data collection when conducting exploratory research in order to gain insight into participants' history, opinions and experiences (Seidman, 2006). Semi-structured interviews were held with a network sample of six people varying from professionals in the field to individuals living with T1D. A semi-structured interview is defined by a pre-set question guide that aims to provide in-depth findings through informal discussions with participants (Collis and Hussey, 2013).

A total of five open ended questions were posed to the participants during the interview focusing on their opinion and experiences with CSII and CGM technologies for self-management of T1D. The questions focused on topics with

regard to health, quality of life, data and communications, impact of technology on day to day lifestyle and openness to new technologies. See Appendix 1. These questions were strategically chosen to gain insight into the perceptions of both devices and also understand the interest in newer technologies such as the Closed Loop System.

With the approval of participants an audio recorder was used during each interview to ensure the insight provided could be validated and transcribed after the interview had taken place. During the interview, light notes were taken however, a less formal approach was maintained throughout to ensure participant engagement and openness.

Secondary data was collated during the literature review phase of the research. This formed the foundations of the theoretical framework adopted during the research. Themes identified in the literature were borrowed during the definition of the interview questions to allow for a more standardised approach to data collection, these themes were:

1. Patient Selection or Suitability
2. Education and Training
3. Health Outcomes
4. Quality of Life

3.10.6 Data interpretation

Data analysis is imperative to qualitative research as it has a major influence on the results of the research conducted (Flick, 2014, p. 3). In order to interpret and understand the data, Braun and Clarkes (2006) approach to thematic analysis was adopted using the NVivo software for computerised qualitative analysis. This involved transcribing the data, generating codes, categorising codes into themes, refining themes and finally drawing conclusions to produce findings. The use of this systematic approach means that key insights and findings were appropriately identified and captured to make connections and linkages between qualitative data from multiple sources.

3.11 Justification of approach

When deciding on an approach to carry out this research a number of considerations were taken into account. The Research Onion by Saunders (2009) was used to guide the approach and decision-making process for choosing an appropriate research method. The research incorporates an

interpretive, inductive, grounded theory, qualitative mono method, cross-sectional approach conducted over a specified number of months.

An interpretivist philosophical approach is deemed the most appropriate philosophy as it is important to understand context and not generalise when interpreting the findings of the research due to the nature of T1D. Shulman et al. (2016) highlight concern that certain diabetes management technologies are valued for their status as novel devices without providing improved outcomes in relation to the individuals' diabetes. This research aims address this issue by understanding the unique reasons behind the subjective views of those partaking in the study to determine the impact of CSII and CGM technologies on T1D.

A qualitative analysis approach is adopted in order to answer the research question by critically analysing current literature in the field and collecting primary data on the subject matter through semi-structured interviews. The selected approach for this research was inductive due to the interpretive nature of the topic, the approach to data collection and the longevity of the research.

The research adopts a grounded theory strategy as this method compliments the interpretive, inductive approach to qualitative research. Grounded theory focuses on the broad areas and themes of research which have been identified to make connections and reaffirm findings. This approach is adopted during the analysis of qualitative semi-structured interviews along with insight gathered from the critical analysis of existing literature specifically focused on the impact of CSII and CGM technologies the self-management of T1D.

A qualitative mono method research choice is adopted in this research as semi-structured interviews were used for the mono source of primary data collection. This choice was adopted due to the type of information and insight required. Opinions and perceptions of technology were of great importance to this study and therefore a quantitative method was deemed insufficient for data collection. Previous literature and secondary data play an important role in forming the basis for the research and in validating the reliability of the findings.

This study is cross-sectional as it focuses on the impact of technology on T1D during a given time frame over the duration of the research. Longevity research which observes a hypothesis over time was ruled out due to the time allowance

of the undertaken research. This research was conducted over a 7-month period from 1st January 2017 to 31st August 2017 during this time frame both secondary and primary data research was employed.

Qualitative studies aim to understand how people feel about something and why they think that way, what their perspectives are, and what a technology means to people (Kaplan and Maxwell, 2005). Due to the nature of the research question and associated research objectives a qualitative, interpretive, inductive, grounded theory approach was selected in order to understand the impact of technology on the self-management of T1D in Ireland. The research was conducted by adopting the thematic approach to analysis as defined by Braun and Clark (2006). Furthermore, triangulation was employed to ensure that credibility, reliability and validity could be instilled in the findings through the use of secondary data in the form of published literature.

3.12 Limitations

According to Davies and Hughes (2014) qualitative research is open to the following limitations:

1. The context, events, conditions and interactions cannot be replicated.
2. The time required for data collection, analysis and interpretation is lengthy.
3. The interviewer's presence may have an effect on the subjects of the study.
4. Confidentiality and anonymity present issues when selecting the findings

Mitigations were put in place to minimise the impact of such limitations prior to conducting the qualitative research. Firstly, an audio recorder was used along with note taking to ensure that all information and data provided during the interview could be gathered for analysis. A structured project plan was implemented with predetermined milestones and target dates for completion of important milestones which would allow for appropriate time management in order to analyse data gathered. Finally, participant's right to anonymity was addressed through the research ethics procedures carried out which secured approval from the Ethics committee to proceed with the research and in turn provided peace of mind to participants that their rights would be respected.

Saunders (2009) states that quality of data during semi-structured interviews can be impacted by data collection methods used and in turn may have an impact on the reliability and validity of the data. An audio recorder was used to

avoid any negative impacts on the quality of data collected during each interview.

This research is based on an interpretive philosophy. According to Gray (2013) this technique allows substantial input from the researcher and therefore, could potentially lead to biased interpretations. Interviewer bias is a major limiting factor to research findings. The risk of bias is reduced as no previous experience with the subject matter and similarly did not know the participants prior to taking part in the study. Triangulation has been employed during the research process.

The use of qualitative methods and semi-structured interviews provide research flexibility. As result of the flexibility associated with semi-structured interviews, collected data can often become difficult to analyse and can potentially lead to failure of the entire research process (Punch, 2013). In addition, the effectiveness of interviews, and especially semi-structured ones, depends considerably on the expertise of the interviewer (Galletta, 2013). This risk was reduced by following Braun and Clarks (2006) thematic analysis approach to interviews. The use of an audio recorder along with NVivo qualitative analysis software reduced the complexity of data collection and analysis.

There are a number of potential limitations to the chosen research methodology with regard to data collection, analysis, reliability and validity however, the research employs best in practice approaches and methodologies when conducting this study in order to minimise the risk of such limitations impacting on the research findings.

3.13 Research Ethics

Ethics are the standards of behaviour that guide interaction with participants and respect the rights of the participant and those impacted by the research (Saunders et al., 2009).

The ethics application was submitted to the Research Approval Committee at TCD on the 28th April 2017. The application to the committee included:

- A signed Ethical Application form.
- Participant information sheet which is provided to any participants in the study prior to agreeing to take part, a detailed account of the intended research purpose, declaration of any conflicts of interest.

- Participants consent form highlighting the rights of the participants including right to anonymity.
- Research Proposal detailing the rationale for the study, the intended participants, and any conflicts of interest.
- Intended interview questions to be asked during interview.

The application included key ethical principles such as to uphold integrity and objectivity, the informed consent of participants, the voluntary nature of participation and the right to withdraw at any time. Protection of the anonymity of participants and security of data management was also noted. Approval of the ethics application was granted by the Ethics Approval Committee on 5th May 2017. Following this approval contact was made to prospective participants whom were invited to take part in a semi-structured interview. Interviews took place over a two-week period between the 8th to the 22nd of May 2017.

3.14 Lessons Learned

When conducting this research and following the process documented in Section 3, there were a number of key learnings identified. Firstly, research design is imperative to an effective research approach and methodology for data collection and analysis. It is important to review the available literature in the field of research in order to determine the most appropriate methodology for the study.

Secondly, ethics plays a major role in justification of research. Ethics provides the leverage required to conduct interviews and creates a platform for trust and transparency between the interviewer and interviewee. The lesson learned in this instance would be to ensure that ethical approval is sought as promptly as possible in order to allow for sufficient time to undertake data collection and interviews.

Thirdly, triangulation is imperative to the credibility of one's research. This was a major lesson learned during the research process. By critically analysing the current literature in the field findings of the primary data collected were validated which enhanced the credibility of findings.

The final lesson learned relates to the process of research. The main strength of qualitative research is that it yields data that provide depth and detail to create understanding of phenomena and lived experiences (Bowen, 2005). While this investigation adopted a qualitative mono method due to resourcing and time

constraints it is felt that there would have potentially been more insight gained and value added if there was an opportunity to use a mixed method approach. That is, using both quantitative and qualitative methods when collecting data.

4 Findings and Analysis

4.1 Introduction

This chapter presents the findings of the primary research undertaken for the dissertation and provides the details of how the data collected during the semi-structured interviews was analysed to identify such findings.

The initial section describes the data collection process which involved semi-structured interviews and question formulation based on key themes identified from the literature review. These themes included patient selection, education and training, health outcomes, and quality of life. A participant profile is presented in this section which provides insight into the interviewees whom partook in the study and differentiates between the adults with T1D and healthcare professionals.

The second section provides an insight into the tools and techniques used in order to arrive at the findings. These tools and techniques were adopted throughout the research data collection phase and included providing context and background of the study to participants, appropriately recording information, semi-structured approach and finally the approach to interview execution.

Thirdly, the Data Preparation section explains the steps taken to prepare the data for analysis in order to enable the most efficient and effective approach to data analysis. Data preparation included listening back to audio recordings of each interview and transcribing the interview into a comprehensive word document. A total of six word documents were uploaded and analysed using the NVivo qualitative software analysis tool.

The fourth section details the steps taken to analyse the data including coding and categorisation. It provides a justification for using the NVivo application as a result of its efficiency and reliability.

The fifth section of this chapter provides an insight into the five themes relating to the impact of CSII and CGM technologies on the self-management of T1D for adults. These themes are:

1. Patient Selection refers to the need for healthcare professionals to choose the right candidates for certain devices in order to ensure they

are the right fit and appropriate for the individuals way of life. This can also be referred to as Suitability.

2. Education and Training refers to the pre-requisite information and knowledge sharing that must be complete prior to using the technologies for self-management of T1D.
3. Health Outcomes refer to the ability of the technologies to alter or change the medical outcomes of the individual in terms of metabolic control along with diabetes related complications.
4. Quality of life refers to the perceived standard of health, comfort, and happiness experienced by an individual as a result of using the technologies.
5. Data and Communication relates to the information produced from both devices and how that information is interpreted to make decisions relating to the management of the individuals' illness.

