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Determinants of Behavioral Intent to Adopt the Closed-Loop Artificial Pancreas Among Diabetes Healthcare Providers

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DETERMINANTS OF BEHAVIORAL INTENT TO ADOPT THE CLOSED-LOOP ARTIFICIAL PANCREAS AMONG DIABETES HEALTHCARE PROVIDERS

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DEDICATION

This dissertation research is dedicated to my daughters Isabella and Kaila. I hope to instill a passion and drive for lifelong learning. I hope you learn that as long as you have the love and support of your family you can accomplish great things. The only obstacles in life are those that are self-imposed.

"I'm looking forward to future generations of the artificial pancreas. I think there will be many obstacles to overcome i.e. reluctance of patient with diabetes to adopt, cost, insurance coverage, and the ability of diabetes healthcare community to adapt and adopt".

Anonymous Healthcare Provider

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ABSTRACT

DETERMINANTS OF BEHAVIORAL INTENT TO ADOPT THE CLOSED-LOOP ARTIFICIAL PANCREAS AMONG DIABETES HEALTHCARE PROVIDERS

Carolyn M. Serrano

Seton Hall University, 2018

Dissertation Chair Dr. Deborah DeLuca, MS., JD.

Background and Purpose of the Study: Diabetes mellitus for both children and adults are broadly defined as a group of complex diseases characterized by high blood glucose, resulting from a defect in either the production of or action of insulin, or both (National Institutes of Health, 2014). There are 29.1 million people in the US that are estimated to have diagnosed or undiagnosed diabetes (Centers for Disease Control and Prevention (CDC), 2014). Type 1 diabetes accounts for approximately 5-10% of all diabetes cases however, it has serious short term and long-term implications (Daneman, 2006).

Technology for diabetes management is rapidly developing and changing (Markowitz, Harrington, & Laffel, 2013). The results of the Diabetes Complications Control Trial (DCCT) demonstrated the importance of glycemic control and lead to an increased interest in technology to achieve control with minimizing hypoglycemia (DCCT, 1993; Cryer,2016). The Artificial Pancreas (AP), is known as the closed-loop

control of blood glucose in diabetes, it is a system that combines a glucose sensor, a computer algorithm, and insulin infusion device (Cobelli, Renard, & Kovatchev, 2011). This innovation has the potential to elevate treatment burden for the patient. Compliance with patients monitoring of glucose, even well-controlled patients is often poor (Clarke & Foster, 2012). The closed-loop system would solve this issue because it requires no patient input (Kudva, Carter, Cobelli, Basu & Basu, 2014). There are currently 18 closed-loop artificial pancreas (CLAP) systems identified as being in clinical phase development, with 5 expected to be available for use at the end 2018 (Trevitt, Simpson, & Wood, 2016).

The role of the healthcare provider puts them in a unique position when it comes to technology acceptance. The healthcare provider–patient relationship is particularly challenging when it involves new treatment technology because the physician must have knowledge of the technology to be able to inform the patient however in many cases, the advancements in technology develop faster than the education required to competently use the devices which leads to a lack of competence and confidence by the practitioner (Caruana, 2012). Normally the end user decides whether to accept or reject the technology or device but in the healthcare environment the healthcare providers play a large part of the decision-making process of whether to use a new medical device such as the closed-loop system (Schonbeck, 2014). The purpose of this study was to create a valid tool entitled "Healthcare Providers Closed-Loop Artificial Pancreas Assessment (HCP-CLAPA)" and then

implement this tool in the appropriate population of healthcare providers who work with patients that have diabetes.

Methods: This study utilized a quantitative methodology with a descriptive, exploratory, cross-sectional and correlational research design to measure the determinants of behavioral intent to adopt the closed-loop artificial pancreas technology. A sample of 207 healthcare providers participated in this study.

Results: Reliability for the HCP-CLAPA overall with 10 constructs combined was good (Cronbach's alpha α= .80). Healthcare providers had a fair understand of the technology with a perceptions of knowledge score of 68%. The binomial regression was significant, $\chi 2(4) = 35.865$, p =.0001. The model explained 24.0%. Of the 9 predictors of behavioral intent to adopt, relative advantage was significant. The odds of adoption were 4.77 times greater when there was a positive relative advantage. In addition, there were no interactions between physicians and non-physicians when it came to the behavioral intent to adopt the closed-loop artificial pancreas by system type. However, the value of the technology for system type was significant for the 24-hour closed-loop artificial pancreas and the hybrid closed-loop artificial pancreas.

Conclusion: The study provides an understanding of factors that influence behavioral intent to use. Intent to use would increase if there is a positive relative advantage above current therapies. Value of a system is based on system attributes. This study did not identify barriers to adoption. However, we know that this technology is not right for everyone considering the complexity of the device. It

requires the right practitioner, right technology type, and right patient. The technology is not generalizable to every patient. Multiple themes uncovered the need for advanced technology planning including: healthcare provider education and relevant policies and procedures to ensure appropriate use.

Keywords: Closed-loop Artificial Pancreas, Healthcare Providers, Behavioral Intent to Use, Technology Adoption, Relative Advantage, Value

Chapter 1

INTRODUCTION

Background of the Problem

Diabetes mellitus for both children and adults is broadly defined as a group of complex diseases characterized by high blood glucose, resulting from a defect in either the production of or action of insulin, or both (National Institutes of Health, 2014). There are 29.1 million people in the US that are estimated to have diagnosed or undiagnosed diabetes (CDC, 2014). There are multiple forms of diabetes however, the two main forms are type 1 and type 2diabetes. Type 1 diabetes accounts for approximately 5-10% of all diabetes cases however, it has serious short term and long-term implications (Daneman, 2006). Type 1 diabetes can develop at any age but it rarely presents in the first six months of life (Tuomilehto, 2013). There are clear geographic differences in the trends in type 1 diabetes, but the overall worldwide annual increase is approximately 3% (DIAMOND Project Group, 2006). Type 2 DM represents the largest proportion of the diabetes population, accounting for 90-95% of diagnosed diabetes in US adults (CDC, 2014). The prevalence and incidence of type 2 diabetes is increasing worldwide (Inzucchi et al, 2012). The economic burden for the health care system is skyrocketing from the cost associated with treatment and diabetes complications. Type 2 diabetes is a progressive disease. It is the leading

cause of cardiovascular disorders, blindness, renal failure, amputations, and hospitalization. The progressive nature of type 2 diabetes often leads to partial or total insulin replacement. Diabetes is also one of the most common chronic diseases of childhood (American Diabetes Association (ADA) et al., 2012). There are approximately 208,000 individuals under the age of 20 estimated to have been diagnosed with diabetes in 2012 in the United States (CDC, 2014).

Technology for diabetes management is rapidly developing and changing (Markowitz et al., 2013). The Artificial Pancreas (AP), is known as the closed-loop control of blood glucose in diabetes, it is a system that combines a glucose sensor, a computer algorithm, and insulin infusion device (Cobelli et al., 2011). Artificial pancreas developments can be traced back 50 years. The past 15 years, the concept of the closed-loop control has made significant advancement, due to the advances in technology and computer-based algorithms (Kudva et al., 2014). The results of the DCCT demonstrated the importance of glycemic control and lead to an increased interest in technology to achieve control with minimizing hypoglycemia (DCCT, 1993; Cryer,2016). The completely automated artificial pancreas is considered the ideal treatment for type 1 diabetes (Ricotti, Assaf, Dario, & Menciassi, 2013). In addition, feasibility has been assessed in the type 2 diabetes population with favorable results, thereby broadening the potential scope of use of the close loop artificial pancreas (Kumareswaran et al., 2014).

Ideally, closed- loop artificial pancreas systems would perform without human interventions operating as a closed process (Kudva et al., 2014). Compliance with

patients monitoring of glucose, even well-controlled patients is often poor (Clarke & Foster, 2012). The closed-loop system would solve this issue because it requires no patient input (Kudva et al., 2014). The availability of glucose sensors and insulin pumps has enabled the development of devices and software to partially or completely automated insulin deliver (Weinzimer, 2012). The literature uses a wide variety of terminology such as artificial pancreas, bionic pancreas, closed-loop, automated insulin delivery, and treat to target system (Kowalski, 2015). These systems will evolve overtime to become more automated and eventually will dose hormones in addition to insulin such as glucagon called dual hormone AP and/ or amylin called a multi-hormone AP. Hybrid closed-loop, fully automated closed-loop, and dual hormone systems are under development at various stages of testing (Forlenza, Buckingham & Maahs, 2016). Recent studies incorporating both insulin and glucagon have extended the closed-loop system from an artificial beta cell to and artificial endocrine pancreas system (Kudav, 2014).

The role of the healthcare provider puts them in a unique position when it comes to technology acceptance. The healthcare provider–patient relationship is particularly challenging when it involves new treatment technology because the physician must have knowledge of the technology to be able to inform the patient however in many cases, the advancements in technology develop faster than the education required to competently use the devices which leads to a lack of competence and confidence by the practitioner (Caruana, 2012). In addition, the decision of healthcare provider to use a new technology can interfere with the

healthcare providers' usual practice and can affect their perception of their professional role and challenge their high professional autonomy (Gagnon et al, 2014; Walter & Succi-Lopez, 2008). Normally the end user decides whether to accept or reject the technology or device but in the healthcare environment the healthcare providers play a large part of the decision-making process of whether to use a new medical device such as the closed-loop system (Schonbeck, 2014).

There are very few studies that have investigated healthcare provider intent to adopt the closed-loop system. Only two bachelorette thesis studies were found on this topic which utilized theories from technology acceptance research (Klabbers, 2014; Schonbeck, 2014). Theories in social science and other domains have examined behavioral intent to use technology or to explain how and why people adopt technologies (Liu et al., 2014). Intent and behavioral decision-based theories have been used to explain usage of technology and results further show that intention is significantly and positively correlated to actual behavior (Davis, 1989; Triandis, 1980). Intention was also found to be a valid proxy measure for behavior among clinicians (Godin, Bélanger-Gravel, Eccles, & Grimshaw, 2008).

In review of the literature no one model fully explains technology acceptance of healthcare providers. Technology Acceptance Model (TAM) is the most widely recognized model of behavioral intention information system literature (Yarbrough & Smith, 2007). TAM was originally grounded on principles adopted from the attitude paradigm the Theory of Reasoned Action (Davis, 1993). The Theory of Reasoned Action (TRA) is used to predict the actual behavior of an individual. Behavioral

intent could be determined by considering both a person's attitude towards an actual behavior and the subjective norm (Fishbein & Ajzen, 1975). Perceived behavioral control was added to the TRA and became the Theory of Planned Behavior (TPB) (Ajzen, 1991). TAM and TAM like models have recently been utilized in the healthcare field as a way of measuring technology acceptance at the organizational level (Holden & Karsh, 2010). Several studies utilizing TAM to assess technology acceptance of physicians revealed that TAM explains approximately 40% of physician's behavioral adoption however, a considerable amount of intention is left unexplained (Chau & Hu, 2002a,2002b). Holden and Karsh (2010) suggest that the issue with TAM and TAM like models are that no two studies tested the same model and variations in definitions and interpretations of constructs may be to blame. Despite their limitations TAM and TAM modified models are useful in considering technology acceptance among healthcare providers. A focus on perceived usefulness, perceived behavioral control (self-efficacy), and attitude is more likely to influence clinicians' acceptance of technology (Chau & Hu, 2001; Holden & Karsh, 2010; Ward, 2013).

Other theories often used in technology adoption are the Roger's (2003) innovation diffusion theory (IDT) and Triandis (1980) Theory of Interpersonal Behavior (TIB). IDT focuses on the rate of adoption of innovations and attempts to explain how an idea or product gains momentum and diffuses through a social system or specific population. The result of diffusion is that people that comprise the social system and adopt a new idea, behavior, or product (Wani, 2015). TIB focuses on

similar behavioral determinants found in TAM and TPB with additional cultural, social, and moral factors not considered in other theories (Gagnon et al., 2003). Both theories have shown to improve the explanatory power of behavioral intention to adopt technology in the healthcare field both alone and in combination with other models (Gagnon et al, 2003; Gagnon et al, 2014; Tung, Chang, Chou, 2008; Mun, Jackson, Park, & Probst, 2006).

TAM lacks the antecedents necessary to fully explain technology acceptance. IDT concentrates on technology but lacks some of the psychosocial construct of TIB. TIB focuses on the psychosocial aspect of the individual adopter and lacks a technology focus. Therefore, a combined theoretical model with constructs from multiple theories may best represent all the constructs necessary to determine closed-loop artificial pancreas therapy acceptance by providers. TAM provided a baseline understand to the development of the study model.

The research model utilized in this study was conceptualized from several theories representing both technological and behavioral aspects of intent to adopt. This model includes constructs from IDT (Rogers, 2003), TPB (Ajzen,1991), TIB (Triandis,1980), perceived risk (Cunningham, 1967), resistance to change (Oreg, 2003), threat to autonomy (Walter & Succi-Lopez, 2008) and value (Ettinger, 1998; Lee& Larsen, 2009). To the author's best knowledge there are no studies combing these concepts in one theoretical phenomenon assessing healthcare professional's intent to use the artificial closed-loop pancreas.

Statement of the Problem

Type 1 diabetes is a condition in which the pancreatic beta cell destruction usually leads to absolute insulin deficiency therefore, requiring exogenous insulin replacement. There is an increase in incidence of type 1 diabetes worldwide. A landmark study, the Diabetes Control and Complications Trial (DCCT) (1993), established the benefit of intensive insulin therapy in reducing long-term and short-term complications, such as retinopathy, nephropathy, and neuropathy. Unfortunately, with the current treatment regimes, it's not possible to maintain normal glucose regulation over the lifetime of the patient with diabetes because of hyperglycemia and treatment induced hypoglycemia, known as iatrogenic hypoglycemia (Cryer, 2016). Diabetes technology has impacted the way people care for their diabetes. Current diabetes technology has limitations of inherent risk and user error. Advances in diabetes technology such as the continuous subcutaneous insulin infusion pump and continuous glucose monitoring, as well as advances in computer algorithm systems have furthered the development of closed loop artificial pancreas systems. Several research teams are investigating artificial pancreas system at various stages of development. This innovation can ease the treatment burden for patients with type 1 diabetes and may be useful in treating insulin requiring patients with type 2 diabetes. The healthcare provider plays a critical role in the diffusion of this technology to patients as healthcare provider typically decide the type of treatment a patient receives. In order for a healthcare provider to recommend a technology, the provider must accept the technology. Little is known about the factors that determine

healthcare provider's intent to use a closed loop AP system in diabetes patient management. Barriers exist regarding what determines healthcare providers' intent to use a closed loop artificial system in diabetes patient management.

Purpose of the Study

The purpose of this research is two-fold; 1) to create a valid survey tool using a Delphi process with a Delphi panel of experts. The tool entitled "Healthcare Provider-Closed-Loop Artificial Pancreas Adoption (HCP- CLAPA)" instrument will address 9 key constructs discussed in the literature related to intent to adopt technology. 2) The created instrument will help identify and understand key factors leading to adoption and potential barriers to adoption of the closed-loop artificial pancreas technology. It will also help determine the differences, if any, among physician's which includes: endocrinologist/diabetologist, internal medicine, primary care and non- physicians which includes: certified and/or licensed and/or registered nurse practitioners, certified nurse specialists, certified diabetes educators and physician assistants who care for patients with diabetes. This survey tool will help develop a holistic understanding of technology acceptance within the context of the individual healthcare provider by integrating key constructs from the Theory of Interpersonal Behavior (TIB), Theory of Planned Behavior (TPB), Diffusion Innovation Theory (IDT), as well as, resistance to change, perceived risk, value, and threat to autonomy thereby adding to the literature on the topic of behavioral intent to use technology.

Variables

The dependent variable in this study is *behavioral intent to adopt (use)* the independent variables in this study are: *relative advantage, perceived behavioral control, facilitating condition, self- concept, habit, perceived risk, perceived value, perceive threat to autonomy, and resistance to change*.

Research Questions

The field of technology acceptance among healthcare providers uncovered several different aspects to acceptance as well as barriers to technology acceptance (Yarbrough & Smith, 2007). Therefore, the overarching research question driving this dissertation study is as follows:

Overarching Research Question

What are the factors that lead to and barriers to healthcare providers' intent to adopt the closed-loop artificial pancreas?

Research Question 1 is descriptive in nature and do not have hypotheses. It describes the healthcare providers perceptions of knowledge regarding the technology.

RQ1. What are the physicians' and non-physicians' perceptions of knowledge regarding the closed-loop artificial pancreas?

The next set of research questions are descriptive in nature and do not have corresponding hypothesis. These questions are based on the healthcare professionals' beliefs of each factor (10) ***(relative advantage perceived behavioral control, facilitating condition, self- concept, habit, perceived risk, perceived value, perceive threat to autonomy, resistance to change, and behavioral intent to use)*** **and closed-loop artificial pancreas system. This question is looking at the differences between** ***physicians' and non-physicians'*** **beliefs regarding the 9 IV and the behavioral intent to adopt the closed-loop artificial pancreas.**

RQ2. What are the *physicians' and non-physicians'* beliefs regarding the 10 constructs and the closed loop artificial pancreas

$RQ2_a$. What are *physician' and non-physicians'* belief s regarding their ***perceived behavioral control*** and the closed-loop artificial pancreas.

$RQ2_b$. What are the *physician's and non- physicians'* beliefs regarding ***facilitating conditions*** and the closed-loop artificial pancreas patients?

$RQ2_c$. What are the *physicians'* and *non-physicians'* beliefs regarding ***self-concept***?

$RQ2_d$.. What are the *physicians'* and *non-physicians'* ***habit*** regarding insulin pump with continuous glucose monitoring and sensor augmented

pump therapy with low glucose suspend recommendations for ***type 1*** patients?

$RQ2_{e.}$ What are *physicians'* and *non-physicians'* beliefs about the ***perceived risk*** of the closed-loop artificial pancreas systems?

$RQ2_{f.}$ What are the *physicians'* and *non-physicians'* beliefs about their ***perceived value*** of the closed-loop artificial pancreas systems?

$RQ2_{g.}$ What are the *physicians'* and *non-physicians'* beliefs regarding their ***perceived threat to autonomy*** when recommending the closed-loop artificial pancreas?

$RQ2_{h.}$ What are the *physicians'* and *non-physicians'* ***resistance to change*** when using the closed-loop artificial pancreas for patient glycemic management?

$RQ2_{j.}$ What are the *physicians'* and *non-physicians'* ***behavioral intent to use*** the closed-loop artificial pancreas systems?

Research Question 3 and it corresponding hypotheses addresses the association between the 9 independent variables (IV) and the dependent variable (DV) behavioral intent to the adoption of closed-loop systems.

RQ3. What, if any, is the **association** between each predictor (9) and healthcare providers' **behavioral intent to use** the closed-loop artificial pancreas systems?

$H3_a$. Healthcare providers with higher ***perceived relative advantage*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_b$. Healthcare providers with higher ***perceived behavioral control*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_c$. Healthcare providers with higher ***facilitating conditions*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_d$. Healthcare providers with higher ***self- concept*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_e$. Healthcare providers with higher frequency of ***habit*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_f$. What, if any is the relationship with ***perceived risk*** intent to adopt the closed-loop artificial pancreas systems?

$H3_g$. Healthcare providers with higher ***perceived value*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

$H3_h$. Healthcare providers with higher ***perceived threat to autonomy*** will have lower behavioral intent to adopt the closed-loop artificial pancreas.

$H3_i$. Healthcare providers with higher ***perceived resistance to change*** will have lower behavioral intent to adopt the closed-loop artificial pancreas.

Research question 4 to 12 address the relationship between each predictor of intent to adopt (9) and healthcare providers behavioral intent to adopt the closed-loop artificial pancreas systems?

RQ4. What, if any, is the relationship between ***perceived relative advantage*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H4. Healthcare providers with higher perceived *relative advantage* will have higher behavioral intent to adopt the closed loop artificial pancreas.

RQ5. What, if any, is the relationship between ***perceived behavioral control*** and behavioral

intent to adopt the closed-loop artificial pancreas systems?

H5. Healthcare providers with higher *perceived behavioral control* will have higher behavioral intent to adopt the closed loop artificial pancreas.

RQ6. What, if any, is the relationship between ***facilitating conditions*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H6. Healthcare providers with higher facilitating conditions will have higher behavioral intent to adopt the closed loop artificial pancreas.

RQ7. What, if any, is the relationship between ***self-concep***t and behavioral intent to adopt the closed-loop artificial pancreas systems?

H7. Healthcare providers with higher self- concept will have higher behavioral intent to adopt the closed loop artificial pancreas.

RQ8. What, if any, is the relationship between ***habit*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H8. Healthcare providers with higher frequency of ***habit*** will have higher behavioral intent to adopt the closed-loop artificial pancreas.

RQ9. What, if any, is the relationship between ***perceived risk*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H9. Healthcare providers with higher perceived risk will have lower behavioral intent to adopt the closed loop artificial pancreas.

RQ10. What, if any, is the relationship between ***perceived value*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H10. Healthcare providers with higher perceived value will have higher behavioral intent to adopt the closed loop artificial pancreas.

RQ11. What, if any, is the relationship between ***perceived threat to autonomy*** and behavioral intent to adopt the closed-loop artificial pancreas systems?

H11. Healthcare providers with higher perceived threat to autonomy will have lower behavioral intent to adopt the closed loop artificial pancreas.

RQ12. What, if any, is the relationship between ***perceived resistance to change*** and behavioral intent to adopt the closed-loop artificial pancreas systems

H12. Healthcare providers with higher perceived resistance to change will have lower behavioral intent to adopt the closed loop artificial pancreas.

Research question 13. addresses the differences between physicians and non-physicians intent to adopt the closed-loop artificial pancreas by system type.

Note: There are 3 closed-loop artificial pancreas systems under investigation: hybrid closed-loop, a 24-hour fully automated insulin only and a dual hormone system which included a combination of insulin and glucagon or insulin and glucagon -like petide-1 agonist (GLP-1) or pramlintide.

RQ13. What, if any, is the difference between **physicians' and non-physicians'** behavioral intent to adopt the closed-loop artificial pancreas technology by system type?

H13. Non-physicians' will have a greater behavioral intent to adopt the artificial closed-loop pancreas systems by system type than physicians.

SIGNIFICANCE OF THE STUDY

Artificial pancreas closed-loop systems are personal medical devices may serve as a plausible treatment option for patients with diabetes which may reduce long term complications and may significantly reduce health care cost (Malchesky, 2013). This innovation has the potential to elevate treatment burden for the patient. Physicians and allied health professionals typically inform patients about available treatment options. This relationship requires well informed physicians. It also requires

the understanding of what leads to technology acceptance and ultimately the intent to adopt technology when the technology is used by the patient for disease management and moreover, may require the healthcare provider to become educated on that device. Understanding technology acceptance or adoption may help to develop processes that can facilitate training for healthcare providers and ultimately improve patient care. Therefore, this study will further research in technology acceptance among healthcare providers.

Operational Definitions:

Closed-loop artificial pancreas involves a mechanical system that consists CGM, CSII insulin pump, control algorithm for calculating rates of insulin delivery and Rapid acting insulin analogs. Three basic types: 24-hr insulin only, Hybrid, and Dual Hormone (Cobelli et al., 2011).

Continuous Glucose Monitor (CGM) Sensor is inserted under the skin Measures interstitial glucose that trends with plasma glucose changes Interstitial glucose is measured every 1-5 minutes. It assesses trends and can predict hyper and hypoglycemia (Hirsch et al., 2008).

Continuous Subcutaneous Insulin Infusion CSII- Insulin Pump-Small external device that delivers insulin 24 hr./day pre-programmable. Meal doses are given based on blood glucose and food intake (Skyler, Ponder, Kruger, Matherson and Parkin, 2007).

Diabetes Mellitus-is defined as a group of complex diseases characterized by high blood glucose, resulting from a defect in either the production of or action of insulin, or both (National Institutes of Health, 2014).

Diabetic Keto Acidosis (DKA) Serious life-threatening complication caused by absolute insulin deficiency, leading to a catabolic state causing metabolic acidosis, hyperosmolality, and electrolyte disturbances (ADA, 2017).

Hemoglobin A1C (HbA1C) is a test reflects an average blood sugar level over the previous two to three months and is now used to as a diagnostic test. ADA Goal <7.0 Adults < 7.5% pediatrics (ADA,2015).

The ADA definition of ***hypoglycemia*** is <70 mg/dl and severe hypoglycemia is defined as third party intervention- despite confirmation of BG, correction by glucose (Cryer, 2016).

Multiple daily injections (MDI)- Multiple 3-5 rapid and 1-2 long action insulin injections per day (Raskin, 2003).

Type 1 diabetes is pancreatic β-cell destruction leading to absolute insulin deficiency There is a strong genetic component and an environmental Triggers (Krolewski, Warram, Rand, & Kahn, 1987).

Self -Measured Plasma Glucose- a capillary blood is applied to disposable 'test-strip'. Glucose is typically measured by glucose oxidase (Clark & Foster, 2012).

Sensor Augment Pump Therapy (SAPT)- A pump and a sensor system together (Hirsch, 2008).

Theoretical Framework

This study adopts an integrated theoretical research framework for the investigating health care provider's behavioral intent towards future use of the closed-loop artificial pancreas for the management of patients with diabetes. In information systems literature integrating theories to improve explanatory power of the model is common (Legris, Ingham, & Collerette, 2003). This model integrated constructs from Theory of Planned Behavior (TIB), Innovation Diffusion Theory (IDT), and Theory of Interpersonal Behavior (TIB). In addition, other constructs were added based on identified gaps in the literature to enhance the understanding of technology acceptance of the closed-loop artificial pancreas (Figure 1).

The artificial pancreas is an emerging technology that is not currently available for use, so it is not possible to measure actual use. Therefore, behavioral intention, a person's subjective probability to perform a specific behavior was chosen as the dependent variable. Behavioral intent has a major mediating effect on intent to use and intention was also found to be a valid proxy measure for behavior among clinicians (Eccles et al., 2006; Godin et al., 2008). Previous studies have also chosen behavioral intention instead of actual use as a dependent variable to investigate technology acceptance(Gagnon, Orruño, Asua, Abdeljelil, & Emparanza, 2012; Hung, Ku, & Chien, 2012; Mun et al., 2006).

The technology acceptance model consists of three constructs; *perceive usefulness (PU), perceived ease of use (PEOU),* and *technology acceptance.* It is the most widely used theory in technology acceptance research. However, TAM was not

used in this study because the constructs could not be easily applied to the population being studies however it was used as a basis for understanding intention to adopt. *Perceived usefulness* consistently predicts healthcare provider's intention to adopt new technology, suggesting that in order to promote use of the technology, it must be perceived as useful (Holden & Karsh, 2010). *Perceived ease of use* defined as the perception that using the system will be free from physical and mental effort (Davis, 1989). For healthcare provider's, the construct of perceived usefulness is supported but perceived ease of use has not been consistently supported across the literature (Holden & Karsh, 2010; Yarborough & Smith, 2007). However, the construct of perceived usefulness has been operationalized differently and differed greatly between studies and the original definition of TAM (Holden & Karsh, 2010). The construct of *relative advantage* is conceptually similar to perceived usefulness (Mun et al., 2006). Relative advantage and perceived usefulness both encompass the degree to which a user feels the target technology is better than the current practice. Relative advantage is defined as the degree in which an innovation is perceived as being better than the idea it supersedes (Rogers ,2003). Therefore, relative advantage was chosen to replace perceived usefulness. In addition, one explanation for the lack of effect on PEOU was due to clinicians having no actual or little hands on experiences with the technology (Van Schaik, Bettany-Saltikov, & Warren, 2002). Since, the artificial closed-loop system is not available for hands on experience PEOU will be ignored in this model. TAM has proven its efficacy for predicting the acceptance of numerous types of technologies across disciplines and cultures (Yarborough & Smith 2007).

Although TAM was originally thought to fully explain technology acceptance, research continued to include external variables in an effort to increase explanatory value. In addition, the original TAM included attitude as mediator to behavioral intention however, TAM2 dropped attitude because it was found to only partially mediate the effect s of behavioral intention (Venkatesh & Davis, 2000).

TAM was originally grounded on principles adopted from the attitude paradigm the Theory of Reasoned Action (Davis, 1993). Perceived behavioral control was added to the TRA and became the Theory of Planned Behavior (TPB) (Ajzen, 1991). A review of these models in healthcare by Holden and Karsh (2010) revealed several strengths, one of the strength of adopting these models in this field has been the ability to find consistently significant relationships specific to perceived behavioral control in relation to technology acceptance. Perceived behavioral control refers to people's perceptions of their ability to perform a given behavior. Therefore, health care providers with higher perceived behavioral control will be more likely to adopt new technology. This model includes perceived behavioral control.

- IDT has been used to study innovations ranging from agricultural to high tech innovations (Mun et al., 2006). Although originating from different disciplines TAM and IDT have some similarities. Both theories share the view that adoption of a particular innovation is determined it perceived attributes (Mun et al., 2006). As stated before, the construct of TAM has similarities to the constructs of IDT. Perceived ease of use is compatible with complexity (Mun et al., 2006). Due to these similarities, *complexity* will be ignored in the current model because the closed-loop

artificial pancreas system is not available for hands on experience and it would be difficult to assess complexity. *Compatibility* was originally included in the framework, but it was eliminated during the Delphi process. *Trialability* is the extent to which the innovation can be tested before a commitment from the adopter and *observability* which is the extent to which the innovation provides tangible results and demonstrability refers to the possibility to demonstrate the results of the new system, could not be operationalized because the closed-loop artificial pancreas was not available for hands on use.

Tam and IDT concentrates on technology but lacks the psychosocial construct of TIB. TIB focuses on the psychosocial aspect of the individual adopter and lacks a technology focus. TIB contains some of the behavioral determinants of TAM but considers cultural, social, and moral factors (Gagnon, et al. 2003). The *perceived consequences* construct is compatible with perceived risk and therefore ignored in this model. *Facilitating conditions* overlaps with PEOU. Facilitating conditions refers to the environmental (external) factors that make the act easy (Triandis, 1977). For the purposes of this study facilitating conditions was operationalized in the context of external support and monitoring systems that may improve ease. Facilitating conditions are conceptualized as direct antecedents to behavior in the original model; this construct will be linked to intention. This approach has been used empirical by Gagnon et al. (2003). In addition, facilitating conditions have shown to have a direct effect on perceived behavioral control in models that have deconstructed perceived behavioral control into self-efficacy and facilitating conditions. This study

model does not deconstruct perceived behavioral control and therefore facilitating conditions will be directly linked to behavioral intent to use. *Social Norms* or social influence had non-significant effects on behavioral intention among physician's (Holden& Karsh, 2010). Physician specific characteristics such as independence and immunity to peer influence may be in part the reason for this as well as if the system was mandated or voluntary (Holden& Karsh, 2010). Social norm seems to have little influence when the system was voluntary. Certainly, in the case of an artificial pancreas it would be considered a voluntary technology for both the providers to prescribe and the patients to use. For this reason, the social norm construct was ignored in this model. *Affect* represents an emotional state that performance of a behavior evokes (Triandis, 1977). Affect was not included in the proposed model because the behavior of interest a professional behavior and less likely to be influenced by affective consequences (Gagnon et al., 2003; Godin et al., 2008). This model retained *self-concept* and *habit*. *Self- concept* is defined as thoughts and feelings of behavioral disposition of which the individual is aware (Triandis, 1977). *Habit* was conceptualized to be link directly to behavior in the original model. Habit was defined as past behaviors predicting future behaviors in terms of frequency (Triandis, 1977). It was operationalized to refer to use of currently available technologies predicting future intent to use the closed-loop artificial pancreas. Currently available systems include SAPT which contain the major components of the artificial closed-loop system with the exception of the control algorithm.

In addition, several other constructs were added to help explain healthcare provider's intent to adopt technology. Perceived Risk Theory has been widely utilized in consumer research (Lim, 2003). This theory proposes that individuals perceive risk because they face potentially undesirable consequences as a result of purchases. Perceived risk is a multidimensional construct which includes: financial, psychological, performance, social risk, time, and safety (Cunningham, 1967). A general definition of perceived risk under the concept of the consumer is "the nature and amount of perceived risk of a consumer in contemplation of a particular purchase action" (Cox & Rich, 1964). In the contexts of medical devices, potential safety problems indicate the importance of performance risk. Health care providers are not personally incurring the cost of the medical device. However, they are aware of economic burden of diabetes and the health economics outcomes research of approved treatments thus, highlighting the importance of financial risk. *Perceived financial risk* is defined as the potential monetary output associated with the initial purchase price as well as the subsequent maintenance cost of the product (Grewal, Gotlieb, & Marmorstein, 1994). *Perceived performance risk* is the possibility of that the product malfunctioning and not performing as it was designed and therefore, failing to deliver desired benefits (Grewal et al., 1994). In the context of a medical devices performance risk can lead to safety issues. Risk when related to safety is defined as the probability or frequency of occurrence of a defined hazard and the consequence of the occurrence (HMSO, 1995). In this study, *perceived financial risk* is defined as the health care providers' perceptions of the potential output associated

with the closed-loop artificial pancreas and all subsequent maintenance costs. It is operationalized in the context of cost to the patient and healthcare system based on the known costs of similar currently available SAPT and hybrid closed-loop systems projecting the perceived cost of the fully automated closed-loop system. *Perceived performance risk* is defined as the probability of the product harming the patient due to malfunctioning. In contrast to general consumers, it is not expected for health care providers would not suffer psychological stress or be concerned with others perceptions regarding their patient's purchase of a closed-loop artificial pancreas and therefore these constructs were not considered in this model. Time- loss was considered a major barrier to physician's acceptance of technology (Yarbrough & Smith, 2007). However, for the purposes of this study time- loss was considered a value-based driver identified as a sacrifice under the operationalized construct of *value*.

Most empirical tests of TAM and healthcare provider specific technology acceptance assume that the new technology provides some value to the user. There are multiple ways to define and operationalize *value*. In terms of healthcare, value has been described as the total benefits received minus the cost. Where the benefits are outcomes and services and the cost is price and non- monetary cost (Ettinger, 1998; Lee & Larsen, 2009). Three value-based drivers are price, time/effort/energy, and conflict (Lapierre, 2000). Price, time, and effort were operationalized in the context of perceived patient outcomes indicating value. To the author's best knowledge this

is the first-time the *perceived value* construct is being conceptualized in the context of technology acceptance.

Healthcare providers differ from other types of users in terms of technology acceptance (Holden and Karsh, 2010). They are medical professionals. A profession was originally defined as a specific occupation with special characteristic with a strong sense of public and social purpose that was served by the professional (Friedson, 1970; Swick, 2000). "Profession" has evolved to be focus on expert knowledge, so that control and application of the specialized body of knowledge is what characterized a profession. Achieving the status of being a member of a profession, professionals are granted professional autonomy (Friedson; 1970; Water & Succi-Lopez, 2008;). Professional autonomy is freedom to practice his/her profession in accordance to his/her knowledge and expertise (Engel, 1970; Walter & Succi-Lopez, 2008). Loss of professional autonomy may reduce the quality of services provided (Engle, 1970). The artificial closed-loop pancreas may potentially affect the professional autonomy of a health care provider thus affecting the quality of patient care. *Perceived threat to autonomy* refers to the degree to which a person believes that a technology would decrease their control over processes, procedures, or content of his or her work (Walter &Succi-Lopez, 2008). In this model, *perceived threat to autonomy* was operationalized in the contexts clinical decisions, patient management, and follow-up care processes.

Industrial societies value a person who is willing to and able to initiate and respond to positively to change, and yet attempts to initiate change are often

accompanied by individuals or groups who resist change (Oreg, 2003). Healthcare technologies are widely expected to improve patient quality of care and to reduce cost however, these technologies are often strongly resisted by the same professional expecting benefit from them (Bhattacherjee & Hikmet, 2007). Withdrawal of already implemented medical innovations is well documented (Lorence & Richards, 2003; Massaro, 1993). Individual differences among perspective users determine how individuals think and behave. Personality traits determine how individuals think and behave in various situations (Nov & Ye, 2008). Personality traits are often used in psychosocial research to explain beliefs and behavior. The introduction of new technology involves change for the user. Social psychological research has identified individual's dispositional inclination to resist change as a personality trait (Oreg, 2003). This trait is called *resistance to change* and could be viewed as a possible deterrent to use of a new technology. Therefore, this model includes the construct resistance to change as a potential barrier to technology acceptance.

To the best of the author knowledge this is the first study that integrates constructs from IDT, TIB and TBP with the construct of perceived value along with potential barrier constructs identified from the literature (perceived risk, resistance to change, and threat to autonomy). The model (Figure 1) is based on the gaps identified in both technology adoption and closed loop- artificial pancreas literature.