The final theme of Data and Communications was not identified during the literature review and however, it was discussed in detail during the interview phase and as a result a new theme was identified.

Finally, the findings section of this chapter is the most important and provides insight into the findings of the primary research based off the analysis of the data. The findings have been divided into sub sections to display insight for the CSII technology followed by the findings of the CGM against each of the five themes.

4.2 Data Collection

As this research followed a qualitative methodology, a semi-structured approach was adopted during interviews. Longhurst (2003) defines a semi-structured interview as "a verbal interchange where one person, the interviewer, attempts to elicit information from another person by asking questions". Although a list of predetermined questions are prepared, semi-structured interviews often unfold in a way that affords the participants the opportunity to discuss and explore issues they feel are important (Clifford et al., 2010, p. 144).

Open questions were posed to the participant during interviews which were each centred on a particular theme relating to the study. The questions prompted discussion with the interviewee and thus created insight into their individual opinions on the impact of CSII and CGM technologies on the self-

management of T1D for adults in Ireland. Themes identified in the literature review include:

1. Patient Selection
2. Education and Training
3. Health Outcomes
4. Quality of Life

The interviews were held over a period of two weeks from May 8th to May 22nd 2017. Both face to face and telephone interviews took place during this time. Face to face interviews were held at various locations including on campus at TCD, an Endocrine clinic in Dublin and at Central Park Industrial Estate in Dublin. Interviews lasted between 45 and 60 minutes. A total of six interviews were held, this was due to the 60% invitation to interview response rate. Details of the participation profiles are shown in Table 1.

4.2.1 Participants

In order to gain a better understanding of the impacts of technologies on diabetes care in Ireland a number of potential candidates were invited to take part in the research. A total of 10 invitations were issued to a range of individuals from professionals in the field of endocrinology to those individuals living with T1D in Ireland aged 18 and over. Of the 10 invitations issued a total of 6 participants responded accepting the invitation. Table 1 provides a profile of each of the candidates whom took part in the study.

Interview number	**Profile**	**Location**	**Years' experience**
Interviewee 1	Diabetes Regional Development Officer	Mayo	>20
Interviewee 2	Type 1 Diabetic	Dublin	<10
Interviewee 3	Type 1 Diabetes Nurse Specialist	Dublin	>20
Interviewee 4	Type 1 Dietician	Dublin	>8
Interviewee 5	Type 1 Diabetic	Kildare	<5
Interviewee 6	Type 1 Diabetic	Dublin	>20

Table 1 Participant Profile

A variety of participant profiles were strategically chosen with the objective to strengthen the validity and reliability of the data collated. Spanning across both

healthcare professionals and individuals living with T1D allows for a more rounded view of the research topic as insights are given from different perspectives.

4.2.2 Tools and techniques

A number of tools and techniques were adopted from the literature based on research best practice during the data collation process to ensure that the interview approach was as efficient and effective as possible. These included:

1. Providing appropriate context and background of the research to the participants.
2. Using appropriate resources to record information.
3. Semi-structured approach to interviews.
4. Identifying the phases involved in the execution of interviews.

Context

Prior to participating in the interviews candidates were provided with an information form which had been approved by the Ethics Committee at TCD, see Appendix 2. This form stated the objective and purpose of the research and provided context to the participant by disclosing a brief background into the reasons for conducting such research. Participants were advised that questions were not mandatory and they had the right to decline any question posed to them. Participants were also required to sign a consent form which allowed the use of their anonymised data during the findings and analysis of the research.

Recording information

In order to ensure that the findings could be efficiently gathered an audio recorder was used to record the interview with the permission of the participants. This allowed engagement and attention to be maintained throughout the interview into the insight provided by the participant as focus was on the conversation and not on note taking. Key learnings and opinions of the interviewee were also jotted down during the interview. After each interview, audio recordings were listened to and the interviews were transcribed into a word document. Appendix 3 contains a sample of interview transcript.

Semi-structured interviews

As the interviews were semi-structured this allowed the interviewee to provide their views and allowed them to discuss their opinions on the topic in great

detail. The questions posed were open ended and this meant that they were open to opinions and not simply a yes or no answer.

Interview execution

According to Whiting (2008), there are six key steps of the interview phase. These are:

1. Rapport Building: Building a relationship throughout the entire interview is extremely important as it creates a calm environment and builds trust with the interviewee.
2. Apprehension: The initial part of the interview can often present elements of doubt or hesitation to answer honestly (DiCicco-Bloom and Crabtree, 2006). Conversing and getting to know the individual before the interview formally begins can reduce apprehension and create a more relaxed atmosphere.
3. Exploration: As the interview evolves, the interviewee begins to provide more comprehensive explanations of their experiences reinforced by the use of open ended questions (DiCicco-Bloom and Crabtree, 2006).
4. Cooperative: At this stage a comfort level is reached and there is the potential for more free discussion.
5. Participation: This is achieved when the interviewee guides and teaches the interviewer based on their experiences (DiCicco-Bloom and Crabtree, 2006).
6. Concluding: This is the final stage of the interview. At this point both parties should feel comfortable and ready to finish.

4.3 Data Preparation

An audio recorder was used as the primary source of data collection while notes on insights were also jotted down during the discussion. This ensured that no data or insights were lost during the interview process. Following each interview, the recorded information was transcribed into a word document. The information was anonymised and each interviewee was identified by a randomly allocated number between 1 and 6 for inclusion in the findings. Audio recordings and transcripts were stored on a secure USB stick and locked away in a safe. Transcribing the information from each interview prepared the data for analysis. Once transcripts were created they were uploaded to NVivo for qualitative data analysis.

4.4 Data Analysis

Computer-assisted qualitative data analysis software (CAQDAS) was used to analyse the raw data collected during the interview phase. Data analysis in qualitative research predominantly involves coding or categorising the data. This requires making sense of large amounts of data by reducing the volume of raw information, followed by identifying significant patterns, and finally drawing meaning from data by building a logical chain of evidence (Patton, 1999).

Coding the data is the most important stage in the qualitative data analysis process and involves subdividing the large amount of raw data, and subsequently assigning them into categories (Stiles, 1993).

NVIVO was the chosen software to analyse the raw primary data of the study as this came recommended by the research supervisor to the study. The tool enables researchers to code documents in an efficient and reliable manner (Peh and Low, 2013). The tool enables the storage of the individual findings and research results in one central location (Silver and Lewins, 2014).

The transcripts from each interview were uploaded to the application and the key nodes or themes were identified. Using this software ensured that clear connections between the findings were achieved by creating insight into the recurring themes throughout each interview. The tool enables prompt identification of trends and patterns in the data which form the basis for the research findings.

4.5 Themes

The primary research presented five themes as a result of participant feedback during interview, four of which were common findings during the literature review. These themes related to the both CSII and CGM technology in terms of their ability to impact the self-management of T1D for adults. The five themes are represented in Figure 3.

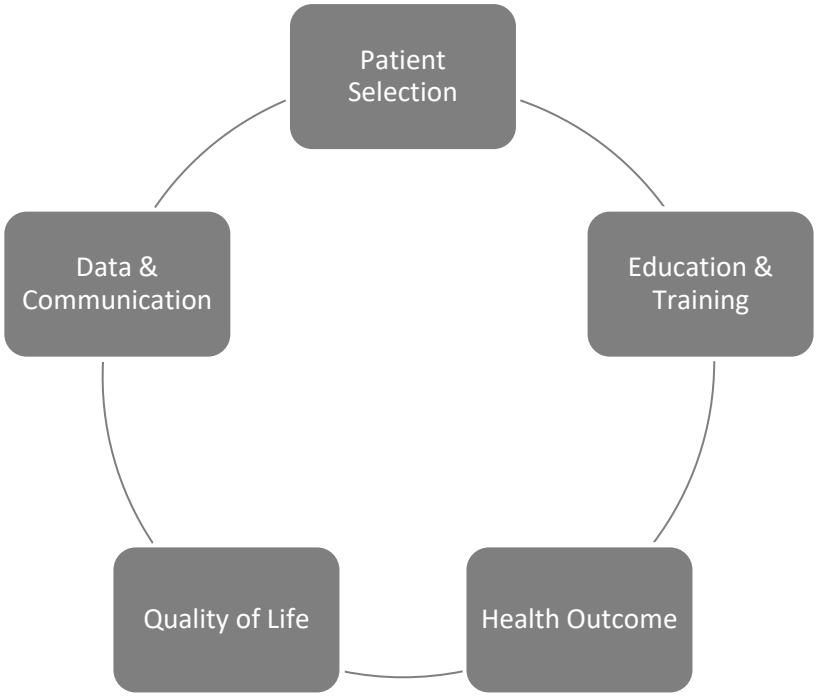

Figure 3 Research Findings

1. Patient Selection refers to the need for healthcare professionals to choose the right candidates for certain devices in order to ensure they are the right fit and appropriate for the individuals way of life. This can also be referred to as Suitability.
2. Education and Training refers to the pre-requisite information and knowledge sharing that must be complete prior to using the technologies for self-management of T1D.
3. Health Outcomes refer to the ability of the technologies to alter or change the medical outcomes of the individual in terms of metabolic control along with diabetes related complications.
4. Quality of life refers to the perceived standard of health, comfort, and happiness experienced by an individual as a result of using the technologies.
5. Data and Communication relates to the information produced from both devices and how that information is interpreted to make decisions relating to the management of the individuals' illness.

4.6 Qualitative research findings

Careful analysis of the findings of the primary research conducted during the data collection phase of the study suggest that both CSII and CGM technology have the ability to impact the self-management of T1D for adults living in Ireland. These findings are categorised into five themes identified during both the primary and secondary data analysis, these include:

1. Patient Selection
2. Education and Training
3. Health Outcomes
4. Quality of Life
5. Data and Communications

Appropriate patient selection and suitability is vital for the success of both CSII and CGM devices. An important finding mentioned in all six interviews is that the use of the technology is completely dependent on the individual. This is in large part due to the fact that both devices require 24-hour attachment to the individual which was noted as the main deterrent for adopting the devices. In spite of this, the interviewees that used the insulin pump said that they 'could not imagine life without it' as it makes self-management much easier.

Prior to using either device an intensive education programme is required to teach the individual how to manage their diabetes on a daily basis, count carbohydrates and adjust insulin dosage accordingly. This was found to be an important prerequisite for device usage.

The insulin pump was noted for having a positive impact on health outcomes of the individual with almost immediate improvements observed from when they CSII therapy commenced. CGM was not deemed to have an impact on health outcome by the six interviewees.