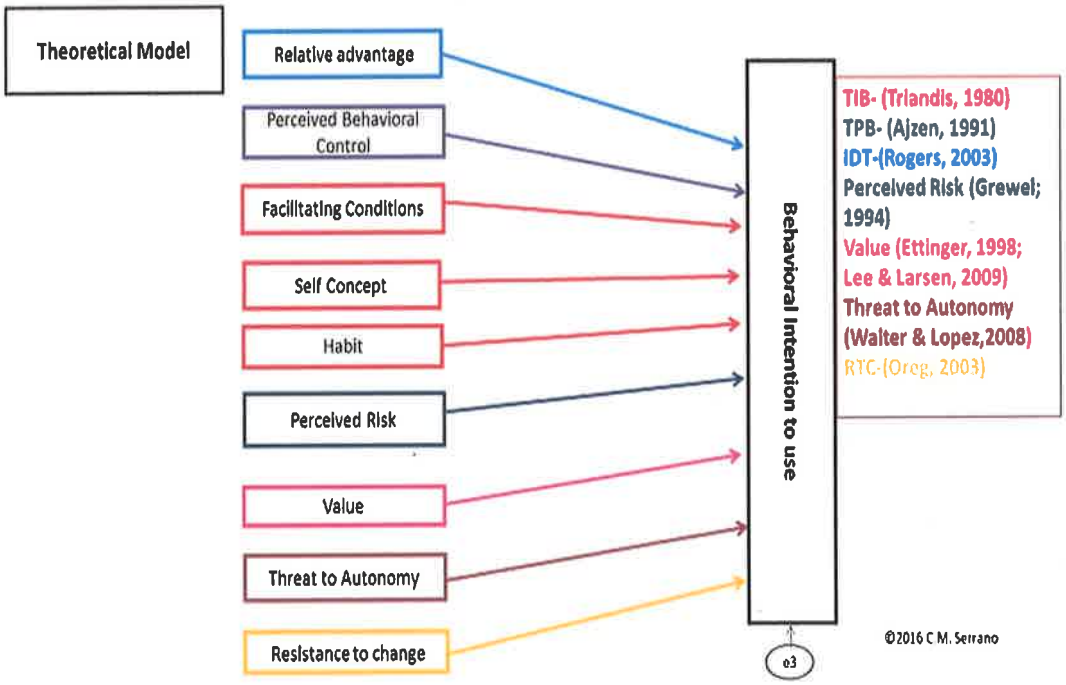


Figure 1. Proposed Theoretical Model

CHAPTER II

REVIEW OF RELEVENT LITERATURE

Diabetes Disease State

There are 415 million people worldwide that have diabetes and 29.6 million nationwide. (ADA, 2015). There are approximately 208,000 individuals under the age of 20 estimated to have been diagnosed with diabetes in 2012 in the United States (CDC, 2014). Type 1 diabetes accounts for approximately 5-10% of all diabetes cases (Daneman, 2006). Optimal diabetes care involves frequent blood glucose monitoring, timing of meals, monitoring of carbohydrate content of meals, and monitoring of physical activity. All children and adults with type 1 and some with type 2 diabetes require multiple daily injections of insulin by syringe, pen, insulin pump or continuous subcutaneous insulin infusion (CSII), or inulin pod (Silverstein et al., 2009; Jacquez et al., 2008).

Type 1 diabetes is a condition in which the pancreatic beta cell destruction usually leads to absolute insulin deficiency therefore, requiring exogenous insulin replacement (Krolewski, Warram, Rand, & Kahn, 1987) There are two forms of type 1 diabetes; type 1A results from a cell mediated autoimmune attack on beta cells and type 1B, which is less common and with no known cause. Type 1B often occurs in individuals of Asian and African descent who have varying degrees of insulin deficiency (Daneman, 2006). Type 1 diabetes has a strong genetic component inherited through the human leukocyte antigen (HLA) genes but factors that trigger the onset of the clinical presentation of the disease are largely unknown (Daneman,

2006). Approximately 10-20% of newly diagnosed type 1 diabetes have a first degree relative with type 1 diabetes (Tuomilehto, 2013). The cumulative risk for those with an affected sibling or parent is approximately 3-7% compared to the general population of less than 1% and the cumulative incidence among identical twins is less than 50% (Tuomilehto, 2013). Therefore, genetic predisposition does not guarantee clinical presentation. The clinical presentation is thought to be triggered by exposure to one or more environmental factors that alter immune function and initiate beta cell destruction (Daneman, 2006). Potential environmental factors include viral infections such as coxsackie virus, mumps, rubella, early exposure to cow's milk protein's, and gluten (Norris et al., 2003; Robles & Eisenbarth, 2001; Virtanen et al., 2000) Type 1 diabetes accounts for approximately 5-10% of all diabetes cases; however it has serious short term and long term implications (Daneman, 2006).Type 1 diabetes can develop at any age but it rarely presents in the first six months of life(Tuomilehto, 2013). There is an increase in incidence of type 1 diabetes up to puberty and peaks between ages 5-7 and 10-14. The highest rates of type 1 diabetes are in Finland and Sardinia with the lowest rates in Venezuela and China (Karvonen et al., 2000). There are clear geographic differences in the trends in type 1 diabetes, but the overall worldwide annual increase is approximately 3%. (DIAMOND Project Group, 2006)

Treatment Goals

HbA1C test reflects an average blood sugar level over the previous two to three months and is now used as a diagnostic test (ADA,2015). For decades, the diagnosis of diabetes has been based on plasma glucose control, either a fasting plasma glucose (FPG) or a two hour seventy-five-gram carbohydrate oral glucose tolerance test (ADA, 2015). A1C test has several advantages over FPG tests which including convenience and greater reliability because of less day to day variability. A normal A1C ranges from 4.0%-6.0%, Pre-diabetes ranges from 5.7% to 6.4%, and diabetes is diagnosed at 6.5% A1C (ADA, 2015). In addition to A1C, fasting plasma glucose (FPG) and 2-hour plasma glucose (2-PG) may be used to diagnose diabetes (ADA, 2016). The criteria for diabetes diagnosis is an FPG of ≥126 mg/dL and a 2-h PG of ≥200 mg/dL (ADA, 2015). Unless a patient has classic symptoms or is in a hyperglycemic crisis then a random plasma glucose of ≥200 mg/dL can be used for diagnosis. It is recommended that the same test be repeated immediately using a new blood sample for confirmation (ADA, 2015). The treatment goals for type 1 diabetes are to utilize insulin therapy aimed at near normal blood glucose and HbA1C goals, prevent diabetic ketoacidosis, and severe hypoglycemia. Achieve the highest quality of life compatible with the daily demands of diabetes management. In children, achieve normal growth and physical development and phycological maturation and to establish realistic goas adapted to individual circumstance (Handelsman et al., 2015) Unfortunately, recent data from the T1D Exchange clinical registry shows that the

mean A1C remains above the recommended target of 7.5% for all age groups, with a peak of 9.2% in late teen years (Miller et al., 2015).

Diabetes technology has impacted the way people care for their diabetes. Portable subcutaneous insulin infusion first became possible in the 1970's and showed improved glycemic control (Tamborlane, Sherwin, Genel, &Felig, 1979). The results of the DCCT demonstrated the importance of glycemic control and lead to an increased interest in technology to achieve control with minimizing hypoglycemia (DCCT, 1993; Cryer,2016). The gold standard for replacement of basal insulin is continuous subcutaneous insulin infusion by means of an insulin pump (Bolli, 2001). An insulin pump is a medical device used in the treatment of diabetes and is described by Skyler, Ponder, Kruger, Matherson and Parkin (2007) as small computerized, external device that delivers rapid or short acting insulin twenty-four hours a day. Most pumps are attached to a thin plastic tubing that has a soft cannula which is inserted under the skin. The insulin pump allows a pre-programmable basal insulin dose continuously throughout the 24 hours to maintain blood glucose levels between meals and overnight. Bolus doses are given by the user before meals based on the glucose level and food intake and supplemental or correction bolus doses of insulin is given to treat hyperglycemia (Skyler, Ponder, Kruger, Matheson, & Parkin, 2007). To date there are over seven different insulin pumps on the market with varying features but the basic basal- bolus concept remains (Grunberger et al., 2014). The American Association of Clinical Endocrinology consensus statement (2014), suggests that CSII appears to be a justified basal bolus insulin therapy for pediatrics

based on the current available data showing consistent reduced A1C compared to multiple daily injection therapy, improvements in quality of life measures, and reductions in sever hypoglycemia .

Several clinical trials have consistently shown improved glycemic control in term of significant mean A1C reductions after 12 months of CSII therapy in pediatric patients as young as 18 months old (Ahern et al., 2002; Weinzimer et al., 2004). Ahern et al. (2002), demonstrated a decrease in frequency of severe hypoglycemic events in pediatric patients on CSII after 12 months compared to pre-pump severe hypoglycemic frequency. Weinzimer et al. (2004), demonstrated insulin pump treatment lowered the frequency of sever hypoglycemia by 53% in their study population over a four year follow up compared to the year prior to starting CSII.

Insulin analogues were developed to more closely mimic physiologic insulin production. Glucose homeostasis in people without diabetes has taught that a low plasma insulin concentration is needed to prevent hypoglycemia between meals (Bolli, 2003). Pharmacokinetic studies of insulin analogue glargine in type 1 subjects demonstrated that basal insulin analogue activity is relatively peak-less and last 24 hours (Lepore et al., 2000). Glargine's unique profile demonstrated efficacy and safety benefits over NPH basal insulin in type 1 patients (Pieber, Eugene-Jolchine, & Derobert, 2000; Raskin et al., 2000; Rosenstock, Park, Zimmerman, & U.S. Insulin Glargine (HOE 901) Type 1 Diabetes Investigator Group, 2000). Therefore, additional studies were completed to evaluate insulin Glargine to the gold standard therapy CSII. Doyle et al. (2004) was the first to establish efficacy of CSII over

multiple daily injections (MDI) with insulin analogue Glargine in pediatric patients. Thirty-two pediatric patients age 8-21 were randomly assigned to receive either CSII or MDI with Glargine for sixteen weeks. The investigators found that CSII achieved significantly lower A1C, with a lower insulin dose, and lower pre-meal blood glucose levels compared to MDI with Glargine in the short term. In addition, a large European evaluation of CSII under real life conditions in 17 countries analyzing insulin pump data from patient's ages 0-18 year of age revealed glycemic targets can frequently be achieved with CSII especially in young children with a low incidence of severe hypoglycemia (Danne et al., 2008). During the past twenty years, CSII pump therapy has become the mainstay for many patients with T1D (Florlenza, Buckingham & Maahs, 2015). A recent report from the T1D Exchange clinical registry revealed an increase in insulin pump use during the examination period from 58% to 62% (Miller, 2015 et al.). The T1D Exchange clinic registry consists of treatment centers that focus on the care of Type 1 diabetes therefore, pump use may be higher than the general population.

Barriers to Diabetes Control

Type 1 diabetes usually present with hallmark symptoms of polyuria which is as excessive urination and polydipsia which is excessive thirst. Frequently, children present in diabetic ketoacidosis at the onset of diabetes (DKA) (ADA, 2015). DKA is a serious life threating complication of diabetes in children caused by the relative or absolute deficiency of insulin (Orlowski, Cramer, & Fiallos, 2008). In attempts to

diagnose type 1 diabetes sooner, the 2017 ADA guidelines suggest staging type 1 diabetes to ensure patients at risk are identified earlier (ADA 2017) The absence of insulin causes the body to go into a catabolic state leading to metabolic acidosis, hyperosmolarity, dehydration, and electrolyte disturbances. DKA can lead to central nervous system changes and cerebral edema which has a high morbidity and mortality (Orlowski et al., 2008). Recently, Type 1 diabetes has been reclassified based on the degree of beta cell destruction to allow for diagnosis prior to the onset of DKA (ADA, 2017). In 1993, the Diabetes Control and Complications Trial established the benefit of intensive insulin therapy in reducing long-term and short- term complications, such as retinopathy, nephropathy, and neuropathy (DCCT, 1993). Despite this knowledge, diabetes complications from type 1 diabetes remains a significant issue (Maahs et al.,2014).

Under normal physiology and during fasting conditions, glucagon is secreted from the pancreatic alpha cell to stimulate the liver to produce glucose. This is used by both insulin independent tissue such as the brain and insulin dependent tissue such as muscle and fat. Under the fed condition, blood glucose increases stimulating the pancreatic beta cell to secret insulin. Insulin secretion causes glucagon production to stop, which decreases glucose output from the liver and increase glucose uptake by the peripheral tissues that are insulin sensitive contributing to normalizing blood glucose (Aronoff, Berkowitz, Schreiner &Want, 2004). The cross talk between the alpha and beta cell of the pancreas and the liver contribute to a balance between gluconeogenesis and glycogenolysis to maintain tight glucose control. Unfortunately,

with the current treatment regimes, it's not possible to maintain normal glucose regulation over the lifetime of the patient with diabetes because of treatment induced hypoglycemia, known as iatrogenic hypoglycemia (Cryer, 2016).

Hypoglycemia puts patients at risk for injury and death (Sequist, 2013). Iatrogenic hypoglycemia in patients with diabetes is defined as all episodes of abnormally low plasma glucose concentrations that expose the individual to potential harm. It is the limiting factor in glycemic control (Cryer, 2016). It causes morbidity in people with diabetes and triggers physiologic and behavioral defenses against subsequent hypoglycemia which ultimately causes recurrent hypoglycemia. Lastly, it prevents euglycemia over the lifetime and therefore prevents the full realization of micro and potentially macrovascular benefits of glycemic control (Cryer, 2016). Patients with type 1 diabetes may have plasma glucose concentrations less than 50 mg/dl as much as 10% of the time and thousands of events over the lifetime. Physical symptoms include palpitations, tremors, anxiety, sweating hunger, cognitive impairments, seizure, coma and potentially death (Cryer, 2016; Towler, Havlin, Craft & Cryer, 1993). Profound hypoglycemia can cause brain death.

Clinical hypoglycemia is a plasma glucose level low enough to cause symptoms or signs. A single value for plasma glucose concentration that define hypoglycemia cannot be assigned because threshold for symptoms shift to a lower plasma glucose concentration after previous hypoglycemia and to higher plasma glucose concentrations in poorly controlled diabetes with infrequent hypoglycemia (Seaquist, 2013). However, the alert value of $\leq$ 70 mg/dl for self-monitoring plasma

glucose (SMPG) and continuous glucose monitoring (CGM) has been established. This alert approximates the lower limit of the normal plasma glucose concentration, the glycemic threshold for glucose counterregulatory system in non-diabetic, and the upper limit of plasma glucose level reported to reduce counterregulatory response to subsequent hypoglycemia (Seaquist, 2013).

The brain requires a continuous supply of glucose from circulation. It cannot synthesize or store more than 20 minutes' supply of glycogen (Cryer, 2016). Therefore, maintenance of plasma glucose at or above normal range is required. Falling plasma glucose causes a sequenced physiologic response. The lower limit of normal plasma glucose causes secretion of a counter regulatory hormones, such as glucagon. Glucagon secretion increases as plasma glucose concentrations fall below the physiologic level. Glucagon is secreted from the pancreatic alpha cell. It rapidly stimulates hepatic glucose production. Glucagon along with insulin, supports the post absorptive plasma glucose concentration in humans (Cryer, 2016; Breckenridge et al, 2007). Hypoglycemia in type 1 diabetes is caused by insulin excess and compromised defenses against falling plasma glucose concentrations (Cryer, 2016). Physical activity increases glucose utilization, which also increases the risk of hypoglycemia (Seaquist, 2013). The demands of daily treatment for people with Type 1 diabetes, the emotional burden of the disease, and its threatening acute and late complications have major effects on the patient's physical, social, and psychological well-being (Bott, Mulhauser, Overmann, & Berger,1998).

Treatment of the patient with type 1 diabetes requires constant regulation of the balance between glucose intake and insulin to avoid hypoglycemia. Regulation of blood glucose includes self- monitoring plasma glucose (SMPG) using a glucometer and healthcare provider regulation of glucose through pattern management of SMPG and the Hemoglobin A1C test (HbA1C). Fear of hypoglycemia conflicts with treatment success for both patients and clinicians. For patients, the percent of people who modify insulin dose was approximately 75% for those who experienced non-severe episodes and 80% for severe episodes of hypoglycemia (Peyrot, 2012). In addition, 72% of primary care physicians and 79% of specialist would treat patients more aggressively if there was no concern about hypoglycemia (Leiter, 2005).

Glucose variability, which refers to the swing in blood glucose levels or fluctuation of glucose levels throughout the day. Glucose variability includes episodes of hypoglycemic and hyperglycemic periods (Suh & Kim, 2015). Excessive glucose variability is associated with increased risk of hypoglycemia. Therefore, therapeutic approaches aim at avoiding hypoglycemic episodes while maintaining target A1C levels (Monnier et al., 2017). Technology such as insulin pump therapy and CGM systems have been successful in reducing hypoglycemia and glucose variability.

Device Errors

Insulin pumps have been advancing in form and in function and now follow the lead of consumer electronics and have offered features such as touch screens,

USB rechargeable batteries, prefilled insulin cartridges, and disposability (Grunberger et al., 2014). Patient safety is a concern as this technology advances. Advanced features increase the insulin pump complexity and can create diagnostic issues with unexplained hyper and hypoglycemia or unexplained pump error messages and alarms (Grunberger et al., 2014). Along with the inherent danger of diabetic ketoacidosis, which is a specific risk of pump therapy for all patients that have type 1 diabetes. The accidental or purposeful interruption of insulin delivery over several hours can lead to increase in blood ketones and development of DKA because the pump patients are only receiving rapid acting insulin with a limited action profile (Grunberger et al., 2014). Insulin pumps have the potential of overmedicating or under-medicating through various mechanical malfunctions such as a depleted battery, kinking in the tubing, occlusions from an infusion set, and/or leakage from the infusion set. Insulin can precipitate and occlude the needle or tubing. There can be hardware or software issues that can lead to over or under delivery of insulin(Cope, Morrison, & Samuels-Reid, 2008). There can also be user error in changing infusion sets and refilling reservoirs.

A 10-year retrospective study of medical device adverse event reports from January 1, 1996 to December 31, 2005 involving insulin pumps used by patients ages 12-21. A total of 1574 adverse events were identified for insulin pumps, including 13 deaths, and serious and fatal adverse events rose by approximately 17% per year from 2001-2009, possibly due to increase in pump use. The top issues associated with these reports were education, noncompliance, problems with sports, and four reports were

cited risk taking behaviors (Cope, Morrison, & Samuels-Reid, 2008). Cope, Samuels-Reid, & Morrison (2012), conducted an additional retrospective search of the MAUDE database for adverse events in children ages 1-12 years involving insulin pumps from January 1, 1996 to December 31, 2009. There were 1774 total events and over half resulted from serious adverse events. There were 5 deaths, 614 reports of hyperglycemia and/ or DKA and 98 reported cases of hospitalizations for hypoglycemia. Reports for device related problems included; bent cannula, battery issues, alarm- related problems, priming issues, delivery problems, breakage, cracking, corrosion, infusion site errors, reservoir issues, kinked tubing, button issues, and disconnections. Adverse events were associated with patient education, device misuse, and pump malfunctions. This study highlights the need for better pump training and understanding of the safe use of insulin pumps in the pediatric population (Cope, Samuels-Reid, & Morrison, 2012).

Technological Progress/Treatment Progress

Continuous glucose monitoring (CGM) represents a vital advancement in diabetes technology (Forlenza et al., 2016). CGM differs from self-monitoring blood glucose which provides a point in time glucose reading, by providing automatic "real-time" information about the trends in glucose and rate of change in glucose. It alerts patients to trends leading to hypo or hyperglycemia (Hirsch et al., 2008). The basic mechanics of CGM involves inserting a sensor under the skin. The sensor measures the glucose in the interstitial fluid and displays values approximately every 1-5

minutes (Hirsch et al., 2008). The interstitial glucose is a different body compartment than blood. The sensor glucose measures can lag rapidly changing blood glucose and because of this lag time CGM is used in tandem with traditional blood glucose monitoring to assess overall glucose dynamics (Hirsch et al., 2008). CGM data does allow the patient to control blood glucose more tightly.

The Endocrine Society recommends children and adolescents with type 1 demonstrating near daily use CGM starting at the age of 8(Klonoff et al., 2011). The American Association of Clinical Endocrinologist (2010), suggest that CGM is strongly recommended for children and adolescents with type 1 diabetes who have achieved HbAIC level less than or near to 7 and are able to wear the device on a near daily basis (Klonoff, 2010). CGM can assist highly motivated families in maintaining target A1C levels and reducing hypoglycemia frequency. It is also recommended for patients with frequent hypoglycemia or hypoglycemia unawareness, elevated A1C and excessive glucose variability (Blevins et al., 2010).

The American Diabetes Association (2015), recommendations state that CGM may be a supplemental tool to self- monitoring blood glucose in those with hypoglycemia unawareness or frequent hypoglycemia. The evidence for A1C lowering is less strong in children, teens, and younger adults due to a variability in adherence to CGM, assessing individual readiness for continuing use of CGM prior to prescribing (ADA, 2015). The ADA standards of care (2016), state people utilizing continuous glucose monitoring and insulin pumps should continue to have access after they turn 65 years of age. In addition, people at risk for developing type 2

diabetes should consider the use of new technology, such as Internet-based social networks, distance learning, and mobile applications, to effectively modify behaviors to prevent diabetes (ADA, 2016). A study by the Juvenile Diabetes Research Foundation (JDRF) demonstrated a 0.53% reduction greater in A1C among 322 adults and children with type 1 diabetes randomized to real-time CGM compared usual care. More specifically, CGM worn up to 6 days a week in type 1 children 8-14 was associated with an A1C reductions (Tamborlane et al., 2008). The amount of sensor use correlated with the magnitude of A1C reduction (Weinzimer, 2012).

Insulin pumps started as miniature syringe pumps and have evolved into more complex devices that are easier and safer to use (Grunberger et al., 2014).For many years, insulin pumps have received data transmitted from glucose meters and more recently they have the added capability to transmit data from the CGM and display it directly on the face of the insulin pump or other remote devices The combination of CGM and CSII pump technology with patients and or the patients' guardians making decisions in insulin dosing is called sensor- augmented pump therapy (SAPT) (Forlenza et al., 2016). The Sensor Augmented Pump Therapy for A1C Reduction (STAR-3) study randomized 485 adults and children to sensor augmented pump therapy or MDI. There was a statistically significant treatment difference in A1C of 0.6% favoring the sensor augmented group verses conventional self-monitoring blood glucose. Children and adolescents ages 7-18 did not significantly benefit from CGM with a total A1C reduction of 0.4% compared to the MDI group with a reduction in A1C of 0.2%(Bergenstal et al., 2010). In addition, the composite endpoint showed

that more patients in the sensor augmented insulin pump arm of the study reached the A1C goal of less than 7% without an increase in severe hypoglycemia or weight gain (Rubin, Borgman, & Sulik, 2011). Despite the benefits of CGM use, overall uptake of CGM remains low at 11% (Forlenza, Buckingham & Maahs, 2016). In addition, of those who tried CGM 41% discontinued use with in the first year. Reasons why patients discontinued CGM included lack of accuracy, intrusive alarms, and discomfort (Polonsky, 2013). There are currently three CGM's approved in the US. The technology limitations of the current CGM devices include the need for multiple daily calibrations using SMBG on two of the three CGMs products, pressure induced attenuation of sensor signal, and interferences from acetaminophen (Baysal, 2014; Maahs, 2015). The results of these studies indicate that continuous surveillance of sensor augmented pump system is required to optimally control patients and patient's decisions on insulin dose is subject to human judgment, error and neglect (Weinzimer, 2012).

In 2013, the FDA approved the first device to alter insulin delivery in response to CGM data. The pump features a "low glucose suspend" meaning that when CGM senses glucose levels that decline below a specific threshold, the pump alarms, and suspends insulin delivery for 2 hours or until the suspension is manually overridden (Grunberger et al., 2014). The low glucose suspend feature would not prevent hypoglycemia, but it would limit the magnitude and duration of hypoglycemia (Weinzimer, 2012). This device has shown to reduce nocturnal hypoglycemia (Bergenstal et al., 2010). Studies have also shown effective overall

hypoglycemia reductions and time spent in hypoglycemia (Danne, 2008). In addition to decreased nocturnal hypoglycemia in patients with the highest incidence of nocturnal hypoglycemia, without significant ketosis or hyperglycemia (Choudhary, 2011). In a real-world study, SAPT with LGS showed significant reductions in BG values < 50mg/dl (Agrawal et al., 2011). A randomized crossover trial of LGS on after exercise in a clinic setting significantly reduced the duration of time spent in hypoglycemia compared to LGS off (Garg, 2012). A home study of type 1 patients with documented nocturnal hypoglycemia were randomized to receive sensor augmented pump therapy with or without the threshold suspend feature for 3 months. Over the 3-month period the use of the SAPT with LGS reduced nocturnal hypoglycemia without increasing HbA1C (Berganstal, 2013). However, this system requires patient decision making on insulin doses.

Maintaining glycemic control as close to the non-diabetic range as possible is effective in preventing or delaying long-term complications of type 1 DM (DCCT, 1993). Most patients are not able to meet the recommended glycemic control range. According to the recent data collected from theT1D exchange clinical registry, glycosylated hemoglobin at enrollment averaged 8.2% and 8.4% (Miller, 2015). This report also showed severe hypoglycemia and DKA were common. The availability of accurate continuous glucose monitoring has made the development of the AP system feasible (Russel, 2014). The concept of a system that responds to changing blood glucose was conceived decades ago. Ideally, these systems would perform without human interventions operating as a closed process (Kudva et al., 2014).

The availability of glucose sensors and insulin pumps has enabled the development of devices and software to partially or completely automated insulin deliver (Weinzimer, 2012). In 2006, the JDRF Artificial Pancreas project began and in 2009, the JDRF outlined a roadmap to the development of the artificial pancreas moving from SAPT systems to hybrid sensor directed suspension of insulin delivery to full closed loop to dual and multi-hormone therapy (Cobelli et al., 2006; Ly et al., 2013; Kolwaski., 2015). A fully closed loop system would not require the user to enter meal boluses and would deliver all insulin without the need for the patient to enter food or exercise events (Forlenza et al., 2016). A closed loop artificial pancreas involves the use of a mechanical system that consists of a CGM, CSII insulin pump, control algorithm for calculating rates of insulin delivery, and rapid acting insulin analogs (Kowalski, 2015). The literature uses a wide variety of terminology such as artificial pancreas, bionic pancreas, closed loop, automated insulin delivery, and treat to target system (Kowalski, 2015). These systems will evolve overtime to become more automated and eventually will dose hormones in addition to insulin such as glucagon called dual hormone artificial pancreas (AP) and /or glucagon-like peptide 1 or pramlintide called a multi-hormone AP. Hybrid closed loop, fully automated closed-loop, and dual hormone systems are under development at various stages of testing (Florenza, Buckingham, & Maahs, 2015). Recent studies incorporating both insulin and glucagon have extended the closed loop system from an artificial beta cell to and artificial endocrine pancreas system (Kudav et al., 2015).

The key component to a fully closed –loop system is the algorithm controller and there are several algorithms. The proportional integral derivative (PID) algorithms determines insulin delivery based on deviation of the current glucose level from the set point; integrated area under the curve between the current glucose and set point and the rate of change from the prior measurement (Weinzmer, 2012). The PID algorithm looks back to changes in glucose over time and is essentially reactive. Model- predictive control (MPC) algorithms attempt to predict how much insulin is needed to achieve a target in the immediate future based on carbohydrates, insulin absorption rates, physical activity and previously administered insulin. This algorithm is proactive. Other closed loop controllers use "fuzzy logic" control. Fuzzy logic control is an advanced process control, which imitates the logic of human thought and much less rigid than calculations that computers perform.

There are three steps for the process of a fuzzy logic algorithm: fuzzification, rules, and defuzzification. Fuzzification is the process of changing an input into fuzzy values. This is achieved with the different types of membership functions. The output is obtained by defuzzification which is the quantifiable result of fuzzy logic (Sasi & Elmalki, 2013). Essentially, fuzzy logic makes decisions on insulin delivery that is similar to a healthcare provider based on CGM output (Trevitt, Simpson, &Wood, 2016). Fuzzy logic has been combined with individualized learning algorithm, fading memory proportional derivative control, and combined PID and MPC controllers for dual hormone systems (Weinzimer, 2012). Bio-inspired algorithms are based on

mathematical model that reproduces pancreatic beta cell insulin release in response to changes in plasma glucose levels (Trevitt, Simpson, &Wood, 2016).

There are currently 18 closed loop artificial pancreas systems identified as being in clinical phase development, with 5 expected to be available for use at the end 2018 (Trevitt, Simpson, & Wood, 2016). There is very little detail on the precise functionality of these systems however approximately two thirds of the systems are using an insulin alone hormonal approach where one-third is using insulin and glucagon or a multi-hormonal approach. Approximately half the systems are using PID control algorithms, MPC algorithms are being used in about one-third of the systems, fuzzy-logic is being used in one-fifth of the systems, and a bio-inspired algorithm is being used in 1 system (Trevitt, Simpson, & Wood, 2016). The current closed loop AP systems have demonstrated the potential for reducing hypoglycemia and improving overall diabetes control.

A randomized cross over study compared usual care for 5 days to 5 days on a dual hormone bionic pancreas (Russel, 2014). A total of 20 adult subjects stayed in a hotel monitored by nursing staff and they were able to move freely in a specified area in Boston. SMPG was monitored day and night along with a blinded CGM. During day 2-5, the bionic pancreas reduced mean glucose levels from 159 mg/dl to 133 mg/dl compared to control. Subjects on the bionic pancreas were in a hypoglycemic state of <60mg/dl 1.5% of the time compared to 3.7% of the time with usual care. A pediatric study using the bionic pancreas which enrolled 32 T1DM patients ages 12 to 20 compared 5 days on the bionic pancreas to 5 days of supervised camp care. Results

demonstrated that the bionic pancreas reduced mean glucose from a mean of 158 mg/dl to a mean of 144mg/dl. Time in hypoglycemia less than 60/mg/dl was 1.3% with the bionic pancreas down from 2.2% with usual care.

Another closed loop AP system called DiAs system enrolled 10 patients with T1D in a crossover trial of closed loop compared to open loop (Brown et al., 2015). These subjects spent 5 days in a residential facility and the closed loop was activated from 11pm to 7 am. The time in target was 82% for the DiAs system compared to 39% in the open loop. Fasting plasma glucose was a mean of 119mg/dl compared to a mean of 154 mg/dl in the open loop. A study of yet another AP system conducted a pediatric camp study and enrolled 21 subjects that were randomized to SAPT with insulin suspension or closed loop control. The mean percent time in range 70-180mg/dl during the day and night were similar. However, the closed loop performed more favorably over time and by day 6 had achieved 80.6% in range compared to 42.8% in the control group (Ly, 2015).

To evaluated portability, wearibility, wireless artificial pancreas system (DiAs) in glucose control at home, overnight-only, and 24 hours closed-loop modes. Thirty patients completed 3 treatment periods: 2-week baseline sensor- augmented pump period, 2 weeks of the overnight only closed-loop at home, following by the 2-week period of 24 hour closed loop. The overnight period glycemic control improved compared to baseline (time <70 mg/dL., primary end-point median 1.1% vs. 3.0%; $P < 0.001$), time in target (70–180 mg/dL: 75% vs. 61%; $P < 0.001$), and glucose variability (coefficient of variation: 30% vs. 36%; $P < 0.001$). Similar improvements

for day/night combined were observed with 24/7 closed-loop compared with baseline: 1.7% vs. 4.1%, P < 0.001; 73% vs. 65%, P < 0.001; and 34% vs. 38%, P < 0.001, respectively. The closed loop running on a smartphone (DiAs) in the home environment was safe and effective. The overnight-only group reduced hypoglycemia and increased time in range overnight and increased time in range during the day. The 24-hour closed-loop mode reduced hypoglycemia and increased time in range for both overnight and daytime. The 24 -hour closed-loop provided additional hypoglycemic protection during the day (Anderson et al., 2016).

A randomized cross over comparing closed-loop to sensor augmented pump therapy in 58 patient s with type1 diabetes portion of time that the glucose level was in the target range was 11.0 percentage points (95% confidence interval [CI], 8.1 to 13.8) greater with the use of the closed-loop system day and night than with control therapy (P<0.001). The mean glucose level was lower during the closed-loop phase than during the control phase (−11 mg/dl; 95% CI, −17 to −6; P<0.001), the area under the curve for the period when the glucose level was less than 63 mg/dl (39% lower; 95% CI, 24 to 51; P<0.001) and the mean glycated hemoglobin level (−0.3%; 95% CI, −0.5 to −0.1; P = 0.002). Among children and adolescents, the proportion of time with the nighttime glucose level in the target range was higher during the closed-loop phase than during the control phase (24.7 %; 95% CI, 20.6 to 28.7; P<0.001), and the mean nighttime glucose level was lower (−29 mg/dl; 95% CI, −39 to −20; P<0.001). The area under the curve for the period in which the day-and-night glucose levels were less than 63 mg/dl were lower by 42% (95% CI, 4 to 65; P = 0.03). Three

severe hypoglycemic episodes occurred during the closed-loop phase when the closed-loop system was not in use. Among patients with type 1 diabetes, 12-week use of a closed-loop system, as compared with sensor-augmented pump therapy, improved glucose control, reduced hypoglycemia, and, in adults, resulted in a lower glycated hemoglobin level (Thabit, 2015).

Conventional insulin management for type 2 diabetes often leads to suboptimal control, resulting in increased risk for comorbidities. The closed loop AP traditional thought to be a treatment option for type 1 diabetes and has clearly shown to be safe and efficacious in patients with type 1 diabetes however, it implications for use in patients with type 2 diabetes as well. A feasibility study conducted in 12 subjects with type 2 diabetes who were insulin naïve were randomized in a crossover design to received either the closed loop AP or usual diabetes treatment in two 24 h visits. Meals were unannounced. 24 hours of the closed loop insulin delivery increased the overall median time in target from 24 to 40%, despite the sensor under reading, the time in target was more prominent overnight with a median of 78% vs. 35% and less time was spent in hyperglycemia 22% vs. 65%. This study proved that the closed loop system is feasible and safe for use in type 2 insulin naïve patients with some adjustments to the system to improve post prandial control. The implications of this broaden the potential scope of use from a smaller population of type 1 patients to a much larger type 2 population (Kumareswaran et al. 2014).

The increase popularity of insulin pumps along with the increase in complexity and user error has given rise to concept of a fully automated artificial

pancreas which has shown great promise in the field of closed-loop system (Hovorka, 2011, Kowalski, 2009). Compliance with patients monitoring of glucose, even well-controlled patients is often poor (Clarke & Foster, 2012). The closed loop system would solve this issue because it requires no patient input (Kudva et al., 2014). However, the utilization of current technology is lower than expected and the acceptance and adoption of the closed loop systems remain unknown.

THEORETICAL DISCUSSION

Theory plays a critical role in research by providing a foundation for the research. The role of theory in research is to provide a rational explanation of the interrelationships among constructs and the explanation of existing conditions or prediction of future outcomes (Rocco & Hatcher, 2011, p.118). Theory provides a fact-based framework that describes a phenomenon. More specifically, theory can provide a model for understanding human thoughts, actions, and behavior. Research can generate, verify, and in some cases, develop a new theory. There is minimal insulin pump therapy research that has been grounded in theory. However, the theoretical models that have been utilized to ground this research have come from information systems literature because AP systems are computerized devices (van Bon, Kohinor, Hoekstra, von Basum, & deVries, 2010). The individual decision to adopt a particular computer technology, the time frame involved with that decision, and how it influences daily life has been the focus of research for many years across multiple disciplines. (Straub, 2009) There are many theories that have been widely used in information systems literature that may help explain the behavioral intent to adopt and AP.

Innovation Diffusion Theory

Theories in social science and other domains have examined behavioral intent to use technology, to explain how, and why people adopt technologies (Liu et al.,

2014). There are several theories that have been used to attempt to explain user acceptance, intention to use and/ or adoption of technology. Indent and behavioral decision-based theories have been used to explain usage of technology and results further show that intention is significantly and positively correlated to actual behavior (Davis, 1989; Triandis, 1980). Intention was also found to be a valid proxy measure for behavior among clinicians (Eccles et al.,2006; Godin et al., 2008).

A theory often used in technology adoption is the Roger's innovation diffusion theory (IDT) (Wani, 2015). This theory focused on the rate of adoption of innovations and attempts to explain how an idea or product gains momentum and diffuses through a social system or specific population. The end result of diffusion is that people that comprise the social system, adopt a new idea behavior or product. Adoption means that the person does something differently than previously. The key to adoption is that the person must believe the idea, behavior, or product is new or innovative. Adoption of a new idea, behavior, or product is a process in which some individuals are more apt to adopt the innovation. There are five established adopter categories. Innovators, these are individuals that want to be first to try the innovation. Early adopter, who represent opinion leaders and are typically in a leadership role. Early majority, who adopt new ideas before the average person. Late majority, who will only adopt an innovation after it has been tried by the majority. The fifth adopter category is laggards, who are bound to tradition and very skeptical of change. There are also five key determinants for the rate of adoption, which are *relative advantage, compatibility, complexity, trialability,* and *observability*. Roger's (2003), defined

relative advantage as the degree to which an innovation is seen as better than the idea that superseded it. *Compatibility* is the degree to which an innovation is consistent with existing values, experiences, and the needs of the adopters. *Complexity* is the extent to which an innovation is perceived as difficult to understand and use. *Trialability i*s the extent to which the innovation can be tested before a commitment from the adopter and *observability* is the extent to which the innovation provides tangible results and demonstrability refers to the possibility to demonstrate the results of the new system (Rogers, 2003). This theory was expanded and adopted to be applicable in information systems research (Moore & Banbaset, 1991). Subsequent research has indicated that certain innovation characteristics such as relative advantage, compatibility and complexity are consistently related to innovation adoption (Agarwal & Prasad, 1998; Tung, Chang & Chou, 2008).