Both devices were deemed to introduce a level of flexibility to the life of the diabetic in terms of making decisions and managing their diabetes when out and about. Furthermore, the CGM was noted for having both a positive and negative impact on quality of life. This is due to the ability for the device to provide peace of mind for the users however it was also noted that constant checking of the CGM device can often times fuel anxiety for the individual.

There is a need to integrate the data from technologies in order to provide a holistic view of information for both the individual and healthcare professionals to enable more efficient decision making. It was noted by the healthcare professionals that gathering data and collating together to draw conclusions can be quite labour intensive and requires data from multiple sources.

CSII and CGM technologies facilitate T1D self-management, however, the responsibility and onus lies with the individual and their support network to leverage technology in order to better manage T1D. The detailed findings of the primary research undertaken in the form of semi-structured interviews are provided in Section 4.6.1 and 4.6.2.

4.6.1 CSII

Of the six participants interviewed, two out of three healthcare professionals were currently working with insulin pump users while one had previous experience but is now focused on T2D. Two out of three T1D participants involved in the study used CSII therapy for insulin administration.

The findings of the research in terms of the impact of the CSII technology on T1D self-management are as follows:

4.6.1.1 Patient Selection

Suitability and patient appropriateness is extremely important prior to prescribing CSII for an individual with T1D. This is in large part due to the hands-on approach required to manage such device. Individuals are required to have a motivation to operate the CSII device along with the commitment to comply with the guidelines for using the technology as the success of the device is completely dependent on the person

"If the person is suitable they can definitely get better control of their diabetes through the pump. The patient must be taken into account and consideration given as to whether the technology is suitable for them with regard to lifestyle. For example, those not used to technology tend to dislike the pump and use of the pump would not be recommended for those who are prone to anxiety related to diabetes management".

Interviewee 3

"While the pump takes away from injections I don't think it reduces the amount of time spent managing diabetes. It still required hands on management".

Interviewee 5

"Those who use the pump tend to really like it. We have only seen two cases out of about 80, where the patient returned the pump to go back on the pen".

Interviewee 4

4.6.1.2 Education and Training

Prior to using the pump, the individual must attend a mandatory education programme. There are two education programmes offered in Ireland for T1D these are the Berger course and the DAFNE course (Forde et al., 2009 p. 11).

- The Berger course is a two-and-a-half-day intensive course which teaches attendees how to adjust their insulin dose depending on their food choice. The course also focuses on improving diabetes self-management skills.
- The DAFNE course takes five days to complete. In this course, people learn how to adjust their insulin dosage to suit their free choice of food, rather than having to work their life around their insulin doses. DAFNE aims to encourage and equip people who have T1D to manage their insulin regimens actively and independently.

The programme offered to T1D patients will vary depending on the clinic. Diabetes management requires a lot of learning in the initial stages. This can often fuel anxiety, for this reason CSII is not recommended for newly diagnosed adults.

"There is an education programme required first before going onto a pump. This shows the person how to carb count and other important self-management tasks".

Interviewee 2

"There is a lot of learning and responsibility involved in managing an insulin pump".

Interviewee 5

The level of education required alongside already existing courses in order to adopt insulin pump technology may be a deterrent for individuals to uptake the

technology. Diabetes technology for self-management is dependent on education from healthcare professionals not only in the initial stages of diagnosis but on an ongoing basis in order to enable and empower the diabetic to manage their illness.

4.6.1.3 Health Outcomes

CSII was noted by a 5 of the 6 participants interviewed for directly improving diabetes related health outcomes of the user. The insulin pump was thought of by those who used it and those who work with it as an excellent technology for suitable candidates. Once confirmation of patient suitability is achieved the individual is provided with the relevant training and support required to use the pump. CSII delivers insulin in a much more efficient manner when compared to MDI. As a result, improvements of glycaemic control are observed almost immediately.

"Insulin pump allows for tighter blood glucose control".

Interviewee 1

"Once I went on the pump I saw an improvement straight away".

Interviewee 2

"There is good evidence that they improve glycaemic control in adults with T1D. There is also stronger evidence that the insulin pump improves HbA1c levels".

Interviewee 4

"The CSII allows the individual to manipulate dosage more quickly".

Interviewee 3

4.6.1.4 Quality of Life

The insulin pump replaces the need for the individual to physically inject insulin in some cases up to six times a day. The insulin is administered through a site on the individuals' abdomen which is changed every 2 to 3 days. The pump has the ability to provide greater flexibility as it allows the individual to input information based on their carbohydrate consumption or physical activity levels and will release required dosages when prompted by the individual. Background insulin is delivered also which can greatly enhance the individuals sleep pattern throughout the night.

Two out of three interviewees with T1D used CSII for administering insulin. Greater flexibility leading to a better quality of life was noted by both users of the CSII device.

“The insulin pump takes a lot of getting used to. The fact that there is no more need to use the pen to inject is great as it gives me more flexibility when out and about with friends”

Interviewee 5

This was reaffirmed by one professional whom stated that:

“It provides flexibility in their daily lives and allows people to think about the pump in the same way that the pancreas works”. “It allows flexibility and unpredictability in daily life, whether you are active, inactive, have several meals or just one”.

Interviewee 4

CSII was also noted for having a potentially negative impact on the quality of life for the individuals using the device. This will vary based on the individual however, it relates to the fact that the device is visible and therefore removes the anonymity associated with their illness.

“Patients are less open to using the pump. I think it is the wearing of the pump puts them off”.

Interviewee 4

“I don't use the insulin pump. I don't like the idea of being attached to something and the fact that it is visible to others removes the anonymity of my diabetes. Especially at work this is something which I don't want to define me”.

Interviewee 6

4.6.1.5 Data and Communication

The theme of data relates to the information produced by each of the technologies. Each technology has the ability to produce insight and reports on trends and metrics. Some of these reports include device usage, insulin level, or the duration of time the device is disconnected along with many more. There are a number of different uses of the data, the main one being that it can be used by the individual to have meaningful and fact driven conversations with their healthcare specialists. In this instance, the theme of data has been broken

into a number of key characteristics which were revealed during the analysis of interview transcripts. These include accuracy of the data, the ability to report on the data and finally the longevity of the data.

Accuracy of data is dependent on the appropriate use of the device. This is why it is imperative that the patient is deemed suitable for using such device and demonstrates motivation and compliance when operating the CSII device. Education, training and ongoing specialist support provide reduce the threat of accuracy issues with the individual use of the device as the person is equipped with the knowledge required to optimally use the device.

CSII technology has the ability to create reports based off the data produced. This information is gathered in an application associated with the individual piece of technology. The information from each device is manually printed off and used during appointments with the T1D patient and their healthcare team. The important thing to note here is that the onus to collate such information is entirely on the individual. Similarly, once data is gathered from the reports and brought to the clinic not all information is integrated. As a result, this makes decision making and connecting scenarios more onerous and time consuming as there a number of attributes which have an impact on the individual's diabetic outcome.

"Gathering data can be clunky"

Interviewee 2

"We look very much at the patterns over time and then look to the day to day. There are a number of considerations we need to look at when reviewing the data. These include carbohydrate intake, insulin, blood glucose levels. Gathering this information is entirely dependent on whether the patient uses the pump correctly and inputs the correct information into the pump".

Interviewee 3

"There is a need to look at finding better ways to integrate the glucose data, with exercise, food etc. From a healthcare professionals point of view using different software's and systems with each device can be difficult to navigate".

Interviewee 4

Longevity of the data is associated with how long or how far back the data can be used to inform clinical decisions. As T1D is managed on a day to day basis the clinic will not use data further back than 14 days. While the trends over time can be useful to the individual from the perspective of looking at their illness long term solely from an information point of view, it cannot be used in a clinical setting.

"We use new data as we could not deal with far back data. It is based on the most recent timescale for example, the last 5 days. If the patient has downloaded more we may use up to 2 weeks however, any further back cannot be used for clinical decision making".

Interviewee 3

There are a number of factors which contribute to the theme of data. In the case of this research focus was on the accuracy of data, the reports created and the longevity of the information. From this the conclusion is drawn that data accuracy is dependent on the individual in order to input the appropriate information into the device. From a reporting perspective, there is a need to integrate data from multiple sources in order to be able to draw conclusions and use the information to make clinical decisions. This can be a time-consuming process. Finally, the information used in making clinical decisions must be recent as T1D can vary in terms of glycaemic levels amongst other important attributes. Decisions cannot be made on historical data older than 14 days at a maximum.

4.6.2 CGM

The CGM device is relatively new in Ireland while the three healthcare professionals interviewed were familiar with the device none of the T1D interviewed had experience with using the technology to monitor blood glucose levels.

All three healthcare professionals partaking in the study noted that there appeared to be a misunderstanding relating to the difference between the CGM and the flash glucose monitor as the flash monitor does not continually monitor glucose. The flash glucose which has been available on the market since October 2016 provides a reading when the site is scanned, this reading is interstitial glucose and not the cells of the blood, therefore the reading will differ from a reading which draws blood to test (Donaghy, 2016). Healthcare

professionals noted that when patients are informed that the use of CGM required calibration and does not completely remove the need to finger prick they are often disheartened.

4.6.2.1 Patient Selection

The theme of usability refers to the ease of use or user friendliness of each device. The most obvious point to note is that for both devices the user is required to be attached to it 24/7. Therefore, this can deter users from adopting such technologies. The participants of the interviews reaffirmed this idea as it was noted that such technologies are not suitable for everyone.

"CGM devices are available on the long-term illness scheme. The use is recommended based on a person's clinical need. This means that if someone wants the CGM, they may not necessarily get it".

Interviewee 1

4.6.2.2 Education and Training

The CGM device is used to monitor blood glucose on an ongoing basis. It is important to note that such technology does not 100% replace the finger prick method as the device requires recalibration up to three times daily. More education is required to inform individuals of the use of CGM technology.

"There has been an upsurge in the number of people asking about the CGM device"

Interviewee 3

"There is a misunderstanding and assumption that CGM replaces blood glucose monitoring, this often creates a challenge when patients enquire about the devices. They are often disappointed when they realise that it does not replace the need to finger prick"

Interviewee 4

The research suggests that there is a need for more education to inform patients of the usage and capability of CGM devices, this is largely due to the unawareness and common misunderstandings made between the CGM and flash glucose monitoring device.

4.6.2.3 Health Outcomes

The CGM device provides information to the individual about their blood glucose levels on a real-time basis and removes the need to finger prick at regular intervals for glucose monitoring. However, a finger prick reading is required at least once per day to calibrate the device. The device gives the individual the ability to decide whether they need to react to their blood glucose levels at any given point in time, based on the readings. The device also has the ability to warn the individual when glucose levels exceed or fall below a predefined level.