This theory has been a pivotal theory in the study of technology in past two decades (Wani & Ali, 2015). Dirkes (2015) examined patient's intention to use the artificial pancreas integrated constructs from the IDT and other technology acceptance models. The constructs used in this study from IDT were compatibility and complexity. Compatibility had a positive influence on the intent to use the AP and complexity had an insignificant effect on the intent to use AP. The author concluded that complexity of the AP is not important in terms of patient adoption. The model used in this study was modified and combined with other models. Each theory was broken down and only used some of the constructs where used. The total explanatory value of the model was 37.9%. Since, these models have been researched

predominantly in the field of information technology, adapting models such as IDT into the healthcare sector may be possible only to a limited extent. However, the construct of compatibility was transferrable as shown by the significant influence on intent to use the AP. There are several limitations to this theory which include the static nature of adopter, it does not foster a participatory approach of adoption, and it does not take individual resources or social support to adopt the innovation into account. Therefore, other theories related to technology need to be considered. Figure 2 shows a theoretical representation of the IDT model.

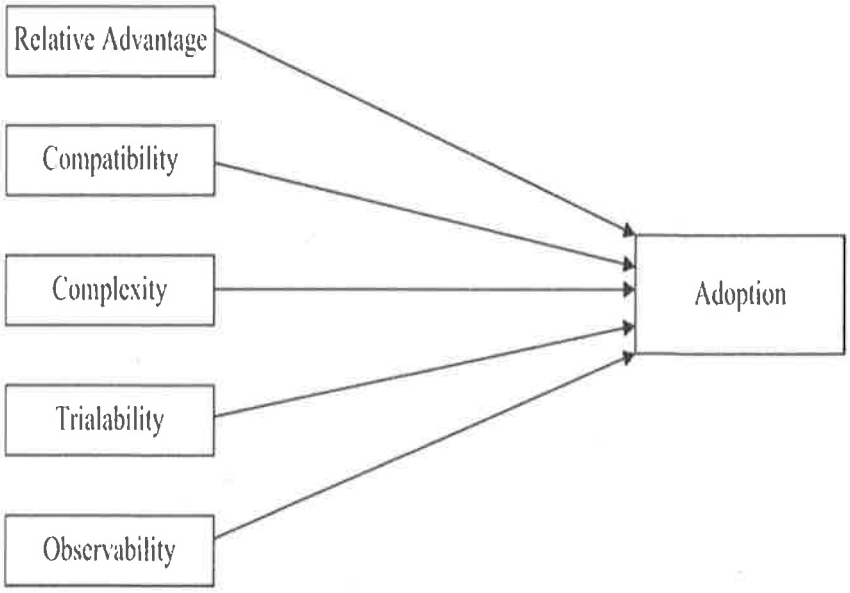


Figure 2. Adaptation of Innovation Diffusion Theory (Rogers, 2003).

Technology Acceptance Model

Technology Acceptance Model (TAM) has been the model which has captured the most attention of the information system community (Chuttur, 2009). Fred Davis' seminal work on the TAM model provided the cornerstone for research

on technology acceptance by professionals and lay people and has initiated a behavioral approach to technology acceptance issues (Ketikidis, Dimitrovski, Lazuras, & Bath, 2012). Davis proposed that technology use is a response that can be explained or predicted by user motivation which, in turn is influenced by an external stimulus consisting of the actual system's features (Chuttur, 2009). Motivation can be explained by three factors: *perceived ease of use*, *perceived usefulness*, and *attitude* toward using the system. Attitude toward a system was a major determinant of whether the user accepted or rejected it. The attitude was influence by perceived usefulness of the technology and perceived ease of use. This model was originally grounded on principles adopted from the attitude paradigm the Theory of Reasoned Action (Davis, 1993). The Theory of Reasoned Action (TRA) is used to predict the actual behavior of an individual. Behavioral intent could be determined by considering both a person's attitude towards an actual behavior and the subjective norm (Fishbein & Ajzen, 1975). Subjective Norm is defined as a person's perception of how others would view them if they did or did not perform that behavior (Fishbein & Ajzen, 1975; Chuttur 2009). TRA is valuable in predicting behavior when the behavior is under the individual's volitional control (Ajzen, 1991; Jeng & Tzeng, 2012). The construct of the subjective norm that was included into the TRA considers the social influence that goes into the use of technology. Davis' did not take the subjective norm into consideration when considering the TAM as this was a construct that he argued had uncertain theoretical status (Chuttur, 2009). The TAM theoretical framework was based on two beliefs, perceived usefulness and ease of use in

predicted a person's behavior. (Davis, 1989) Perceived usefulness (PU) is defined as the degree to which a person believes that using a particular system would enhance his or her job performance. Perceived ease of use (PEOU), in contrast refers to the degree to which a person believes that using a particular system would be free of effort (Davis, 1989). The TAM model proposes that PEOU has a direct effect on PU and each influences attitude toward behavioral intent. Since its inception TAM has become a well-established robust, powerful model for predicting user acceptance in the information systems literature (Venkatesh & Davis, 2000). TAM is a theory that has gone through several changes. In an updated version TAM2, attitude component was removed from the model, which mediated some influence of perceive usefulness and perceived ease of use. In an attempt to explain the reason for which a person would perceive a system as useful they proposed the addition of other variable such as subjective norm, image, job relevance, output quality and result demonstrability (Venkatesh, 2000). According to, Venkatesh (2000) individuals will form early perceptions of perceived ease of use of a system based on several anchors related to individual's beliefs regarding computers and computer use. These anchors are computer self- efficacy, computer anxiety, computer playfulness, and perceptions of external control. These anchors became the model of determinants for perceived ease of use. Further development of the TAM model included the combination of TAM2 (Venkatesh & Davis, 2000) and the model of determinants for perceived ease of use (Venkatesh, 2000) into the integrated TAM 3 model (Venkatesh & Bala, 2008).

Figure 3 shows a theoretical representation of the original TAM2 without the attitude component.

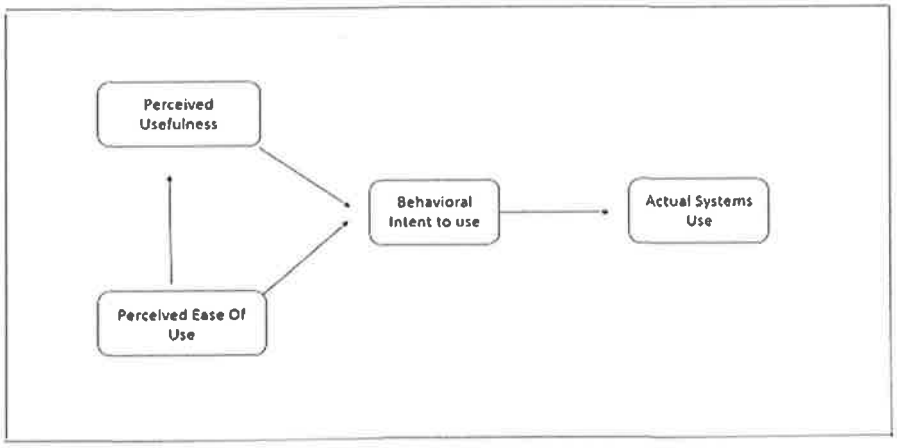


Figure 3. Technology Acceptance Model 2 (Davis, 1989).

Vetkatesh et al., (2003), further developed the TAM model and combined 8 models into an integrated unified model called the Unified Theory of Acceptance and Use of Technology (UTAUT). UTAUT was tested was tested and validated and explained 70% of the variance in intention and 50% of the variance in use. Recently UTAUT has become a widely used model of individual technology adoption. The UTAUT had three direct determinants of intent to use which are performance expectancy, effort expectancy, and social influence. It also has two direct determinants of technology use, behavioral intention and facilitating conditions along with four contingencies which are age, gender, experience and voluntariness. This theory has been used to assess physician's intent to use and EMR system by Vetkatesh, Skyes, and Zhang (2011). The full UTAUT model explained only 21% of the variance in predicting intention and use, which is much lower than the 70%

explained in the original tests (Venkatesh, 2003). Venkatesh, Skyes, and Zhang (2011), adjusted the model and dropped three of the contingencies keeping only age. The model with only age as a moderator performed better resulting in 44-47% of variance explained. Similar results were found when utilizing the UTAUT model in the adoption of various healthcare information technologies (Phichitchaispoa & Neanna, 2012; Maillet, Mathieu, &Sicotte, 2015). The authors stated that UTAUT in its original form is too expansive and minimally useful in explaining intent and use of EMR systems but simplifying and integrating other theories to enrich UTAUT may be needed (Venkatesh, Skyes, and Zhang, 2011).

It wasn't until more recently that researchers have adopted the TAM and TAM like models into the healthcare field as a way of measuring technology acceptance at the organizational level (Holden & Karsh, 2010). A review of these models in healthcare by Holden and Karsh (2010) revealed several strengths, one of the strength of adopting these models in this field has been the ability to find consistently significant relationships specifically in relation to perceived usefulness and acceptance of technology. As well as, perceived behavioral control has been found to be significantly related to technology acceptance. Perceived behavioral control was added to the TRA and became the Theory of Planned Behavior (TPB) (Ajzen, 1991). Perceived behavioral control refers to people's perceptions of their ability to perform a given behavior. This predictor seemingly leads to intention. A general rule, the more favorable the attitude and the subjective norm, and the greater the perceived control the stronger should the person's intention to perform the

behavior. Meaning that an individual needs to feel confident in their ability to use the technology in order to accept it (Holden & Karsh, 2010). However, the adoption of these models in the healthcare field has shown some challenges and doesn't fully explain technology acceptance.

Healthcare professionals, may differ from students and other technology users in their intellect and ability to learn technology faster. They tend to be pragmatic and base their technology acceptance on usefulness (Holden & Karsh, 2010; Ward, 2013). Chau & Hu (2002), assessed telemedicine acceptance of physicians related to patient care and management utilizing TAM, Theory of planned behavior (TPB), and a decomposed (TPB). They targeted clinical department chiefs in tertiary hospitals for support in this study. A total of 408 questionnaires were completed for analysis. Based on its direct and indirect effect via attitude perceived usefulness was the most significant factor affecting physician's acceptance of telemedicine. Perceived ease of uses had no significant effect on perceived usefulness or attitude. Attitude and perceived behavioral control appeared to have an influence on behavioral intent. Subjective norm had no significant effect on behavioral intent. Perceived behavioral control was found to have a significant direct effect on behavioral intent though weaker than perceived usefulness or attitude. TAM in this population resulted in an R^2 of approximately .40, indicating although a considerable amount of behavioral intention was explained. However, there is a substantial amount variance left unknown. Based on the degree in which each model fit the data the authors concluded

that TAM than TPB was more appropriate a depicting individual physician's acceptance in explaining intent to use telemedicine technology.

Kuo, Liu & Ma (2013), investigated the effect of nurses' technology readiness on the acceptance of mobile electronic medical record system and found consistent with the viewpoint of TAM, perceived ease of use had a positive effect on perceived usefulness and both perceived ease of use and perceived usefulness had direct effects on behavioral intent. The total variance explained by this modified model was 35%. Other studies using TAM and mixed populations including nurses found similar results in terms of construct relationships (Aggelidis & Chatzoglou, 2009; Wu, Shen, Lin, Greenes, & Bates, 2008). The construct of perceived usefulness is supported but perceived ease of use has not been consistently supported across the literature. Holden and Karsh (2010) suggest that the issue with TAM and TAM like models are that no two studies tested exactly the same model and there were variations in definitions and interpretations of constructs. Despite their limitations TAM and TAM modified models are useful in considering technology acceptance in healthcare. A focus on perceived usefulness, perceived behavioral control (self-efficacy), and attitude is more likely to influence clinicians' acceptance of technology (Chau & Hu, 2002; Holden & Karsh, 2010; Ward, 2013).

There have been two known studies identified in the literature on TAM utilization assessing the perception and future acceptance of an AP in patients (van Bon et al., 2010; Bevier et al., 2014). van Bon et al., (2010) conducted in-depth interviews based on the TAM constructs of twenty-one type 1 patients after a short

introduction of the artificial pancreas and how it would function. The questions assessed perceived usefulness, subjective norm, image, perceived ease of use, self-efficacy, and training, and technical skills and training. The authors concluded that the overall acceptance of the artificial pancreas was positive and the intent to used was depend on overall trust in the artificial pancreas which was related to glucose control provided by the artificial pancreas (van Bon et al., 2010).

Bevier et al., (2014) conducted a pilot study of attitudes if the AP clinical trial participants towards future acceptance of the technology. They examined treatment stratification, factors of motivation to participate in clinical trials and constructs of TAM. The authors found that perceived usefulness was ranked higher than perceived ease of use which has implications for acceptance of the AP system and long-term use. Patients will need to be shown the effectiveness of the AP system in order to make acceptance of the system easier. The authors state that it will be important to assess the effect of the AP on the quality of life and degree of trust. Relinquishing of diabetes management control over to an automated system will be a significant hurdle to adoption of the AP

The two previously mentioned physician's acceptance studies of the AP utilized constructs from IDT and TAM (Schoenbeck, 2014; Klabbers, 2014). Schoenbeck (2014) investigated constructs from the innovation diffusion theory, theory of planned behavior and TAM, in addition to the concept of innovativeness to investigate the influence of personal and product characteristics on acceptance of the AP (Schoenbeck, 2014; Klabbers, 2014). Innovativeness, refers to the individual

behavior towards innovation. The author states that if more innovative physicians have the ability to conceive the potential benefits of an AP system in an early stage of development could result in their level of intent to use. The author chose to investigate complexity, innovativeness, and perceived usefulness effects on intent to use. The model explained 39% of the variance in intent to use. Innovativeness and complexity was not significant. Perceived usefulness explained the majority of the variance in physician's intent to use an AP system. This is in line with other TAM models investigating a physician's intent to use a medical technology (Chau &Hu, 2002).

Klabbers (2014), focused on a physicians' decision- making process in prescribing an artificial pancreas. The research focused on 54 physicians' that specialize in diabetes and investigated the relationship between the subjective norm and the intention to use or prescribe the artificial pancreas. The theoretical foundation of this study was the decomposed theory of planned behavior and only used the subjective norm construct to predict intention to use. The subjective norm is a one-dimensional belief construct alongside several multidimensional belief constructs represented by the social referent groups of physicians'. The subjective norm was defined by the perceptions one may have of the social expectations of referent others to commit or not to commit a certain behavior. The social referent groups tested were colleagues, superiors, subordinates, and patients. The study showed that the subjective norm was a significant positive determinant of intention to use or prescribe the artificial pancreas with only the patient social referent group

exhibiting a similar significant positive relationship. The subjective norm explained 7.5% of the variation in the intention to use. When combining all four referent groups the model explained 7.6% of the variation of intent to use and when the four referent groups where looked at individually the model explained 22% of the intent to use with patients exhibiting the greatest positive influence on intent to use, indicating that patient demand may lead to an increase in physician usage.

The TAM, UTAUT and IDT theoretical models have been widely used in management information systems research and in healthcare to explain technology acceptance on an organizational level. These models have been used to a lesser extent on the patient and physician level to explain technology acceptance of the AP System. However, each of these models have limitations proven by the low explained variance in the intent to use medical technology. TAM proved to explain approximately 40% of the variance in the intent to use medical technologies among both patients and physicians'. Therefore approximately 60% of the variance is unknown rendering this model is incomplete. Constructs related to the UTAUT theory explained even less variance of intent for physician use of an AP system. TAM and TAM like models which are based on the Fishbein and Azjen's TRA (1975), have been found to be lacking in certain respects (Thompson, Higgins, & Howell, 1991). The TAM model lacks the subjective norm and therefore, seldom use constructs related to the social environment, it also assumes that there are no barriers to the use of the technology (Chau and Hu, 2001). Other theories maybe provide a clearer understanding of technology adoption such as the Theory of Interpersonal Behavior.

Theory of Interpersonal Behavior

Triandis (1980), proposed a theory that incorporates many of same constructs as TRA and TAM but also modifies and redefines them, called the Theory of Interpersonal Behavior (TIB) (Thompson, Higgins, & Howell, 1991). Figure 4 shows a theoretical representation of TIB. According to Triandis (1980), behavior is determined by three dimensions: intention, facilitating conditions, and habit. *Behavioral intention* is a cognitive antecedent to an act and refers to the individual's motivation towards the performance of the act or behavior. *Facilitating conditions* include the state of the actor and the environmental conditions that make the act easy. Conversely, barriers include environmental conditions that might impede the act. *Habit* refers to past behavior predicting future behavior. It considers the frequency of the behavior. The TRA takes all beliefs that a person has about a behavior, whereas Triandis, distinguishes between beliefs that link emotions to the act and beliefs that link the act to *future consequences*. He argues, that behavioral intentions are determined by feelings people have towards the behavior *(affect)*, what others think they should do *(social factors)*, and by the expected consequence of the behavior. Behavior is influenced by habits, by behavioral intentions, and by facilitating conditions (Thompson, Higgins, & Howell, 1991). Intention is formed by attitudinal, normative, and identity beliefs. Affect, refers to the emotional state that the behavior evokes. Perceived consequences refer to subjective probability that certain consequences will follow a behavior. The TIB incorporates social and personal norms. Social norms are formed by normative and role beliefs. Normative beliefs are

the cognitive evaluation of the referent group's opinions about the realization of the behavior. Role belief refers to the extent to which an individual thinks someone of his/her age, gender, and social stature should behave. The personal normative belief the personal obligation regarding performing or not performing the behavior and self-identity refers to the degree of accordance between the individual's perception of self and the characteristics the individual associate with the realization of the behavior (Gagnon et al., 2003).

The TIB has been used to study information systems. Thomson et al. (1991) studied PC utilization based on a modified TIB and found that the model explained 24% of the variance explained. Bergeron, Raymond, Rivard, & Gara, (1995) investigated executives' determinants of executive information systems (EIS) utilizing a modified TIB model and found that 52% of the variance of executives' internalization of the EIS was explained by affect, perceived consequences and support. However, the TIB constructs could not significantly explain information systems utilization. Gagnon et al., (2003) investigated interpersonal behavior to the study of telemedicine adoption by physicians'. The author's original model explained 85% of the variance in telemedicine adoption. However, in the original model there were non-significant structural coefficients including affect, habit, and perceived consequences. Therefore, another model was tested using only significant theoretical constructs. The strongest predictors of intent were normative factors which encompassed social and personal norms and self-identity. Together these two constructs predicted 81% of the variance in physician adoption of telemedicine.

These results differ from previous reports using this theory in technology acceptance. Previous studies modified the original theoretical model with the exception of Gagnon (2003), which only had slight variation from the original model. The evidence from Gagnon et al. (2003), suggests that technology acceptance for physicians' is driven by normative factors. However, this theory is related to the social environment and individual more so than the technology itself. Therefore, an integrated model may prove to be more effective in predictive behavioral intent to use technology. Research indicated that time, organizational issue, system issues, and personal characteristics are significant barriers to healthcare provider's technology acceptance and therefore constructs representing these barriers should be included in an integrated model (Yarborough & Smith 2007).