While the study did not explicitly identify a direct correlation between the CGM device and improvement to health outcomes of the diabetic, the device enables the individual to make more informed decisions regarding blood glucose levels and can reduce uncertainty regarding their blood sugar levels.

4.6.2.4 Quality of Life

Flexibility in terms of this study relates to the ability of the diabetic to live somewhat flexibly regarding decisions made throughout the day. Diabetes management requires structure and pre-planning with regard to food intake and physical activity. The use of technology can somewhat reduce the burden and overhead on this for the individual.

“Technology removes guessing and makes it easier to manage diabetes on a day to day basis”.

Interviewee 2

The research found a correlation between the CGM device and the quality of life of the patient was noted by all three healthcare professionals interviewed with regard to the association between the CGM technology and increased anxiety in a number of patients. This is usually as a result of the fact that they monitor glucose levels at any given time which means that they could react to something that may not be required. This can in turn lead to information overload or what the professionals call ‘Diabetic Burnout’.

“Information overload fuels anxiety”.

Interviewee 3

In spite of this the CGM technology was praised by two healthcare professionals for providing peace of mind on the go for individuals that use the CGM for glucose monitoring.

“I think it is a good tool for active people as it provides flexibility when on the go”.

Interviewee 1

“It can really help for example when getting into the car. They can take a quick look at their device and check to see if I am ok. It provides the individual with reassurance when on the move”. The devices also have the ability to send alerts or warnings based on when levels reach a certain predetermined limit. For the individual, “It means that they have peace of mind and do not always have to eat to keep blood glucose levels up”.

Interviewee 3

The research suggests that the ability of CGM to impact on quality of life is largely dependent on the individual. Unfortunately, in this instance real-life user experience was not gained from the perspective of a person with T1D as the participants of the interviews did not use such device.

4.6.2.5 Data and Communication

The theme of data relates to the information produced by each of the technologies. Each technology has the ability to produce insight and reports on trends and metrics. Data from the CGM device is instantaneous and can be used by the individual to guide decision making.

Despite this, an interesting discovery during the interview phase is that CGM reports cannot be used by to make clinical decisions. This is in large part due to the accuracy as a result lag time associated with the monitoring of glucose from interstitial cells versus and blood cells.

“The CGM data is not used to make clinical decisions”

Interviewee 4

A useful attribute of the device is the ability to programme the device to alert the user if glucose levels drop below or go above a pre-determined level. This

enables the user to take a proactive approach to self-management in terms of taking precautions to avoid hypoglycaemic episodes.

The findings of the data analysis suggest that while CGM is not used to make clinical decisions, the individual can benefit from the real-time data produced by the device in terms of monitoring their blood glucose levels to achieve good glycaemic control and avoid hypoglycaemic episodes through the use of alarms.

4.7 Summary of findings

The finding of the primary research conducted during the data collection phase of this dissertation suggest that technology has the ability to impact the self-management of T1D for adults living in Ireland in a number of ways. These have been identified through the themes highlighted in the research. These are patient selection, education and training, health outcomes, quality of life and data and communications.

Appropriate patient selection is vital to ensure patient suitability to using both CSII and or CGM technologies for the self-management of T1D. This is in large part due to the impact of the device on the patient's quality of life in terms of the need to wear the device 24/7. Motivation engagement and compliance are required from the patient in order to achieve positive outcomes of using both devices.

Education is one of the most important attributes of self-management. There are a number of factors that must be managed closely in order to control T1D and blood sugar levels and reduce the risk of the individual suffering from diabetes related illnesses. These include carbohydrate counting, bolus and basal counting along with consideration for activities including exercise or even alcohol consumption.

"Technology requires a steep learning curve. It's not suitable for someone newly diagnosed".

Interviewee 1

CSII is associated with improving diabetes related health outcomes of the user. The insulin pump was thought of by those who used it and those who work with it as an excellent technology for suitable candidates. Once confirmation of patient suitability is achieved the individual is provided with the relevant training

and support required to use the pump. CSII delivers insulin in a much more efficient manner when compared to MDI. As a result, improvements of glycaemic control are observed almost immediately. While the study did not explicitly identify a direct correlation between the CGM device and improvement to health outcomes of the diabetic, the device enables the individual to make more informed decisions regarding blood glucose levels and can reduce uncertainty with regard to their blood sugar levels.

Both devices were deemed to introduce a level of flexibility to the life of the diabetic in terms of making decisions and managing their diabetes when out and about. This in turn is associated with a perceived improvement in the quality of life of the individual. Conversely, the fact that both devices are attached to the individual 24 hours a day was associated with deterring people from using the devices due to the reduced anonymity of the individuals T1D along which in turn could fuel anxiety. Despite this, the interviewees that used the insulin pump said that they could not imagine life without it as it makes self-management much easier.

There is a need to integrate the data from both technologies in order to provide a holistic view for both the individual and healthcare professionals to make better decisions. It was noted by the healthcare professionals that gathering data and collating information to draw conclusions can be quite labour intensive and requires data from multiple sources.

The outcome or impact of the use CSII and CGM for self-management of T1D is completely dependent on the individual. For this reason, not all individuals with T1D are suited to using the technology. Technology has the ability to impact the self-management of T1D for adults in Ireland in a number of ways which have been identified in relation to patient selection, education and training, health outcomes, quality of life and data and communications. Technology acts as a facilitator and enabler however, it does not directly manage diabetes. The onus still falls with the individual to closely manage and monitor their insulin levels and make both proactive and reactive decisions for optimum glycaemic control.

5 Conclusion and Future Work

5.1 Introduction

This final chapter provides an overview of the details of the research, highlighting the findings and discussing whether the research question has been answered. It also includes recommended future work to be carried out relating to the field of study.

The research set out to understand the factors contributing to the uptake of CSII and CGM technologies by adults with T1D in Ireland. This was achieved by conducting a critical analysis of the current literature in the field along with qualitative primary research in the form of semi-structured interviews, to determine the impact of both CSII and CGM technologies on the self-management of T1D in Ireland from the perspective of diabetics and healthcare professionals. The main purpose of this research was to answer the research question:

> What is the impact of CSII and CGM technologies on the self-management of Type 1 Diabetes for adults in Ireland?

5.2 Research Findings

The literature review of the study established four common themes contributing to the impact of both CSII and CGM on the self-management of T1D. These include patient selection, education and training, health outcome and quality of life.

5.2.1 Impact of CSII

As stated in section 2.2.5, when coupled with appropriate patient selection and an effective education programme, CSII has the ability to positively impact self-management of T1D by enhancing the health outcomes and quality of life of the individual (Hanaire, 2011). CSII therapy allows suitable users to attain optimum glycaemic control and stability (Lachin et al., 2000, Bruttomesso et al., 2009). This result was endorsed during semi-structured interviews where participants using CSII noted seeing benefits almost immediately in terms of improved stability of glycemic levels along with increased flexibility when switching from MDI. The success of self-management using CSII is underpinned by ongoing education and support provided by healthcare professionals which adapt to the needs of the individual (Morrison and Weston, 2013). During interview,

healthcare professionals stressed the need to ensure that the mandatory education and training programmes were complete prior to considering a patient for a CSII. Furthermore, if the appropriate measures are followed, CSII has the ability to enhance the self-management of T1D through improved health outcomes of the individual along with enhancing their quality of life through greater flexibility.

5.2.2 Impact of CGM

Section 2.3.4 CGM has the ability to impact the self-management of adults living with T1D in a number of ways. Patient selection and education is vital for the initial use of the device in order to ensure adherence and compliance. Healthcare professionals stressed the importance of patient suitability for using the device as it requires motivation and compliance and must be worn at least 70% of the time in order to see benefits (Deeb et al., 2015). The ADA (2016) recommendations that the CGM is used in suitable candidates above the age of 25 years. Subsequently, ongoing support is required for the individual to allow them to meet their therapeutic goals. While the CGM has been proven to improve glycaemic control, for patients using such device there is a reliance on the individual to comply with the guidelines and instructions provided during the training programme (Floyd et al., 2012).

Conversely, there are negative outcomes associated with the use of the CGM device with regard to quality of life. CGM can lead to increased anxiety as a result of triggering alarms and alerts for glucose levels (Benhamou et al., 2012). Anxiety was observed by healthcare professionals who subsequently noted for some patients the constant flow of information can trigger anxiety and lead to diabetic burnout or fatigue. As the literature suggests there is further research required to determine the impact of CGM devices on T1D (Lind et al., 2017).

5.3 Research Recommendations

The objectives of the research were:

1. Identify the key areas contributing to the use of CSII for T1D self-management by adults in Ireland.
2. Identify the key areas contributing to the use of CGM for T1D self-management by adults in Ireland.
3. Understand the perception of CSII from real life experience.
4. Understand the perception CGM from real life experience.
5. Determine the barriers to uptake (if any) of CSII and CGM.

5.3.1 Contributing factors of CSII usage

Appropriate patient selection along with an effective education and training programme have been identified as the key areas contributing to the use of CSII devices for self-management of T1D for adults in Ireland.

5.3.1.1 CSII Patient selection

A recurring feature in the literature and semi-structured interviews was the requirement for appropriate patient selection prior to introducing an individual to CSII. Patient selection is an extremely important attribute to ensure suitability of the device for the individual. Self-management is entirely dependent on the individual and therefore physicians and clinics need to make sure that the technology is a right fit for the patient. As noted by an interviewee, CSII is time consuming from both a clinical and individual point of view. This is why effective candidate selection for CSII is vital for safeguarding success (Morrison and Weston, 2013).

The success of the device is entirely dependent on the individual's motivation and education in terms of how they use the device. A lack of proper education, diminished motivation, deliberate insulin omission, and behavioural attitude can affect patients' compliance (Giani et al., 2015). There is an ongoing deliberation as to what patients are most suited to using the insulin pump and whether the benefits of using such device are greater than MDI specifically in relation to attaining optimum glycaemic control (Krzymien et al., (2016).

5.3.1.2 CSII Education and Training

CSII requires constant engagement from the individual to ensure the device is being used appropriately. The importance of education and training regimens is reaffirmed in the literature and the semi-structured interview phase. Prior to using an insulin pump the patient is required to attend a mandatory education

programme. The programme will vary depending on the clinic as there are currently two courses available for T1D in Ireland, the DAFNE and the Berger course. The aim of these training programmes is to enable individuals with T1D to actively and independently manage their illness (Forde et al., 2009). Patients must complete the specified education and training programme in order to use CSII for self-management of T1D and ensure that benefits can be realised, (Hanaire, 2011). Additionally, ongoing support and education can increase adherence and treatment satisfaction leading to improved glycaemic control (Giani et al., 2015). Diabetes technologies may improve and reduce the burden of self-management on the day to day life of the diabetic however, they do not remove the need for patient education and compliance (Krzymien et al., 2016).