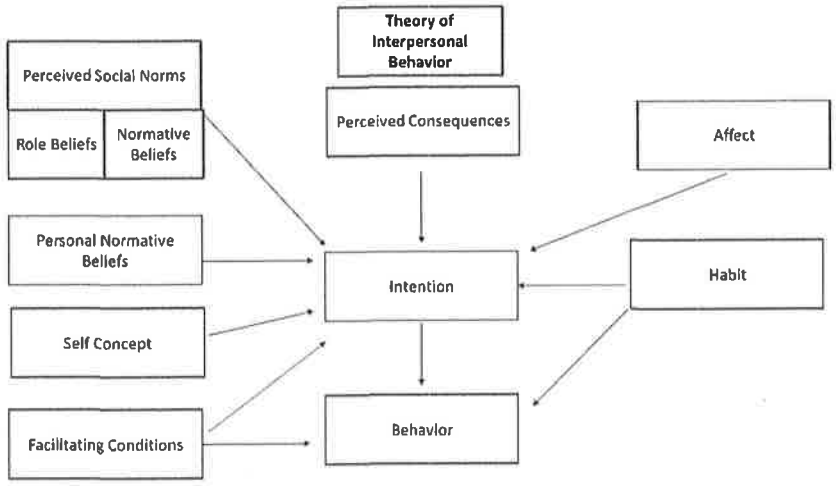


Figure 4. Theory of Interpersonal Behavior (Triandis, 1980).

Integrated Models

Each of the above-mentioned theories focus on different determinants to explain behavior in the adoption of technology. IDT, and TIB and model focuses on the psychosocial aspects of the individual adopter whereas, TAM model focuses on the technology. It is evident from the literature that the no singular theoretical model completely explains technology acceptance for healthcare providers. It is a common practice in both information system research and healthcare technology acceptance research to combine models in attempts to gain more predictive power to ascertain factors that lead to technology acceptance.

Gagnon et al. (2014) combined TAM with a psychosocial model to determine physicians' acceptance of a new interoperable electronic health records (EHR) system. The investigators first tested the original TAM model with PEOU and PU on behavioral intent to use this new EHR system. The Model resulted in an explanatory power of 44%. They then investigated an extended TAM with the antecedents of CSE and demonstrability. Demonstrability is a construct from IDT and refers to the extent to which the tangible results of using an innovation can be observable and communicable (Yi, Jackson, Park & Probst, 2006). Demonstrability has been found to be a significant determinant of both PU and PEOU. The extended TAM showed 48% of the variance in PU is explained by PEOU and demonstrability and CSE explained 6% of the variance in PEOU. The third model tested was a psychosocial model which included PEOU, social norms, and professional norms effect on behavioral intent.

The professional norm construct was added to better adapt TIB to healthcare professionals. This variable was defined by Gagnon et al. (2006) to refer to the integration of the self of the specific normative pressures of one's professional group. It has been shown to significantly improve the predictive validity of the personal normative construct. Model 3 explained the 53% of the variance in behavioral intent after removing personal identity, social norm, and CSE which were not significant. Model 4 was the integrated model. This model added demonstrability to the final psychosocial model which had an explanatory power of 55%. In addition, the authors added two new constructs. Resistance to change and information about change. Resistance to change is defined by Nov and Ye (2011), as a personality factor and by definition people that are resistance to change have difficulty breaking routines and are stressed when faced with change. Information about change is a construct that recognizes that change can be disruptive and focuses on the importance of change management. It refers to the information received about the technology and it ability to help the adopter make a decision about use (Gagnon et al., 2014). The authors concluded that TAM explained a significant proportion of behavioral intent and PEOU was augmented by CSE. Therefore, the combined theoretical model with constructs from different models may best represent all the constructs necessary to determine closed loop artificial pancreas therapy acceptance by providers.

This study adopted an integrated theoretical framework to investigate health care provider's behavioral intent to adopt (use) towards future use of the closed-loop artificial pancreas for the management of patients with diabetes. In information

systems literature integrating theories to improve explanatory power of the model is common (Legris, Ingham, & Collerette, 2003). This model integrated constructs from TIB, TBP, and IDT. In addition, other constructs were added based on identified gaps in the literature to enhance the understanding of technology acceptance of the closed-loop artificial pancreas (Figure 1). To the best of the author knowledge this is the first study that integrates constructs from TIB, TBP, and IDT. In addition to enhance the explanatory value of this model, potential barrier constructs were identified from the literature and added to the model. These constructs are perceived risk, resistance to change, and threat to autonomy. Lastly, the construct value was operationalizing and added to the model based on the gaps identified in the literature.

TECHNOLOGY

Closed-loop Artificial Pancreas

Technology for diabetes management is rapidly developing and changing (Markowitz, Harrington, & Laffel, 2013). The Artificial Pancreas (AP), is known as the closed-loop control of blood glucose in diabetes, it is a system that combines a glucose sensor, a computer algorithm, and insulin infusion device (Cobelli et al., 2011). AP developments can be traced back 50 years. The past 15 years, the concept of the closed-loop control has made significant advancement, due to the advances in technology and computer-based algorithms (Kudva et al., 2014). The results of the DCCT demonstrated the importance of glycemic control and lead to an increased interest in technology to achieve control with minimizing hypoglycemia (Diabetes

Control and Complications Trial, 1993; Cryer,2016). The completely automated artificial pancreas is considered the ideal treatment for type 1 diabetes (Ricotti et al., 2013). In addition, feasibility has been assessed in the type 2 diabetes population with favorable results, thereby broadening the potential scope of use of the close loop artificial pancreas (Kumareswaran et al., 2014). The completely automated artificial pancreas is considered the ideal treatment for type 1 diabetes (Ricotti, 2012). In addition, feasibility has been assessed in type 2 population with favorable results broadening the potential scope of use of the close loop artificial pancreas (Kumareswaran et al., 2014).

Maintaining glycemic control as close to the non-diabetic range as possible is effective in preventing or delaying long-term complications of type 1 diabetes (DCCT, 1993). Most patients are not able to meet the recommended glycemic control range. According to the recent data collected from the T1 diabetes exchange clinical registry, glycosylated hemoglobin at enrollment averaged 8.2% and 8.4%in the most recent update (Miller et al., 2015). This report showed severe hypoglycemia and diabetic ketoacidosis (DKA) were common. The availability of accurate continuous glucose monitoring (CGM) has made the development of the artificial pancreas system feasible (Russel, 2014). The concept of a system that responds to changing blood glucose was conceived decades ago. Ideally, these systems would perform without human interventions operating as a closed process (Kudva et al., 2014). The availability of glucose sensors and insulin pumps has enabled the development of devices and software to partially or completely automated insulin deliver (Weinzimer,

2012). In 2006, the Juvenile Diabetes Research Foundation (JDRF) Artificial Pancreas project began and in 2009, the JDRF outlined a roadmap to the development of the artificial pancreas moving from sensor-augmented insulin pump therapy systems to hybrid sensor directed suspension of insulin delivery to full closed loop to dual and multi-hormone therapy (Cobelli et al., 2006; Ly et al., 2013; Kolwaski, 2015). A fully closed loop system would not require the user to enter meal boluses and would deliver all insulin without the need for the patient to enter food or exercise events (Forlenza et al., 2015). A closed loop artificial pancreas involves the use of a mechanical system that consists of a CGM, CSII insulin pump, control algorithm for calculating rates of insulin delivery, and rapid acting insulin analogs (Kowalski, 2015). The literature uses a wide variety of terminology such as artificial pancreas, bionic pancreas, closed loop, automated insulin delivery, and treat to target system (Kowalski, 2015). These systems will evolve overtime to become more automated and eventually will dose hormones in addition to insulin such as glucagon called dual hormone artificial pancreas (AP) and/ or amylin called a multi-hormone AP. Hybrid closed loop, fully automated closed-loop, and dual hormone systems are under development at various stages of testing (Florenza et al., 2015). Recent studies incorporating both insulin and glucagon have extended the closed loop system from an artificial beta cell to and artificial endocrine pancreas system (Kudav et al., 2015).

The key component to a fully closed –loop system is the algorithm controller and there are several algorithms. The proportional integral derivative (PID) algorithms determines insulin delivery based on deviation of the current glucose level

from the set point; integrated area under the curve between the current glucose and set point and the rate of change from the prior measurement (Weinzimer, 2012). The PID algorithm looks back to changes in glucose over time and is essentially reactive. Model- predictive control (MPC) algorithms attempt to predict how much insulin is needed to achieve a target in the immediate future based on carbohydrates, insulin absorption rates, physical activity and previously administered insulin. This algorithm is proactive. Other closed loop controllers use "fuzzy logic" control. Fuzzy logic control is an advanced process control, which imitates the logic of human thought and much less rigid than calculations that computers perform. There are three steps for the process of a fuzzy logic algorithm: fuzzification, rules, and defuzzification (Sasi & Elmalki, 2013). Fuzzification is the process of changing inputs into fuzzy values. This is achieved with the different types of membership functions. The output is obtained by defuzzification which is the quantifiable result of fuzzy logic (Sasi & Elmalki, 2013). Fuzzy logic has been combined with individualized learning algorithm, fading memory proportional derivative control, and combined PID and MPC controllers for dual hormone systems (Weinzimer, 2012). Current closed loop AP systems have demonstrated the potential for reducing hypoglycemia and improving overall diabetes control (Weinzimer, 2012).

A large outpatient pivotal trial for a hybrid closed-loop artificial pancreas demonstrated people with type 1 diabetes on therapy experienced less glycemic variability (33% to 30%), more time in target 66.7% to 72.3%), less exposure to hypoglycemia and hyperglycemia and reduced AIC (7.4 to 6.9). In addition, the

hybrid closed-loop automated insulin delivery was associated with few serious or device related adverse events (Bergenstal et al., 2016)

A randomized crossover study compared usual care for 5 days to 5 days on a dual hormone bionic pancreas (insulin and glucagon) (Russel et al., 2014). Subjects stayed in a hotel monitored by nursing staff with free mobility in a specified area in Boston. SMPG was monitored day and night along with a blinded CGM. During day 2-5, the bionic pancreas reduced mean glucose levels from 159 mg/dl to 133 mg/dl compared to control. Subjects on the bionic pancreas were in a hypoglycemic state of <60mg/dl, 1.5% of the time compared to 3.7% of the time with usual care. A pediatric study using the bionic pancreas which enrolled 32 T1DM patients ages 12 to 20 compared 5 days on the bionic pancreas to 5 days of supervised camp care. Results demonstrated that the bionic pancreas reduced mean glucose from a mean of 158 mg/dl to a mean of 144mg/dl. Time in hypoglycemia less than 60mg/dl was 1.3% with the bionic pancreas down from 2.2% with usual care.

Another closed loop AP system called DiAs system enrolled 10 patients with T1D in a crossover trial of closed loop compared to open loop (Brown et al., 2015). These subjects spent 5 days in a residential facility and the closed loop was activated from 11pm to 7 am. The time in target was 82% for the DiAs system compared to 39% in the open loop. Fasting plasma glucose was a mean of 119mg/dl compared to a mean of 154 mg/dl in the open loop. Anderson et al. (2016), reported the results of a multicenter multinational trial testing free-living use of the Dias system in 30 adults. The non-randomized study included 3, two-week treatment periods using a SAP in

the first period and a closed loop AP overnight and in the third period they used the AP 24 hours a day. The overnight period glycemic control improved compared to baseline (time <70 mg/dL, primary endpoint median 1.1% vs. 3.0%; P < 0.001), improved time in target 75 %vs 61% (70–180 mg/dL P < 0.001), and improved Glucose variability (coefficient of variation: 30% vs. 36%; P < 0.001). Similar improvements for day/night combined were observed with 24/7 closed-loop compared to baseline (time <70 mg/dL, primary endpoint median 1.7% vs. 4.1%; P < 0.001), improved time in target 73 %vs 65% (70–180 mg/dL P < 0.001), and improved Glucose variability (coefficient of variation: 34% vs. 38%; P < 0.001).

A study of yet another insulin-only AP system conducted a pediatric camp study and enrolled 21 subjects that were randomized to SAPT with insulin suspension or closed loop control. The mean percent time in range 70-180mg/dl during the day and night were similar. However, the closed loop performed more favorably over time and by day 6 had achieved 80.6% in range compared to 42.8% in the control group (Ly et al., 2015).

Conventional insulin management for type 2 diabetes often leads to suboptimal control, resulting in increased risk for comorbidities. The closed loop AP traditional thought to be a treatment option for type 1 diabetes and has clearly shown to be safe and efficacious in patients with type 1 diabetes however, it implications for use in patients with type 2 diabetes as well. A feasibility study conducted in 12 subjects with type 2 diabetes who were insulin naïve were randomized in a crossover design to received either the closed loop AP or usual diabetes treatment in two 24 h

visits. The closed loop insulin delivery increased the overall median time in target from 24-40%, despite the sensor under reading, the time in target was more prominent overnight with a median of 78% vs. 35% and less time was spent in hyperglycemia 22% vs. 65%. This study proved that the closed loop system is feasible and safe for use in type 2 insulin naïve patients with some adjustments to the system to improve post prandial control (Kumareswaran et al., 2014).

The increase popularity of insulin pumps along with the increase in complexity and user error has given rise to concept of a fully automated artificial pancreas which has shown great promise in the field of closed-loop system (Hovorka et al., 2011; Clarke & Foster, 2012; Kowalski, 2009). Compliance with patients monitoring of glucose, even well-controlled patients is often poor (Clarke & Foster, 2012). The closed loop system would solve this issue because it requires no patient input (Cobelli et al., 2011). The potential of the artificial closed loop pancreas to reduce long term complications may significantly reduce health care cost but will require cost effectiveness research and an expanded insurer base to make this a growing market (Malchesky, 2013). However, currently there is marked geographical variations in usage of available diabetes technologies such as insulin pump therapies, suggesting different payers and clinicians have different interpretations of the value and experience with this technology (Barnard et al., 2015). The projected increases in diabetes and the aging population could drive the demand of the artificial pancreas (Malchesky, 2013). However, it will require adoption of this technology by healthcare provider to make this a viable treatment option for patients with diabetes.

Barriers to Artificial Pancreas Adoption

The role of the healthcare provider puts them in a unique position when it comes to technology acceptance. Information exchange refers to the type and amount of information exchanged between physician and patient. The flow of information can be a one way or two-way exchange. Historically, the relationship between healthcare provider and patient was often characterized as a principal-agent relationship whereas, the patient is the principal and the physician is the agent (Rogers, 2003). The principal appoints an agent to advise them in making decisions about treatment or make decisions on the principal's behalf (Nguyen, 2011). This paternalistic approach was based on the assumption that there was one single best treatment, healthcare provider would have the knowledge of treatments available, healthcare providers are in the best position to evaluate the best options between treatments, and healthcare providers have a legitimate investment in each treatment decision based on the welfare of the patient (Charles, Gafni, & Welan, 1999). Problems with this paternalistic relationship have been well documented and have led to informed and shared models of treatment decision- making (Charles et al.,1999; Nguyen, 2011). The physician –patient relationship is particularly challenging when it involves new treatment technology because the physician has to have technical knowledge of the technology to be able to inform the patient however in many cases, the advancements in technology develop faster than the education required to competently use the devices which leads to a lack of competence and confidence by the practitioner (Caruana, 2012). Normally the end user decides whether to accepts or rejects the

technology or device but in the healthcare environment the health care providers such as physician play a large part of the decision-making process of whether or not to use a new medical device such as the closed loop system (Schoenbeck, 2014).

Typically, the care of a patient with diabetes is left up to an endocrinologist and certified diabetes educator however, the Affordable Care Act has placed greater focus on the primary care medical home (PCMH) for multidisciplinary care (Kahn & Anderson, 2009). Therefore, endocrinologist, physician's such as internal medicine physician's and family practitioners, and some nurse practitioners who specialize in diabetes represent the group of potential prescribers of the closed loop system. Acceptance of this technology represents one of the prerequisites of the adoption and the sustainability of this device (Klabbers, 2014). However, the decision of healthcare provider to adopt a new technology can interfere with the providers' usual practice and can affect their perception of their professional role and challenge their high professional autonomy (Gagnon et al, 2014; Walter & Succi-Lopez, 2008).

The work by Yarbrough and Smith (2007) in the field of technology acceptance among physicians uncovered several different barriers to technology acceptance such as disruption or change in practice patterns, personal characteristics, system specific issues, and organizational issues. The cost of physician time has also been identified as significant barriers to technology acceptance (Nov & Schecter, 2012; Yarbrough & Smith, 2007). While time is required for anyone learning a new technology, this is a particular issue for healthcare providers considering that time will reduce the number of patient visits thereby reducing revenue (Yarbrough &

Smith, 2007). Along with safety and efficacy the developer of new technologies should also consider the desire and capabilities of the patient and their caregiver (Liberman, Buckingham, & Philip, 2011). Adherence to therapy is crucial for Type 1 diabetes and therefore, technology developed for helping patients should consider human factors before, after and during development. There is limited published data on the psychosocial and human factors assessments of artificial pancreas devices (Barnard et al., 2015). Technology has changed the lives of patients living with diabetes however, despite the availability of new meters, pumps, syringes, CGMs, and communications tools, utilization has been limited (Liberman et al., 2011).

Gaps in the literature

There is very little known about the factors that lead to or barriers to healthcare providers intent to adopt or not adopt diabetes technology. There no known studies that have investigated healthcare provider's technology acceptance of the closed loop system. Only two bachelorette thesis studies were found on this topic (Klabbers,2014; Schoenbeck,2014). While these two studies have clear limitations of scope they do contributed to the understanding of AP adoption of healthcare providers there are other contributing factors that have yet to be uncovered. There has been no application of theories commonly used in technology acceptance of diabetes medical devices used in patient care among U.S. healthcare providers. There is no adequate survey tool available to measuring technology acceptance of the closed-loop artificial pancreas among healthcare providers.

Rationale for the Study

Normally the end user decides whether to accept or reject the technology. Healthcare providers play a large role in the decision-making process (Schoenbeck, 2014). Acceptance of this technology represents one of the prerequisites of the adoption and the sustainability of this device (Klabbers, 2014). Healthcare providers technology acceptance can influence patient access. It's important to understand what leads to healthcare provider technology acceptance when used by the patient for disease management and the healthcare provider plays a significant role in the decision-making process. Understanding technology adoption may help to develop processes that can facilitate training for healthcare providers and ultimately improve patient care.

Chapter III

METHODOLOGY

Introduction

This dissertation took place in several steps. First, creation and validation of a new survey instrument was completed through a modified Delph process by a panel of experts. Subsequently, participants were recruited through several organizations and professional associations as well as through snow ball sampling techniques.