5.3.2 Contributing factors of CGM usage

In agreement with factors contributing to CSII usage, appropriate patient selection and education and training have also been recognised as the key determinants for consideration of the use of CGM devices for self-management of T1D for adults in Ireland.

5.3.2.1 CGM Patient selection

CGM technology is still considered to be relatively new, therefore the distribution of such devices must be closely managed for patients with T1D (ADA, 2016). Careful assessment and patient selection is vital to ensure that the device meets expectations and the needs of the individual (Benhamou et al., 2012). Furthermore, the extent of benefit realisation from CGM is dependent upon adherence to the use of the technology and on the interpretation of data to make positive changes in treatment management (Benhamou et al., 2012). For this reason, appropriate patient selection is an extremely important factor for the success of CGM as patients must express motivation to comply with the guidelines for use of the device. The ADA, backed by numerous studies, recommends that CGM should be restricted to users over the age of 25 years old. A number of clinical trials have found a direct correlation between the success of CGM and age (Tamborlane et al., 2008; Deeb et al., 2015; ADA, 2016).

5.3.2.2 CGM Education and Training

Similarly, appropriate education and training is vital to ensure the benefits realisation of CGM usage. Although novel technologies bring promise of positive outcomes, it not used correctly as the manufacture intended then they can often fail (Giani et al., 2015). For this reason, effective and appropriate training along

with patient motivation are vital for success of the CGM. In order to reap the benefits associated with CGM usage the individual requires a specific education programme along with ongoing support from a trained healthcare specialist (Benhamou et al., 2012). Technical training is essential to optimise reliability and safety of use (Joubert and Reznik, 2012).

5.3.3 Perception of CSII

Insight on the perceived impact of CSII technologies was gathered during semi-structured interviews and reaffirmed by the literature. Two themes, health outcomes and quality of life, were identified as being critical to the impact of CSII on T1D management. Health outcomes relates to the ability of the technologies to impact the health of the individual. Secondly, quality of life looks at the impact of the technology on the ability of the user to uphold general well-being.

5.3.3.1 CSII Health Outcomes

The findings of the semi-structured interviews concluded that CSII can directly improve diabetes related health outcomes of the user. CSII was noted by healthcare professionals along with users of the device for being ‘an excellent technology for suitable candidates’. CSII delivers insulin in a more efficient manner when compared to MDI. As a result, improvements of glycaemic control can be observed almost immediately in suitable candidates (Tamborlane et al., 2008).

5.3.3.2 CSII Quality of Life

CSII replaces the need for MDI which in some cases can be up to six times a day. Insulin is administered through a site on the individuals’ abdomen which is changed every 2 to 3 days. The pump has the ability to provide greater flexibility as it allows the individual to input information on carbohydrate consumption or physical activity levels and will release required dosages when prompted. Background insulin is delivered also which can greatly enhance the individuals sleep pattern throughout the night. Greater flexibility leading to a better quality of life was noted during interview by users of the CSII device. Conversely, CSII was noted for having a potentially negative impact on the quality of life for the individuals using the device due to the fact that the device is worn externally and is visible. Therefore anonymity of T1D is removed for the user.

5.3.4 Perception of CGM

The perception of CGM technology from real life experience was gathered during interviews with healthcare professionals. Participants interviewed with T1D did not have experience using CGM. However, in line with CSII two common themes were identified. Health outcomes and quality of life are imperative to the ability of CGM to have an impact the self-management of T1D management.

5.3.4.1 CGM Health Outcomes

CGM provides information to the individual about their blood glucose levels on a real-time basis and removes the need to finger prick at regular intervals for glucose monitoring (Tamborlane et al., 2008). However, a finger prick reading is required at least once per day to calibrate the device. The device gives the individual the ability to decide whether or not they need to react to their blood glucose levels at any given point in time, based on the readings. The device also has the ability to warn the individual when glucose levels exceed or fall below a predefined level (Benhamou et al., 2012). The qualitative research did not explicitly identify a direct correlation between the CGM device and improvement to health outcomes of the diabetic. The device enables the individual to make more informed decisions regarding blood glucose levels and can reduce uncertainty with regard to their glucose levels.

5.3.4.2 CGM Quality of Life

Diabetes management requires structure and pre-planning with regard to meal times and exercise (Alvarado-Martel et al., 2015). The use of technology can somewhat reduce the burden and overhead on this for the individual. CGM enhances quality of life by increasing the flexibility of decision making and providing peace of mind on the go (Joubert and Reznik, 2012). It was discovered during interviews that CGM can also negatively impact quality of life in terms of increased anxiety through the continuous flow of information which may lead to the individual reacting with insulin to a reading when it may not necessarily be required. In the long term, this can lead to patient fatigue or ‘Diabetic Burnout’.

5.3.5 Barriers to uptake

Barriers to uptake relate to the reasons why CSII and CGM usage is not chosen by adults to self-manage T1D. Barriers to uptake were identified during semi-structured interviews, the findings of which are detailed below in section 5.3.5.1 and 5.3.5.2.

5.3.5.1 Barriers to uptake of CSII

The barriers to uptake for CSII have been identified during the semi-structured interview phase of the research. It was revealed that the main barrier to uptake for this technology is as a result of the requirement for the individual to be attached to the device 24 hours per day. Also, consideration must be given to the level of resourcing required in order to sanction a CSII device for use by a patient. As noted by one healthcare professional during interview, not all T1D clinics in Ireland provides expertise for CSII. Therefore, the individual may be required to travel long distances in order to receive treatment.

5.3.5.2 Barriers to uptake of CGM

While CGM devices were noted in general for being a good innovation, the consensus from the healthcare professionals was that there is more development required in order to improve the accuracy and relatability of the devices. None of the T1D participants interviewed had experience with the CGM device. It was revealed that while CGM reduces the number of times finger pricking is required the requirement to recalibrate the device with blood glucose often deters people. Further research is required in order to determine the additional barriers to uptake of the CGM (Lind et al., 2017).

5.4 Approach to research

5.4.1 Research method

Qualitative studies aim to understand how people feel about something and why they think that way, what their perspectives are, and what a technology means to people (Kaplan and Maxwell, 2005). Due to the nature of the research question and associated research objectives a qualitative, interpretive, inductive, grounded theory approach was selected in order to understand the impact of technology on the self-management of T1D in Ireland. The research was conducted by adopting the thematic approach to analysis as defined by Braun and Clark (2006). Furthermore, triangulation was employed to ensure that credibility, reliability and validity was instilled in the findings through the use of secondary data in the form of published literature. By using a qualitative approach to research focus was maintained on the purpose and context of the research during data collection from varying social dimensions (Mason, 1996).

5.4.2 Data Analysis

CAQDAS was used to analyse the raw data collected during the interview phase. The data was coded and categorised which revealed patterns and correlations between insights. This enabled meaning to be drawn from data by building a logical chain of evidence (Patton, 1999).

NVIVO was the chosen software to analyse the raw primary data of the study as this came recommended by the research supervisor to the study. The tool enables documents to be coded in an efficient and reliable manner (Peh and Low, 2013). The transcripts from each interview were uploaded to the application and the key nodes or themes were identified. Using this software ensured that insight could be gained into the findings by recognising recurring themes throughout each interview. As noted in section 4.4 NVivo enabled prompt identification of trends and patterns in the data which form the basis for the research findings.

5.4.3 Data Interpretation

Braun and Clarkes (2006) approach to thematic analysis was adopted using the NVivo software for computerised qualitative analysis to interpret the qualitative research data. This involved transcribing audio recordings, generating codes, categorising codes into themes, refining themes and finally drawing conclusions to produce findings. The use of this systematic approach enabled key insights and findings to be captured.

5.5 Generalisability of Findings

Qualitative research focuses on appropriate depiction of the research events and understanding the key issues under investigation (Leung, 2015). Generalisability is related to how theories generated in one research setting can be applied to another research setting (Yin, 2013). As noted in Section 3.11 the research was carried out using a grounded theory approach. This research formed a pragmatic method to generalisability which adopts the use of a systematic approach to sampling, data triangulation and the use of secondary data to validate findings (Leung, 2015). The findings of the research in terms of the five themes relating to the impact of technology for the self-management of a chronic illness may be generalised outside the research setting. Both technologies can be replicated for use in base on circumstance for patients with T2D. Similarly research on the broader topic of technology for the self-

management of chronic illness may adopt a similar qualitative approach to research.

5.6 Contribution to the Field of Research

The research dissertation adds to the current state of knowledge in the subject of the impact of CSII and CGM technology on the self-management of T1D by creating a holistic view of the contributing factors which have an impact on the use of both CSII and CGM devices by adults with T1D.

In addition, the research contributes to the field of research by achieving the objectives as discussed in Section 5.3 above. These objectives were:

1. Identify the key areas contributing to the use of CSII for T1D self-management by adults in Ireland.
2. Identify the key areas contributing to the use of CGM for T1D self-management by adults in Ireland.
3. Understand the perception of CSII from real life experience.
4. Understand the perception CGM from real life experience.
5. Determine the barriers to uptake (if any) of CSII and CGM.

The findings of the research suggest that the use of CSII and CGM can impact the self-management of T1D for adults in a number of ways.
CSII can impact the self-management of T1D in terms of the ability of the device to improve health outcomes and quality of life for the individual. These benefits can be observed given the pre-requisite of appropriate patient selection and education is followed.

Numerous studies have shown that the CGM device can impact the self-management of T1D for adults with regard to health outcomes in terms of glycaemic control along with providing both positive and negative impacts on quality of life.

For T1D adults in Ireland it is estimated that only 6% of the entire T1D population use these devices to manage their illness (Noctor and Firth, 2010). This is in large part due negative perception around the requirement to wear the devices 24 hours a day. Provided the appropriate selection of patients and effective education, both CSII and CGM devices have the ability to greatly impact the self-management of T1D in terms of improved health outcomes and a perceived enhancement of quality of life.

5.7 Limitations of the Research

There are a number of limitations identified in relation to the research. The first of which relates to the use do the qualitative mono method for data collection which collates the insight gathered on the views of each of the six participants to the study. While insight was gathered with regard to the research topic in terms of the impact of CSII and CGM on the self-management of T1D the sample of participants was limited in size which could have an impact on objectivity to the research topic. To avoid such limitation in the future the recommendation would be to use a larger sample size relative to the population by adopting a mixed method to data collection which would include both quantitative and qualitative research techniques. This would further reinforce triangulation of data and thus add to the diversity of findings produced.