Research Design

This dissertation study which focuses on the newly created and validated tool Healthcare professionals closed-loop artificial pancreas adoption tool (HCP-CLAPA). This is a non- experimental survey-based study. It is descriptive, exploratory, cross-sectional and correlational. Demographic characteristic of the sample was organized through a descriptive design to describe the sample. The study is exploratory as it involves examining a phenomenon to gain new insight and to increase knowledge on this topic. This study is cross-sectional because data was collection at one point in time. A correlational design was used to investigate the relationships among the predictor variables and behavioral intent to use the closed-loop artificial pancreas.

Instrument Development: Delphi Technique

The Delphi is a group facilitation technique which seeks to obtain anonymous consensus of expert opinions from a series of structured questionnaires (Hasson, Keeney, & Mckenna, 2000). The Delphi Process is utilized to establish validity of the tool. This Delphi study involved 6 experts. Five or more individuals is a reasonable

number of participants according to Armstrong (1985). The selection of the experts involved non-probability sampling techniques, specifically, purposive sampling. In purposive sampling, participants are selected for a purpose, in this case, to apply their knowledge to a certain problem. Recruitment of participants who have knowledge and an interest in the topic help to increase the content validity of the Delphi. The purpose of the Delphi is to forecast if the proposed questions will be appropriate for eventual survey use. The Delphi technique is a series of rounds interspersed by controlled feedback, that seek to gain the most reliable consensus of a group of experts (Linstone & Turoff, 2011). In order for, the Delphi to have been considered effective and the tool to have established validity 80% consensus is needed (Hasson et al., 2000). Once consensus was reached on the construct variables and survey questions and statements, the tool was considered to have validity. Six individuals were targeted and contacted who met the inclusion criteria for participation in the Delphi study as expert reviewers of the new survey tool (Appendix A).

These individuals were selected based on their knowledge and expertise in the field of technology acceptance research, diabetes, diabetes technology, and survey research. One technology acceptance theory expert (PhD level) who was identified in the literature as an expert in the field of technology acceptance among healthcare providers, two adult endocrinologist highly experience and well published in the area of diabetes disease state, treatment and technology, one pediatric endocrinologist also well published in the area of pediatric diabetes and very knowledgeable in diabetes technology, and one doctorate level nurse practitioner, certified diabetes educator

who is has over 20 years of insulin pump management experience, worked on one of the diabetes landmark trials and has published in the area of diabetes formed the Delphi panel of experts for the creation of the survey tool.

Assessing Validity

This Delphi technique is intended to establish validity of the tool, specifically face and content validity. Construct validity was assessed as part of the Cronbach's alpha. Face validity was used to determine if the test seems to measure what it is intended to measure (Alreck & Settle, 2004). The experts analyzed the validity of the test at face value by looking at whether the test appeared to measure the target construct. This was established through a survey worksheet which was created for the expert reviewers, in which they were asked if each variable/question measures the concept and if it was clear or not. The initial Round 1 Survey Worksheet was sent and completed by all expert panelists of the Delphi (Appendix B). Content validity was used as the estimate of how much a measure represented every single element of a construct (Alreck & Settle, 2004). Content validity was also established through the survey worksheet, which asked the experts to provide in the comments section their thoughts on whether the survey statement should be removed or appended.

Once expert panelists completed the Round 1 Survey Worksheet (Appendix B) PI reviewed the responses, edits and suggestions of the panelists and prepared a condensed, version of the initial Survey Work for Round 2 (Appendix C). This worksheet contained the survey statements that were shown to need correction or revision based on the panelists responses from Round 1. Upon

completion of round 2, the PI reviewed the responses, edits and suggestions of the panelists and prepared a condensed, version of Round 2. Only survey statements that were shown to need a correction or revision based on the panelist responses were included in Round 3. Upon completion of Round 3 in which 80% consensus was reached by the expert panelists, the Delphi Process was considered complete.

Construct validity is the appropriate inferences made on the basis of observations or measurements as to whether a test measures the intended construct (Anastasi, 1988) Construct validity was established through Cronbach's Alpha Analysis.

Principal Investigator Created Tool

The Principal investigator created tool was entitled "Healthcare Provider Closed-Loop Artificial Pancreas Adoption" (HCP-CLAPA) Instrument (Appendix G). This Survey instrument addresses the following constricts: *relative advantage, perceived behavioral control, facilitating condition, self- concept, habit, perceived risk, perceived value, perceive threat to autonomy, resistance to change, and behavioral intent to use.*

Relative advantage as the degree to which an innovation is seen as better than the idea that superseded it (Roger's, 2003). This construct comes from the IDT and has been found to be highly associated with behavioral intent to use or adopt. A sample of statements pertaining to Relative Advantage can be found in Figure 5.

Relative Advantage

1. I expect that a closed-loop artificial pancreas system will reduce long term complications (i.e. kidney damage) more effectively than current treatments.
2. I expect that using a closed-loop artificial pancreas system will enhance my effectiveness in patient glycemic management compared to currently available insulin pump technology.
3. I expect the artificial pancreas systems will offer more durable glycemic control for patients over current regimes.

Figure 5 Likert statements for Relative Advantage variable. The 3 statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Perceived behavioral control refers to people's perceptions of their ability to perform a given behavior (Ajzen, 1991). This construct consistently found significant relationships specific to technology acceptance (Holden & Karsh, 2010). A sample list of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 6.

Perceived Behavioral Control

1. I would have the ability to use the artificial closed-loop pancreas for glycemic management in patients.
2. I expect that using a closed-loop artificial pancreas system for patient management would be entirely within my capability.

Figure 6. Likert statements for Perceived Behavioral Control variable. The statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Facilitating conditions include the state of the actor and the environmental conditions that make the act easy (Triandis 1980). Facilitating conditions were conceptualized as direct antecedents to behavior in the original TIB model. A sample

list of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 7.

Facilitating Conditions

1. I would recommend a closed-loop artificial pancreas system for patient care, if there was web-based medical monitoring that would alert **me** of issues (e.g. dysglycemia and technical malfunctions
2. I would recommend a closed-loop artificial pancreas system for patient care, if 24 -hour technical support was available.

Figure 7. Likert statements for Facilitating Conditions variable. The statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Self-concept is a construct from TIB and is defined *as* thoughts and feelings of behavioral disposition of which the individual is aware. It is conceptualized as an antecedent to behavior. A sample of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 8.

Self-Concept

1. I am comfortable with using new technology in treating patients.
2. I am an individual who can adapt easily.

Figure 8. Likert statements for Self-Concept variable. The statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Habit refers to past behavior predicting future behavior. It considers the frequency of the behavior and in the TIB is a direct antecedent to behavior. A sample of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 9.

Habit

1. In the past 12month period, what percent of Type 1 patients have you recommended to use an insulin pump with continuous glucose monitoring?
2. . In the past 12month period, what percent of Type 1 patients have you recommended to use a sensor augmented pump therapy with low glucose suspend?

Figure 9. Likert statements for Habit variable. The statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

In addition, several other constructs were added to help explain health care provider's intent to adopt technology. Perceived Risk Theory has been widely utilized in consumer research (Lim, 2003). This theory proposes that individuals perceive risk because they face potentially undesirable consequences as a result of purchases. *Perceived risk* is a multidimensional construct which includes: financial, psychological, performance, social risk, time, and safety (Cunningham, 1967). A general definition of perceived risk under the concept of the consumer is "the nature and amount of perceived risk of a consumer in contemplation of a particular purchase action" (Cox & Rich, 1964). In the contexts of medical devices, potential safety problems indicate the importance of performance risk. Health care providers are not personally incurring the cost of the medical device. However, they are aware of economic burden of diabetes and the health economics outcomes research of approved treatments thus, highlighting the importance of financial risk. Perceived financial risk is defined as the potential monetary output associated with the initial

purchase price as well as the subsequent maintenance cost of the product (Grewal et al.,1994). Perceived performance risk is the possibility of that the product malfunctioning and not performing as it was designed and therefore, failing to deliver desired benefits (Grewal et al., 1994). In the context of a medical devices performance risk can lead to safety issues. Risk when related to safety is defined as the probability or frequency of occurrence of a defined hazard and the consequence of the occurrence (HMSO, 1995). In this study, perceived financial risk is defined as the health care providers' perceptions of the potential output associated with the closed-loop artificial pancreas and all subsequent maintenance costs. It is operationalized in the context of cost to the patient and healthcare system based on the known costs of similar currently available SAPT and hybrid closed-loop systems projecting the perceived cost of the fully automated closed-loop system. Perceived performance risk is defined as the probability of the product harming the patient due to malfunctioning. In contrast to general consumers, it is not expected for health care providers would not suffer psychological stress or be concerned with others' perceptions regarding their patient's purchase of a closed-loop artificial pancreas and therefore these constructs were not considered in this model. Time- loss was considered a major barrier to physician's acceptance of technology (Yarbrough & Smith, 2007). However, for the purposes of this study time- loss was considered a value-based driver identified as a sacrifice under the operationalized construct of value.). Perceived Risk was conceptualized as direct antecedents to behavior. A sample list of

the HCP-CLAPA Likert statements that address this variable can be seen in Figure 10.

Perceived Risk

1. The closed-loop artificial pancreas system could pose a risk to glycemic control of a patient due to malfunctioning.
2. In general, a closed-loop artificial pancreas system could pose a risk to the patient due to wireless interference causing communication disruption.
3. A closed-loop artificial pancreas could pose a life threating risk to patients due to malfunctioning.

Figure 10. Likert statements for Perceived Risk variable. The sample statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Most empirical tests of TAM and physician-specific technology acceptance assume that the new technology provides some value to the user. However, there is little evidence to indicate value of technology in the healthcare setting (Yarbrough & Smith, 2007). There are multiple ways to define and operationalize value. In terms of healthcare, value has been described as the total benefits received minus the cost. Where the benefits are outcomes and services and the costs are price and non-monetary cos (Ettinger, 1998; Lee & Larsen, 2009). Three value-based drivers are price, time/effort/energy, and conflict (Lapierre, 2000). Price, time, and effort were operationalized in the context of perceived patient outcomes indicating value. To the author's best knowledge this is the first-time value is being conceptualized in the context of technology acceptance models. Perceived Value was asked in general and per system type. It was conceptualized as a direct antecedent to behavior. A sample

list of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 11.

Perceived Value

1. In general, I believe patient outcomes from a closed-loop artificial pancreas system will be worth the effort it will take to adapt current office policies/practices to care for patients using such technology.
2. I believe improved patient outcomes from a 24-hour fully automated **insulin only** closed-loop artificial pancreas systems will be worth the effort it will take for me to change the way I manage diabetes.
3. Considering the cost versus benefits, I believe that improved outcomes for patients will be worth the cost a patient will pay to use a 24-hour fully automated **dual hormone** closed-loop artificial pancreas technology.
4. I believe improved patient outcomes from a **hybrid** closed-loop artificial pancreas system will be worth the effort it will take for me to change the way I manage patients with diabetes.

Figure 11. Likert statements for Perceived Value variable. These statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Health care providers are medical professionals. A profession was originally defined as a specific occupation with special characteristic with a strong sense of public and social purpose that was served by the professional (Friedson, 1970; Swick, 2000). "Profession" has evolved to be focus on expert knowledge, so that control and application of the specialized body of knowledge is what characterized a profession. Achieving the status of being a member of a profession, professionals are granted professional autonomy (Friedson; 1970; Water & Succi-Lopez, 2008;). Professional autonomy is freedom to practice his/her profession in accordance to his/her knowledge and expertise (Engel, 1970; Walter & Succi-Lopez, 2008). Loss of

professional autonomy may reduce the quality of services provided (Engle, 1970). The artificial closed-loop pancreas may potentially affect the professional autonomy of a healthcare provider thus affecting the quality of patient care. Perceived threat to autonomy refers to the degree to which a person believes that a technology would decrease their control over processes, procedures, or content of his or her work (Walter &Succi-Lopez, 2008). In this model, perceived threat to autonomy was operationalized in the contexts clinical decisions, patient management, and follow-up care processes. Perceived Threat to Autonomy was conceptualized as a direct antecedent to behavior. A sample of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 12.

Perceived Threat to Autonomy

1. I suspect that using the closed-loop artificial pancreas system will decrease my control over my clinical decisions.
2. I suspect that using the closed-loop artificial pancreas would decrease my professional discretion with patient care management.

Figure 12. Likert statements for Perceived Threat to Autonomy variable. The sample statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Industrial societies value a person who is willing to and able to initiate and respond to positively to change, and yet attempts to initiate change are often accompanied by individuals or groups who resist change (Oreg, 2003). Healthcare technologies are widely expected to improve patient quality of care and to reduce cost however, these technologies are often strongly resisted by the same professional

expecting benefit from them (Bhattacherjee & Hikmet, 2007). Withdrawal of already implemented medical innovations is well documented (Lorence & Richards, 2003; Massaro, 1993). Individual differences among perspective users determine how individuals think and behave. Personality traits determine how individuals think and behave in various situations (Nov & Ye, 2008). Personality traits are often used in psychosocial research to explain beliefs and behavior. The introduction of new technology involves change for the user. Social psychological research has identified individual's dispositional inclination to resist change as a personality trait (Oreg, 2003). This trait is called resistance to change and could be viewed as a possible deterrent to use of a new technology. Therefore, this model includes the construct resistance to change as a potential barrier to technology acceptance. Resistance to Change was conceptualized as a direct antecedent to behavior. A sample list of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 13.

Resistance to Change

1. Using a closed-loop artificial pancreas system to manage patients seems like a hassle to me.
2. The closed-loop artificial pancreas system will increase my stress level regarding the way I manage patients with diabetes.

Figure 13. Likert statements for Resistance to Change variable. The sample statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

Behavioral intent use was selected as a proxy measure because it has a major mediating effect on intent to use and intention was also found to be a valid proxy

measure for behavior among clinicians (Eccles et al., 2006; Godin et al., 2008). A sample list of the HCP-CLAPA Likert statements that address this variable can be seen in Figure 14.

Behavioral Intent to Use (adopt)

1. The chances that I will use a closed-loop artificial pancreas (all systems that are appropriate) in patient glycemic management when it becomes available is very high.
2. The chance of me adopting a closed-loop artificial pancreas (all systems that are appropriate) in patient glycemic management whenever it becomes available is highly unlikely

Figure 14. Likert statements for Behavioral Intent to use variable. The sample statements are in no particular order. For a sample of the order in which each statement appears within the HCP-CLAPA, see Appendix G.

In addition, ten perceptions of knowledge were included to determine the participants' perception of knowledge regarding the closed-loop artificial pancreas technology (Figure 15). The perception of knowledge questions measures one domain of cognitive understanding which is knowledge (Clauss & Geedy, 2012). Perceptions of knowledge refer to what an individual perceives to know about the subject (e.g., a closed-loop artificial pancreas system). Healthcare provider's knowledge comes from previous education, experiences and is also through medical literature, lectures, and peer to peer engagement (ASA, 2014).

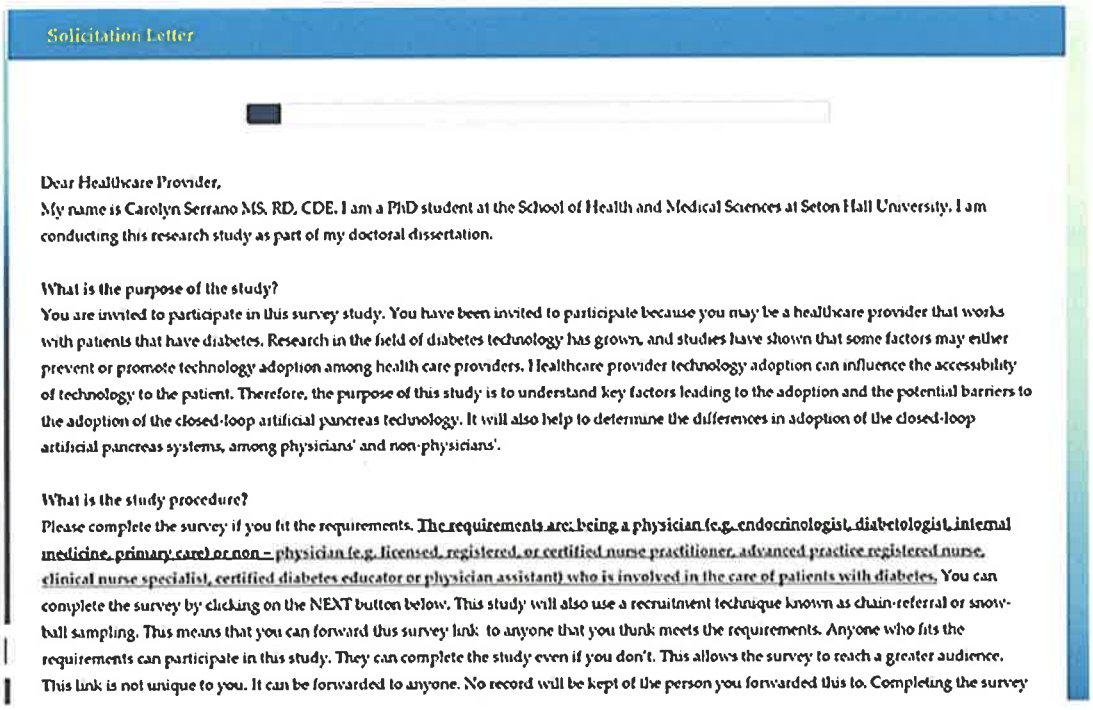
Perceptions of Knowledge

1. Ideally, a fully closed-loop artificial pancreas system would perform without human intervention.
2. The goal of the artificial pancreas system is to improve insulin replacement and by doing so bring glucose to near normal levels with reduced hypoglycemia.
3. Closed-loop artificial pancreas systems are surgically implanted.

Figure 15. Sample perceptions of knowledge statements.

The HCP-CLAPA, is a 77-question tool and was developed by generating questions to quantify constructs specific to the technology and population in question as well as to quantify constructs that had not yet been measured empirically. The tool consists of 8 demographic questions with 2 qualifying question,10 perceptions of knowledge questions with a 3-point Likert scale, 52 questions based on 10 theoretically grounded constructs with a 5-point Likert scale. Likert scaling most often uses 5 points with scaling of points higher than 5 it can be more difficult to determine the meaning of the responses between points (Krosnick & Presser, 2010). In addition, because of the length of the study over 50 questions, a 5-point Likert scale was used to reduce complexity for the user. For a snapshot of the beginning of the survey assessing constructs see Figure 17. Demographics usually include variables such as age, sex, marital family status, education and employment (Alreck & Settle,

2004). Demographic questions are used to identify groups (Figure 18). These questions were created by the PI and added to the HCP-CLAPA instrument (Appendix G). In addition, 5 open ended questions were added to further inform the quantitative results. A snapshot of the participant Letter of Solicitation in the electronic survey form can be seen in Figure 16. For the full version of the letter of solicitation see Appendix F.