In addition to this another limitation was observed with regard to conducting semi-structured interviews. As more interviews were conducted the skills and techniques were improved over time in terms of approaches to note takings, interview techniques and preparation. Therefore, the quality of insight gained from the first interview may not be deemed as insightful as that of the sixth interview. The adoption of Braun and Clarkes (2006) thematic analysis approach to interviews was adopted in an attempt to mitigate this risk. There were a number of lessons to be learned while conducting these interviews.

The final limitation was identified during the analysis of the qualitative data using the CAQDAS. Analysing large amounts of qualitative data produced as an output of the semi-structured interviews proved challenging in terms of identifying codes and categories to analyse the data. However, this was reduced with the standardisation of themes during the literature review phase which were borrowed during the formulation of the interview questions.

5.8 Opportunities for Future Research

As noted in Section 1.3, diabetes places a significant burden of care on the individual, healthcare professionals and the wider health system (Tracey, 2016). Continuous improvements and innovations in technology and healthcare can greatly improve the management of chronic illness and reduce long term costs (Hitachi, 2016).Technology for the self-management of diabetes is constantly evolving. The introduction of SAP therapy presents an opportunity to enable a closed loop system for diabetes management. This is a pertinent area for future research

This research focused on the impact of two devices on the self-management of T1D for adults in Ireland. However, there are many more available on the market including bolus calculators, smart watches, mobile applications and many more. This presents many opportunities for further research in relation to the technology available for the self-management of T1D. Further opportunities for research exist in the space of other technologies in terms of their impact on the self-management of diabetes. Similarly, these devices can be adapted for T2D. Therefore, this could be explored in more detail with regard to the ability of CSII and CGM to impact on the self-management of T2D.

5.9 Conclusion

This research sought to better understand the impact of CSII and CGM on the self-management of T1D. Based on the literature review conducted during this study the themes of patient selection, education, health outcome and quality of life were deemed imperative to impacting the use of both technologies. Additionally, these findings were reaffirmed in the qualitative research analysis with the addition of one further theme relating to Data and Communications.
Semi-structured interviews were undertaken with six participants varying from individuals with T1D to healthcare professionals specialising in T1D. The main insight gained was that when prescribed to suitably selected patients, both CSII and CGM devices can improve the health outcome and quality of life of the individual. However, the challenge exists with regard to providing rigorous training and ongoing support in order to ensure that patients are using the devices both effectively and efficiently.

The findings of the study conclude that while technologies can impact the self-management of T1D for certain individuals it must be understood that the cost vs. benefit of using devices can diminish in the long run (Shulman et al., 2016). Therefore, appropriate patient selection is vital in order to get the best out of using each of these devices (Hanaire, 2011).

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Appendices

Appendix 1: Interview Questions

Question 1

A) What is your opinion of Continuous Subcutaneous Insulin Infusion or Insulin Pump therapy for the self-management of Type 1 Diabetes?
B) What is your opinion of the Continuous Glucose Monitor (CGM) for the self-management of Type 1 Diabetes?

Question 2

A) How do you use the data gathered from the Continuous Subcutaneous Insulin Infusion device?
B) How do you use the data gathered from the Continuous Glucose Monitoring device?

Question 3

In your opinion how does technology impact the day to day lifestyle choices of an adult with type 1 diabetes?

Question 4

In your experience, how open are adults with Type 1 Diabetes to trying new technologies for self-managing their illness?

Question 5

The closed loop system, also known as the Artificial Pancreas technology integrates the CGM, an algorithm for individual insulin requirements and an insulin pump to deliver the required insulin dosage automatically to the patient.

How do you think the introduction of this device in Ireland could impact adults living with Type 1 Diabetes?

Appendix 2: Ethical Approval Documentation

1. Ethical approval application

School of Computer Science & Statistics
Research Ethics Application

Part A

Project Title:

Healthcare in the Digital Age: How are advances in technology impacting the self-management of type 1 diabetes in Ireland?

Name of Lead Researcher (student in case of project work): Orla O'Carolan

Name of Supervisor: Paula Roberts

TCD E-mail: ocarolao@tcd.ie Contact Tel No.: 0860769855

Course Name and Code (if applicable): MSc. Management of Information Systems

Estimated start date of survey/research: 15th May 2017

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Signed: ..... Date: 28/4/2017
Lead Researcher/student in case of project work

Ethics Application Guidelines – 2016

Part B

Please answer the following questions.		*Yes/No*
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		Yes - audio
Will your project deliberately involve misleading participants in any way?		No
Does this study contain commercially sensitive material?		No
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		No
Does your study involve any of the following?	Children (under 18 years of age)	No
	People with intellectual or communication difficulties	No
	Patients	Yes

CHECKLIST

Please ensure that you have submitted the following documents with your application:

1.	• SCSS Ethical **Application Form**	Yes
2.	• **Participant's Information Sheet** must include the following: a) Declarations from Part A of the application form; b) Details provided to participants about how they were selected to participate; c) Declaration of all conflicts of interest.	Yes
3.	• **Participant's Consent Form** must include the following: a) Declarations from Part A of the application form; **b)** Researchers contact details provided for counter-signature (your participant will keep one copy of the signed consent form and return a copy to you).	Yes
4.	• **Research Project Proposal** must include the following: a) You must inform the Ethics Committee **who** your intended participants are i.e. are they your work colleagues, class mates etc. b) How will you recruit the participants i.e. **how** do you intend asking people to take part in your research? For example, will you stand on Pearse Street asking passers-by? c) If your participants are under the age of 18, you must seek both parental/guardian AND child consent.	Yes
5.	• Intended **questionnaire**/survey/interview protocol/screen shots/representative materials (as appropriate)	Yes
6.	• **URL** to intended on-line survey (as appropriate)	N/A

Notes on Conflict of Interest

1. If your intended participants are work colleagues, you must declare a potential conflict of interest: you are taking advantage of your existing relationships in order to make progress in your research. It is best to acknowledge this in your invitation to participants.
2. If your research is also intended to direct commercial or other exploitation, this must be declared. For example, *"Please be advised that this research is being conducted by an employee of the company that supplies the product or service which form an object of study within the research."*

Notes for questionnaires and interviews

1. If your questionnaire is **paper based**, you must have the following **opt-out** clause on the top of each page of the questionnaire: *"Each question is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to."*
2. If you questionnaire is **on-line**, the first page of your questionnaire must repeat the content of the information sheet. This must be followed by the consent form. If the participant does not agree to the consent, they must automatically be exited from the questionnaire.
3. Each question must be **optional**.
4. The participant must have the option to **'not submit, exit without submitting'** at the final submission point on your questionnaire.
5. If you have open-ended questions on your questionnaire you must warn the participant against naming **third parties**: *"Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised."*
6. You must inform your participants regarding **illicit activity**: *"In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities."*

Ethics Application Guidelines – September 2016

School of Computer Science and Statistics
Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.

Signed: ..... Date: 28/4/2017
Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external or other TCD Ethics Committee approval has been received, please complete below.

External/TCD ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: N/A Date: N/A
Lead Researcher/student in case of project work

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on the submission checklist is accounted for) and are in a form that is suitable for review by the SCSS Research Ethics Committee

Signed: ..... Date: 28/4/2017
Supervisor

Completed application forms together with supporting documentation should be submitted electronically to the online ethics system - https://webhost.tchpc.tcd.ie/research_ethics/ When your application has been reviewed and approved by the Ethics committee, hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room 104, Lloyd Building, Trinity College, Dublin 2.

Ethics Application Guidelines – 2016

1. *Participant Information Sheet*

TRINITY COLLEGE DUBLIN
INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

Background

The number of people with diabetes is rapidly increasing worldwide. Type 1 diabetes in particular is primarily dependent on and managed through technology, whether this is through the device that reads blood glucose levels or the insulin pump that administers insulin when instructed. Technology is expanding rapidly in this space. The purpose of this research is to explore the current and future technologies available to Type 1 diabetics in Ireland and to determine how they impact the self-management of the disease for adults. This research is topical as the number of adults with type 1 diabetes in Ireland is increasing year on year. The treatment and maintenance of both type 1 and type 2 diabetes is dependent on information technology. Innovation in the devices and tools for diabetes self-care and management has the potential to greatly impact the daily life of an individual suffering with diabetes.

Procedures of participation

Participants were selected for interview based on their experience with Type 1 diabetes (direct or indirectly). Participation will take place in the form of an interview where the researcher will ask the interviewee a list of pre-determined questions. These questions will be to prompt a qualitative interview. The participant is not obliged to answer all questions. The key focus of this research surrounds self-management technologies for Type 1 diabetes

In order to get the best out of the discussion the researcher intends to take notes during the interview along with the use of an audio recorder.

Please note: No audio recordings will be made available to anyone other than the research/research team, nor will any such recordings be replayed in any public forum or presentation of the research.

Data Retention

Signed consent forms and original audio recordings will be retained securely at the researcher's home in Newbarn, Kilsallaghan, Co. Dublin where they will be stored in a safe protected by a lock. No other party will have access to this data until after the

degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation you are entitled to access the information you have provided at any time.

Conflicts of interest

This research forms part of a course requirement for completion of the Management of Information Systems master's programme, a post-graduate taught course offered by Trinity College Dublin. This research is entirely self-funded and therefore to the best of my knowledge is not exposed to any financial or other conflicts of interest. If during the course of this research project any conflict of interest arises I will undertake to inform the University as expeditiously as possible. By agreeing to partake in this study you also confirm that you do not perceive there would be any scenarios that could give rise to a conflict of interest as a result of your participation in this research.

Voluntary participation

Participation in this study is voluntary and therefore the participant has the right to withdraw at any stage during the process. Should the individual wish to withdraw from this study there will be no penalties and all previously given information will be omitted from the research.

Duration of the participant's involvement

Involvement to this research will take part in the form of an interview and is expected to last no longer than one hour.

Anticipated risks/benefits

There are no perceived risks to the participant by partaking in this research.

The primary benefit in partaking in this research surrounds giving the participant an avenue to discuss their experiences with technologies for self-managing Type 1 diabetes in Ireland.

Anonymity

Participants in this study reserve the right to remain anonymous during analysis, publication and presentation of results and findings of the research. Under no circumstances will any individual participant be identified within this study. Data from interviews will be aggregated to provide an overall result.

Please note: non-anonymised data in the form of signed consent forms and audio recordings are collected and retained as part of the research process.

In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities.

Debrief

Thank you for taking part and providing your input for this study on the impacts of technologies for self-management of type 1 diabetes in Ireland.

This research will be published for the purpose of submitting for my dissertation which forms part of the Management of Information Systems master's degree 2016/17 at Trinity College Dublin. It may be additionally be used for peer-reviewed publication arising from the research.

Participants are invited to request a copy of the completed research.
If you have any queries regarding any part of the study following the interview please do not hesitate to contact me directly by email or telephone:

Orla O'Carolan E: ocarolao@tcd.ie M: 0860769855

2. Participant Consent Form

TRINITY COLLEGE DUBLIN

INFORMED CONSENT FORM

Healthcare in the Digital Age: How are advances in technology impacting the self-management of Type 1 Diabetes in Ireland?

Researcher: Orla O'Carolan

Background

The number of people with diabetes is rapidly increasing worldwide. Type 1 diabetes in particular is primarily dependent on and managed through technology, whether this is through the device that reads blood glucose levels or the insulin pump that administers insulin when instructed. Technology is expanding rapidly in this space. The purpose of this research is to explore the current and future technologies available to Type 1 diabetics in Ireland and to determine how they impact the self-management of the disease for adults. This research is topical as the number of adults with type 1 diabetes in Ireland is increasing year on year. The treatment and maintenance of both type 1 and type 2 diabetes is dependent on information technology. Innovation in the devices and tools for diabetes self-care and management has the potential to greatly impact the daily life of an individual suffering with diabetes.

Procedures of participation

Participation will take place in the form of an interview where the researcher will ask the interviewee a list of pre-determined questions. These questions will be to prompt a qualitative interview. The participant is not obliged to answer all questions.

In order to get the best out of the discussion the researcher intends to take notes during the interview along with the use of an audio recorder.
Please note: No audio recordings will be made available to anyone other than the research/research team, nor will any such recordings be replayed in any public forum or presentation of the research.

Data Retention
Signed consent forms and original audio recordings will be retained securely at the researcher's home in Newbarn, Kilsallaghan, Co. Dublin where they will be stored in a safe protected by a lock. No other party will have access to this data until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation you are entitled to access the information you have provided at any time.

Conflicts of interest
This research forms part of a course requirement for completion of the Management of Information Systems master's programme, a post-graduate taught course offered by Trinity College Dublin. This research is entirely self-funded and therefore to the best of my knowledge is not exposed to any financial or other conflicts of interest. If during the course of this research project any conflict of interest arises I will undertake to inform the University as expeditiously as possible. By agreeing to partake in this study you also confirm that you do not perceive there would be any scenarios that could give rise to a conflict of interest as a result of your participation in this research.

Voluntary participation
Participation in this study is voluntary and therefore the participant has the right to withdraw at any stage during the process. Should the individual wish to withdraw from this study there will be no penalties and all previously given information will be omitted from the research.

Duration of the participant's involvement
Involvement to this research will take part in the form of an interview and is expected to last no longer than one hour.

Anticipated risks/benefits
There are no perceived risks to the participant by partaking in this research.
The primary benefit in partaking in this research surrounds giving the participant an avenue to discuss their experiences with technologies for self-managing Type 1 diabetes in Ireland.

Anonymity

Participants in this study reserve the right to remain anonymous during analysis, publication and presentation of results and findings of the research. Under no circumstances will any individual participant be identified within this study. Data from interviews will be aggregated to provide an overall result.

Please note: non-anonymised data in the form of signed consent forms and audio recordings are collected and retained as part of the research process.

In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities.

Debrief

Thank you for taking part and providing your input for this study on the impacts of technologies for self-management of type 1 diabetes in Ireland. This research will be published for the purpose of submitting for my dissertation which forms part of the Management of Information Systems master's degree 2016/17 at Trinity College Dublin. It may be additionally be used for peer-reviewed publication arising from the research. Participants are invited to request a copy of the completed research.

If you have any queries regarding any part of the study following the interview please do not hesitate to contact me directly by email or telephone:

Orla O'Carolan E: ocarolao@tcd.ie M: 0860769855

Declaration:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).
- I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

Participant's Name (BLOCK CAPITALS):

_____

Participant's Signature: **Date:**

_____ _____

Statement of investigator's responsibility:

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

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Appendix 3: Sample Interview Transcript

Interviewer: What is your opinion of the Continuous Glucose Monitor (CGM) for the self-management of T1D Diabetes (T1D)?

Interviewee: I think that CGMs are in general a really good innovation in T1D management. Unfortunately, I think there are some misunderstandings about them out there. I think there is an assumption that they completely replace blood glucose monitoring and when you look at how they function optimally that is not the case as at the moment calibration against blood glucose is still required. I think that is always a challenge when patients come to us, asking about them, they come under the assumption that they replace blood glucose monitoring and are then disappointed that they then don't. But, aside from that, I think that they give really good information outside of those standard times when people need to do a finger-prick. I think they have a great utility, the ones that can maybe be linked up to pumps in particular for hypo management. I think the evidence isn't great yet, but they are particularly helpful for people with hyperglycaemia. So, whether in time there will be evidence that they improve that. I guess then, we will be in a better position to say they are useful for most people. I think that there is still a bit of confusion out there of the differences between continuous glucose monitoring and flash glucose monitoring. Again, I am not sure that companies who produce these things are doing much to make that clear to people. There is definitely a sales pitch around it. There is very little evidence around flash in terms of it improving HbA1c outcomes or helping with hypos. So as a result certainly, in our practice here, we really try to make that distinction, so that the person understands the pros and cons of each, particularly if they are going to self-fund.

Interviewer: The devices are can be considered to be quite expensive.

Interviewee: They are very expensive, yes. So, if they are going to spend money on this, do they have a really good understanding of what one offers versus the other? At the moment though, I suppose the big advantage of continuous glucose over flash monitoring is alerts typically with the systems we have available. Somebody who is going to spend money on some kind of glucose monitoring in order to be alerted of their blood glucose because the flash system is not very useful right now. So, we would encourage them to go down the route of CGM if that is what they want to get out of it. I guess, as with everything in diabetes management, I think, from our point of view, it is about having good conversations about what they want out of the technology. If we understand that, I think we are in a better position to say "well this can offer you that, whereas that won't". Like we would do with medications or different types of insulins, explore the other options. So, I think, yeah, pros and cons. But in general, they are good products. I think there is a lot of potential down the line as they become more accurate. Assuming the intention of the companies is that they will replace glucose monitoring

and I am sure that will come in time. They might be more accurate or imbedded or whatever way they get around that to calibrate.

Interviewer: I guess there is a bit of a gap in knowledge and understanding, that there isn't that much of an understanding that is doesn't completely replace the glucose meter.

Interviewee: Yes. It doesn't completely replace that part. It's just giving information. I suppose, the huge part of diabetes management is people making decisions about what to do. That hasn't been fully replaced by technology either. So, whether you are getting the information from a CGM or a finger stick, that part of the person needing to know what to do with the information is still there. And again, I think that when people hear about it first, they think that the technology will do that part of it and it doesn't. It just provides information.

Interviewer: The insulin pump has been around for quite a while now. But in terms of self-management using a pump, how do you think that has an impact for T1D. What is your opinion of the insulin pump for diabetes management?

Interviewee: I am pro insulin pumps. I think there is good evidence that they can improve glycaemic control in adults with T1D. I think it's about 0.5% HbA1c if you look at it on average, but if you look inside those studies, some people get really dramatic improvements in glycaemic control. So, I think that if I was weighing up the two technologies, there is stronger evidence around insulin pumps for improving glycaemic control than CGMs as a standalone. I think that we should be and I certainly would be pro the insertion of pumps as a technology rather than CGM on its own. They replicate, as close as we can at the moment, to what a pancreas is doing. You have lots of features that give people better flexibility. I think temporary basal rates on pumps are amazing. And that's the big thing that people with pens often struggle with is again if their day becomes different to what they thought it would be where they are suddenly busier or less busy. With pens, you need to have made that decision that mornings to be able manage things well. Pumps allow you to make better real-time decisions about turning up or down insulin. So, I think they definitely give better flexibility. If I was to presume from a dietician's perspective, we talk to people on pens about this absorption curve with food. We will say most foods are absorbed and get in within that 3 hour nice curve that you will get from a bolus with a pen but in reality, lots of foods take longer than that. They cause a peak or they go on for longer than that. Some of them can cause a bigger spike. I think it definitely gives us more flexibility to manage the types of bolus people can use to try and match their food a bit better. And in reality, most or lots of people don't just eat these lovely 50g carbs meals that we assume. It works really well with pens and I think that if lifestyle is erratic that the pump gives more options for flexibility. I suppose the biggest cons are then with the theoretical decay that you see in practice very rarely. We tend to find that if people are testing their blood glucose, they are not

running into as many problems because they know if they are not getting their insulin. So here in my centre we have a pathway to pumps. The first step is always a structured education programme. We have a course called DAFNE here. There are a couple of options but here in this centre, that is what we offer. That teaches people how to make decisions around insulin dosing and carb counting. Whether you are going to use a pump or a pen, you need those skills. We always say do the course first and at least that bit is box ticked. Then moving on to a pump, our next step would be getting people to use a bolus advisor metre. It is a technology that functions as a glucose meter. But it has the algorithms that you would get with a pump programmed into it. So it is effectively similar to the technology you would get in the pump in relation to pre-programming your insulin ratios. We get people to use that: A) because it has some effect on glycaemic control and B) because it gives people an idea what it would be like with a pump. So, every time I need to eat, I need to test, put in my carbs and then get that information back from the metre. We feel that gives people an opportunity to test out the technology. Not wearing the technology but performing that self-monitoring bit. The next step is we get people to come in and look at pump options because there are options out there. There is also a UK website we recommend for pump users. We would ask people to look on there. It is a forum to look at real life experiences of using a pump. If people want to talk to users, we get them to talk to them. It is quite a structured process. Hopefully if people decide that they want to come onto a pump that they have really thought and examined it. We feel that has worked well. We have about 80 people on pumps and we have only ever had 3 people come back off a pump. We think that is because we really encourage people to think about it and not go out on a whim to go on a pump. They go through this process where they decide if it is the right thing for them. I think that the way that you introduce the idea of pump therapy and the journey that people go on before starting on a pump is important for getting the best out of it.

Interviewer: There is this idea that technology solves everything, but really you are going to be connected to this device 24/7

Interviewee: And it is really hard work. It is hard work living with T1D. I don't think to be fair that people come in thinking that this will make everything better but I would say if you ask someone who is on pump, is it any less work than when you are on pens, they would probably say no. You still have to engage in all those self-managing behaviours, testing, changing the insulin, making decisions about insulin, rechecking to see if that works and patterns. None of those things are different in the bigger picture on a pump than it would be on pens. I think that most people that go on pumps or at least in my opinion, they don't want to come back off of it because of the flexibility it allows. It is not that it takes the work out of T1D. That would be amazing that we could get to that point, but it seems to make it easier for people to fit into your normal day.

Interviewer: I think you kind of mentioned it early. The data that is created or that is stored in these devices, starting with CGM first. That data is gathered over time or shows trends over time. Do you use that information from these devices and do you find it beneficial?

Interviewee: I guess what we will do with people using a flash glucose monitor, we do have software that people can come in and download the information about their flash. Or people can download it onto their own software and then send it as a PDF if they want an opinion on it. The challenge there is that, really, we should be only making decisions on blood glucose from finger-pricks. So really you get a lot of information back from the flash glucose monitor that you cannot use unfortunately. People can get really annoyed with this then. They might think “Oh you know, you are saying that I should be using the information”. So we use this then more so for trends as opposed to decisions. With CGM, we probably have less experience probably than a diabetes nurse working with that data. We try to use the integrated software. I don’t have any experience of anyone using the CGM as a standalone independent of the pump. So in any of our pump users who also use a CGM, we would try to use the software that integrates both data sets. Just looking at blood glucose levels on its own isn’t particularly helpful. You would need to know the carbs and you would need to know the insulin. Sometimes you would need to know what the carbs were if you were looking at absorption or you are looking at meals that are trailing on. Someone could say that it was 100g or carbs but that was an Indian takeaway you would expect it to take 6 hours to absorb, where as if it was 100g of spaghetti Bolognese it would probably be quicker absorption. You definitely need all the information you can get and sometimes additional information. I think that is the way we try to use the data. We try and get integrated as much as possible and then try to encourage a supplemented food diary. If they wanted to sit in a session and look at patterns, that would be in my experience best. Just to keep a food diary for a few days and then bring in their pump and their meter or CGM. We would do a download of it all and try to piece it all together. I think bits of information are unhelpful and that is sometimes what you get from the CGMs or even from the pumps. You get this huge amount of data but not always meaningful data. You can’t really use it to make decisions. You might be sitting down with someone and they might have done a download of the pump or CGM and they see a hypo. That might have also happened 3 days in a row. We might try to understand what went on there. But you don’t really know did they estimate the carbs right, was it an unusual food or were they particularly active that day. If you don’t have all the data, you can’t interpret it. That is a challenge with CGM is that there is work to still do there. Finding better ways to integrate the glucose data with behavioural data and whether it is food or exercise.

Interviewer: There is an application called Diasend which integrates data, have you ever used that?

Interviewee: We don't but we should. Diasend is an online tool. There is also some kind of unit that you can get, that you can physically upload data. We are keen to start using it here but we don't have it at the moment. For us a challenge as a diabetes educator is all the different pumps and CGMs. They all have their own software. It is very confusing. We had 2 people in this morning and they were both on different pumps. We open the first software and you have to re-orientate yourself to how you get the insulin and card data in. Then moving over to the other device and the software is completely different. We are hoping with Diasend, the data is no different regardless of which device you are using. At least we would have a way of getting all the data in.

Interviewer: So this would streamline it all?

Interviewee: Yes. We have a challenge here in this hospital since we do not have Wi-Fi and there is not great IT support. I think that is probably in any HSE clinic. Lots of things are firewalled; you have to get IT in to install software to resolve all those kinds of problems. At the moment we have a laptop that is independent of the HSE network and we store all the data on that but we could do that better with more IT support. It is something we are actively looking into. We would love to actually, in other hospitals, people will come into clinic and upload their pump in clinic and get print outs. We don't have that facility at the moment here either. The best that we can do, is allow patients to upload to that laptop while they are in with us. So I think that there is a lot of potential and a lack of infrastructure within the HSE, especially IT support, makes it difficult. There are people probably doing things in a more efficient way. So we will often do, if they really want to drill down into some data with us, to do an upload at home on their own software and bring some printouts then to clinic. That is the most fail-safe way of doing it at the moment.

Interviewer: As you mentioned, the information overload as well can be quite daunting. I know you mentioned before around the CGM technology, that it can be good, but then there is the guy who constantly use it to track and that can lead to other things. There are pros and cons. When you switch off as a patient too.

Interviewee: We had a lady in this morning, she was testing an hour after she would eat and was reacting. Even though she knows that the insulin she has taken hasn't finished its work and that it's not probably a good or safe idea to correct again an hour later, she needs to let the insulin do its job. She was describing to us how difficult it is to sit there and know that she is high. Whereas before she was able to scan, she would not know and sit it out. Sometimes when you have the information, it's tough to sit back and not react to it. So we would consider that as part of the training for CGM, to train people to let the insulin do its work. I also think that is an interesting one from a research perspective, I have noticed and it is anecdotal, that it is creating a lot of anxiety around postprandial hyperglycaemia in T1D and there is no evidence that postprandial

hyperglycaemia outside of pregnancy in T1D is problematic. It is actually pre-prandial glucose levels that drive A1C and A1C is what drives risk. All the data would suggest that we do not need to be getting worried about pre-prandial in T1D. CGMs had really highlighted it to people and they will come into you talking about how they should not be having these spikes. Postprandial spikes are completely normal with the insulins we have. That is the limitations of where we are. We know that they don't do harm once the pre-prandial are on target. It has definitely driven that conversation far more often obviously and maybe not always in a helpful way.

Interviewer: This leads onto my next question, in terms of the likes of the CGM and the impact on the day to day lifestyle choices of an adult with T1D diabetes. How does that in your opinion, impact the idea of the "diabetic burnout" and the fatigue that people suffer from?

Interviewee: I think that once again it's that information overload and not being able to switch off from your diabetes. That's always a balance. We have individuals who never test their blood glucose. That's not a good thing either. Then, typically people who want a CGM are people that are interested in what their blood glucose levels are anyway. They are testing quite a lot. It adds more to that. It definitely fuels anxiety on the information overload side of things. We have had a couple of people who have for very complex reasons they just find it very difficult to engage with diabetes. They hate testing, don't test, won't test and cannot bargain with themselves to. For some of those people wearing a CGM and being able to check in from time to time is helpful. In my experience, once again this is very anecdotal, for those people (we probably have about 5 or 6 people) who we recommend to go onto a CGM just because they were not testing. It is probably the opposite of what you are talking about but we will ask them to try it out and see. We find that people, for the first couple of months, really engage with the information and then it would peter out again. It was really just trying to treat a symptom but not a cause. So if a person is really struggling with managing their diabetes or testing or knowing when to take an action, I am not sure that CGM makes that better. Shorter term maybe but not in the longer term. Engaging with them from a psychology point of view and finding out whatever is going on with that person has surprised us. We maybe naively thought that maybe if people just had the information to do something. We thought that maybe them not having the information is part of them not doing anything with it. We definitely have people now using CGMs and not necessarily acting on it. We park it after a while. Some people I don't think it impacts on self-management and then the other side of the spectrum has other people over using the data and getting overwhelmed. There are probably loads of people in the middle who use it appropriately. I don't think we have the experience yet. In some ways I think that our opinion is potentially biased because we are chasing down people who are not testing or have poor glycaemic control to use the device. Then people who are coming back to us often are the people who are worried. There are people who are in the middle then who we

might not engage with them as much or see as much of them. I guess that will come out in the wash in the next ten years as it becomes more of the norm and we see more people who are using CGM.

Interviewer: Looking at the other piece of technology, the insulin pump. How do you think that has an impact on the day-to-day?

Interviewee: So, on their day-to-day management?

Interviewer: Yes and the lifestyle choices they make daily.

Interviewee: I think by and large it has a positive impact. I think, in my experience, more positive than a CGM as a standalone around flexibility in particular. It allows people to think about their insulin in a way that's more like how their pancreas would be behaving. And from my point of view that's what I want people to do. It's not about restricting or beating themselves up all the time and not getting the right result. It's about accepting that my pancreas doesn't really work. That sucks. I can never replicate fully what my pancreas used to do. But to manage my condition as well as I can, I have to try to do that with the tools that are available to me and for a lot of people, a pump is the best tool practically. So it allows them to switch up and down their insulin, it allows them to manipulate their insulin in a very flexible way so that they can make the lifestyle choices they want. They can be active, they can be inactive, they can eat once a day and they can eat 16 times a day. It allows that flexibility. As we stand, at the point you are diagnosed, they will still go on to pens as a first line and still for a lot of people, wearing a pump puts them off. That's still outweighs the potential benefits of lifestyle flexibility. What I think is going to be really interesting is the under 5's policy in Ireland now. All under 5's diagnosed with T1D automatically go onto a pump. We are going to have a whole generation of people who have never not known pumps. I think that is going to be interesting in relation to how people use their pumps. That flexibility has always been there. Does it just become the norm? Maybe being flexible with your decision making, won't become part of the decision making anymore.

Interviewer: That's an interesting point actually.

Interviewee: Yes, because you can sell the flexibility to people actually. Because people want flexibility and when you explain to them they really like the idea of being able to replicate their insulin more quickly and to be more flexible but it's the wearing that really puts people off. So if they have never been given the choice in that, I think it will be interesting. Do those kids stay on pumps all the way through? Because obviously they will have the option of coming off when they come into adolescence or adulthood. They will be making their own choices about it. It will be interesting to see if people stay

on them or come off them. Is the wearing of them as big of a deal as we think it is because in my experience that is the biggest deterrent for people?

Interviewer: That they are attached to it?

Interviewee: Because they are attached to it, wearing it. It makes your diabetes much more public and you can see it. You have to think of ways to hide it if you don't want it to be seen. You have to think about it in your job, if you have an active job. Where do I put it so it's not falling off or getting caught in things? That's the deterrents I suppose.

Interviewer: I suppose that's the different aspects to managing diabetes. From an individual's perspective, there are the technologies but there is psychological aspect too. And in the day-to-day, the technology is not going to cure or get rid of the negative perceptions that you have in your head that you are carrying around the device whereas the person sat beside you in work isn't.

Interviewee: Yes. And lots of people are really private about their diabetes and don't tell their work colleagues or friends. With pens, you can hide it to a greater degree than a pump. A pump is definitely much more in your face. You could probably argue then, that things like the CGM are the opposite because that is about discreet checking. There is that contrast there which I had not thought about until now.

Interviewer: Because they vary.

Interviewee: Yes.

Appendix 4: Technology

Below is an example on a Medtronic insulin pump which links to the CGM Mini Link Transmitter to display interstitial glucose levels. The information can then be uploaded with to the Care Link portal for analysis. The wireless blood glucose monitor is used to calibrate the device by providing readings of blood glucose when tested by the individual (Medtronic, 2017).

Figure 4 Medtronic Sensor Augmented Therapy