Solicitation Letter

Dear Healthcare Provider,
My name is Carolyn Serrano MS, RD, CDE. I am a PhD student at the School of Health and Medical Sciences at Seton Hall University. I am conducting this research study as part of my doctoral dissertation.

What is the purpose of the study?
You are invited to participate in this survey study. You have been invited to participate because you may be a healthcare provider that works with patients that have diabetes. Research in the field of diabetes technology has grown, and studies have shown that some factors may either prevent or promote technology adoption among health care providers. Healthcare provider technology adoption can influence the accessibility of technology to the patient. Therefore, the purpose of this study is to understand key factors leading to the adoption and the potential barriers to the adoption of the closed-loop artificial pancreas technology. It will also help to determine the differences in adoption of the closed-loop artificial pancreas systems, among physicians' and non-physicians'.

What is the study procedure?
Please complete the survey if you fit the requirements. The requirements are: being a physician (e.g. endocrinologist, diabetologist, internal medicine, primary care) or non – physician (e.g. licensed, registered, or certified nurse practitioner, advanced practice registered nurse, clinical nurse specialist, certified diabetes educator or physician assistant) who is involved in the care of patients with diabetes. You can complete the survey by clicking on the NEXT button below. This study will also use a recruitment technique known as chain-referral or snow-ball sampling. This means that you can forward this survey link to anyone that you think meets the requirements. Anyone who fits the requirements can participate in this study. They can complete the study even if you don't. This allows the survey to reach a greater audience. This link is not unique to you. It can be forwarded to anyone. No record will be kept of the person you forwarded this to. Completing the survey

Figure 16. Snapshot of the Healthcare provider closed-loop artificial pancreas assessment (HCP-CLAPA) letter of the solicitation.

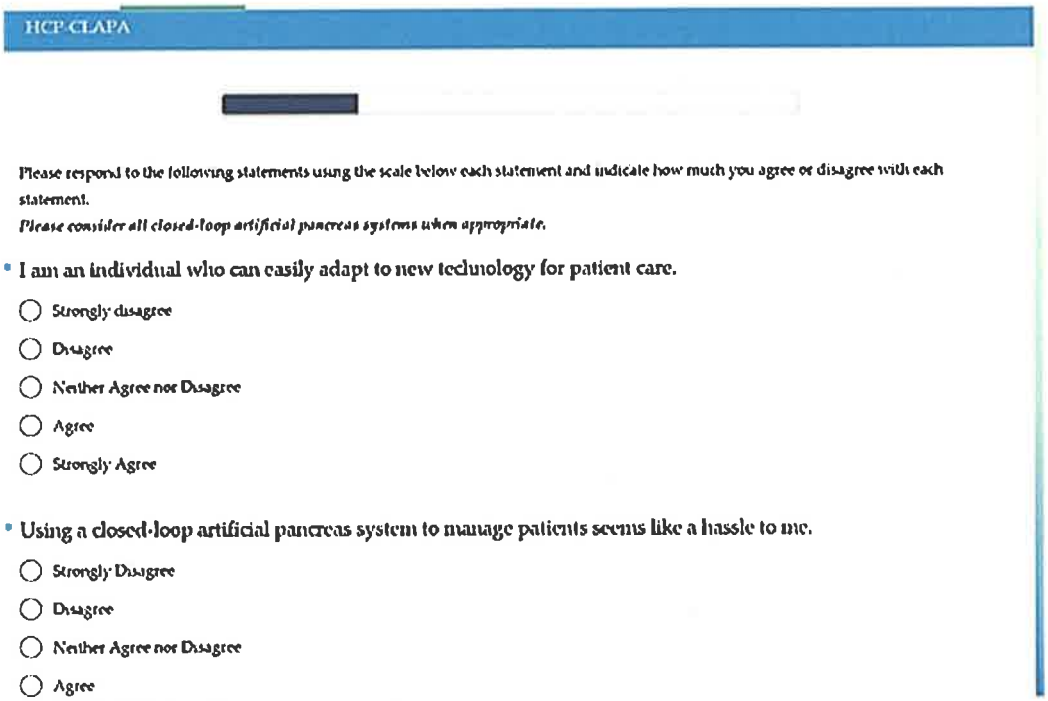


Figure 17. Snapshot of the beginning of the Healthcare Provider Closed-Loop Artificial Pancreas Assessment Survey (HCP-CLAPA) found on SurveyMonkey®. The figure illustrates the start of the construct questions in Likert format. Information on the full survey can be found in Appendix G.

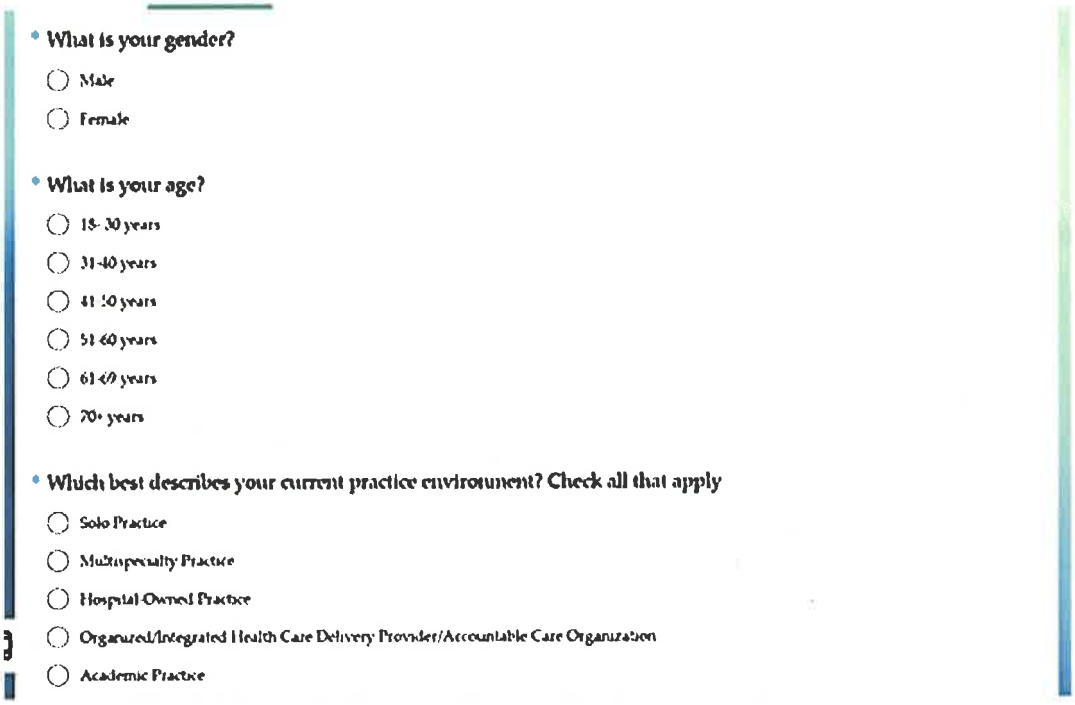


Figure 18. Snapshot of the demographic survey as found on SurveyMonkey®. This figure illustrates the demographic survey that askes participants their gender, age, years treating diabetes. Additional demographic questions immediately followed. Information on the full demographics can be found in Appendix G.

Inclusion/ Exclusion Criteria

To be included in the research study, participants had to be physician's endocrinologist/diabetologist, internal medicine/primary care MD/DO), and non-physicians (registered/ licensed/ certified nurse practitioners (NPs), certified nurse specialist (CNS), physician assistants (PA's) and certified diabetes educators (CDE's). CDEs are defined as healthcare providers who have the education, experience, and credentialing needed to effectively work with people across the spectrum of diabetes to better enable them to engage in impactful self-care (American

Association of Diabetes Educators, 2014). There are three diabetes specific credentials Certified Diabetes Educator (CDE) Board Certified in Advanced Diabetes Management (BC-ADM) and Certified Diabetes Technology Clinician (CDTC). Participants were excluded if they did not the inclusion Criteria. Additionally, if participants had no knowledge of the closed-loop artificial pancreas or if they had worked or currently work directly in the development or simulation testing of a closed-loop artificial pancreas system (Figure 19).

Inclusion	Exclusion
Physician (*endocrinologist/diabetologist, internal medicine/primary care MD/DO)*	**Is Not** Physician (*endocrinologist/diabetologist, internal medicine/primary care MD/DO)*
Non-physicians *(nurse practitioners (NPs), certified nurse specialist (CNS), and physician assistants PA's) and certified diabetes educators CDE's.*	**Is Not** Non-physicians (nurse practitioners (NPs), certified nurse specialist (CNS), and physician assistants PA's) and certified diabetes educators CDE's.
Individuals who are **not** involved in the development of a closed-loop artificial pancreas and	Individuals who were or **are** involved in the development of a closed-loop artificial pancreas or
Individuals who are **not** involved in simulation testing of a closed-loop artificial pancreas and	Individuals who were or **are** involved in simulation testing of a closed-loop artificial pancreas or
Individuals who identify themselves as having basic or higher knowledge of the closed-loop artificial pancreas and	Individuals who identify themselves as having no knowledge of the closed-loop artificial pancreas
Must be 18 years of age or older and	Individuals below 18 years of age or older or
Must be English speaking/ reading individuals	Non- English Speaking/ reading individuals

Figure 19. Inclusion and Exclusion Criteria for participants for the survey instrument.

Participant Recruitment

Upon approval by Seton Hall Institutional Review Board (IRB) (Appendix E), Survey participants who met the inclusion criterial were recruited from the following organizations: American Association of Diabetes Educators, Metropolitan New York Association of Diabetes educators, Novo Nordisk Medical Liaisons, and Close Concerns Diabetes Q&A the Research co. (Appendix E). Subjects were recruited through snowball sampling. Snowball sampling is a technique where the researcher accesses informants through contact information that is provided by other informants and then yet another informant. This procedure is accumulative and dynamic (Noy, 2008). Snowball sampling assumes that people with like characteristics, behaviors or interests, form associations, and it is this relationship, which the researcher uses to select a sample (Hek and Moule, 2006).

Social Media

Social medical was used as a direct conduit to medical professionals. Social media was utilized to recruit participants from practice groups. For Facebook™ as a recruitment method, The PI posted a link to the study survey and asked Facebook friends to snowball the link (Figure 20). In addition, the PI had to gain access approval for closed groups. The PI had to provide information on the parameters being studied and professional background. Once approved, the PI was able join the group and share a brief post with the survey link to the study (Figure 21).

For Twitter™ as a recruitment method, the PI tweeted medical professionals asking them to participate. Tweets were sent out using appropriate hashtags to attract

the necessary medical professionals. The tweets were concise to allow for posting per Twitter ™ policy (Figure 22).

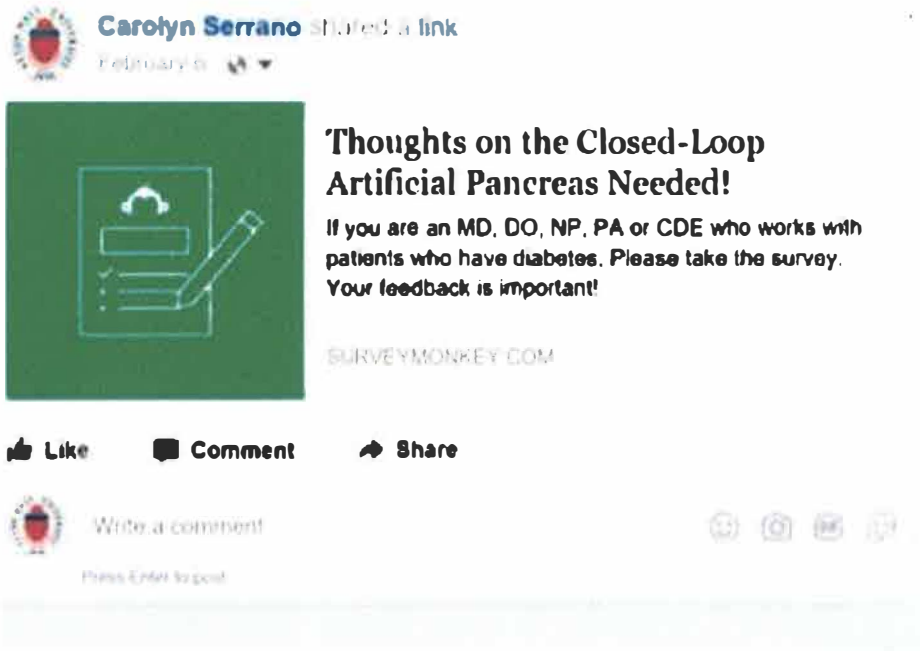


Figure 20. Sample Facebook post created for recruitment of medical professionals on Facebook. This page was for contacts to forward to potential participants.

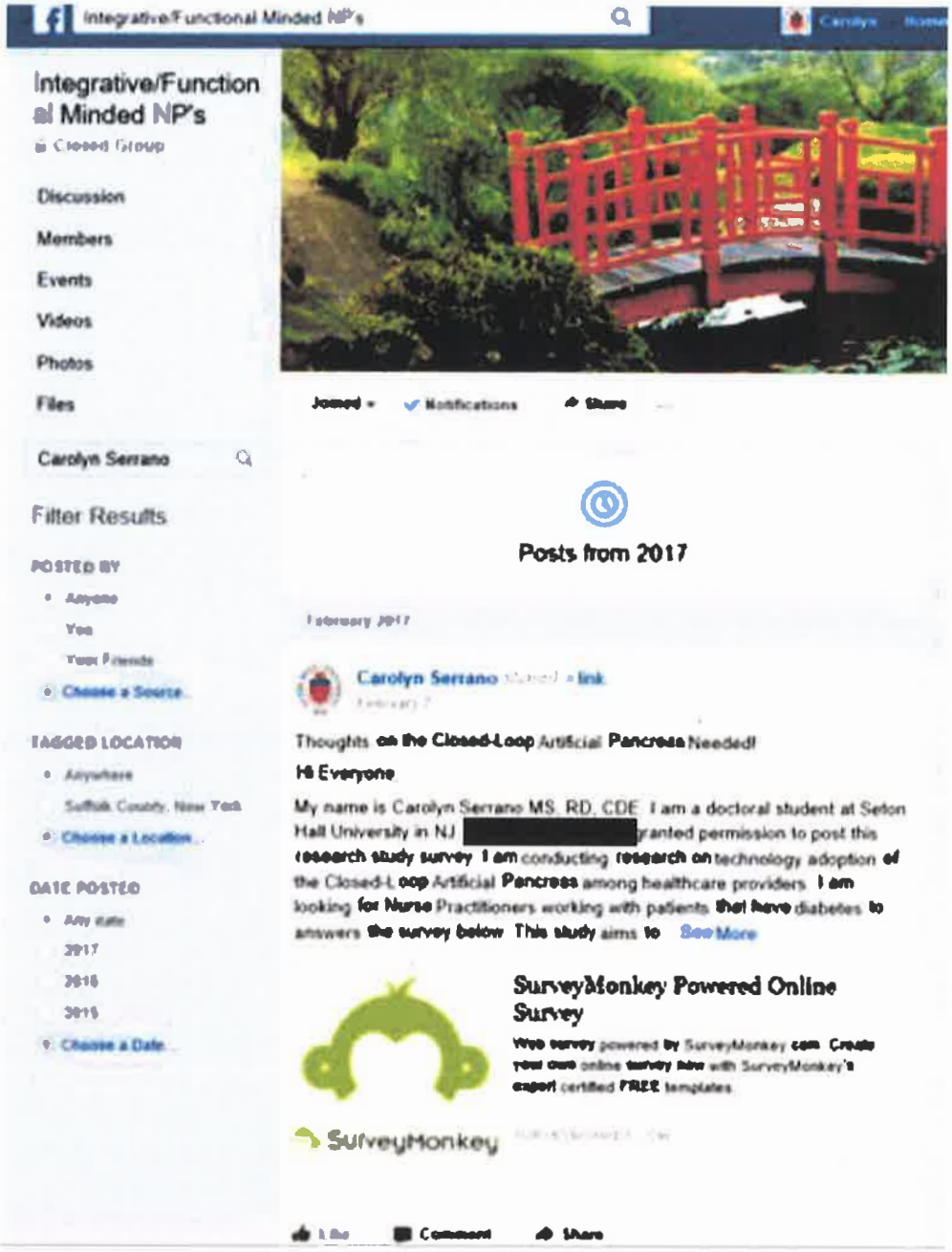


Figure 21. Sample Facebook Post created by PI for the recruitment of medical professionals on Facebook. This particular page was for nurse practitioners.

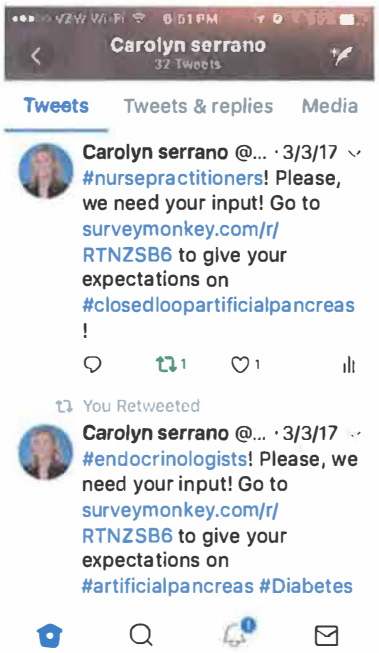


Figure 22. This is a snapshot of sample tweets used by PI for recruitment of medical professionals on Twitter™. There is a change in language used which includes the hashtag (#) for the tweet to be visible and attract the required participants.

For Linkedin® the PI followed similar procedures as Facebook where by the PI posted a link so that contacts could either take the survey or forward the survey to potential participants (Figure 23). The survey responses were anonymous and not collected form named individuals, it is unknown how many responses came from social medical (e.g. Facebook, Twitter, Linkedin)

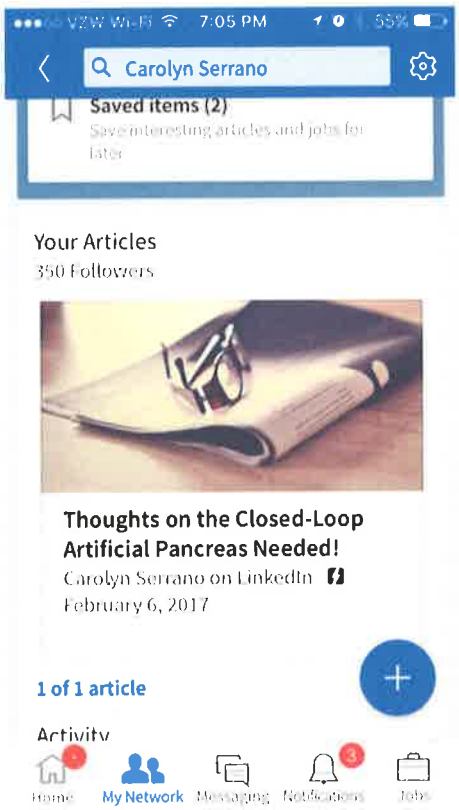


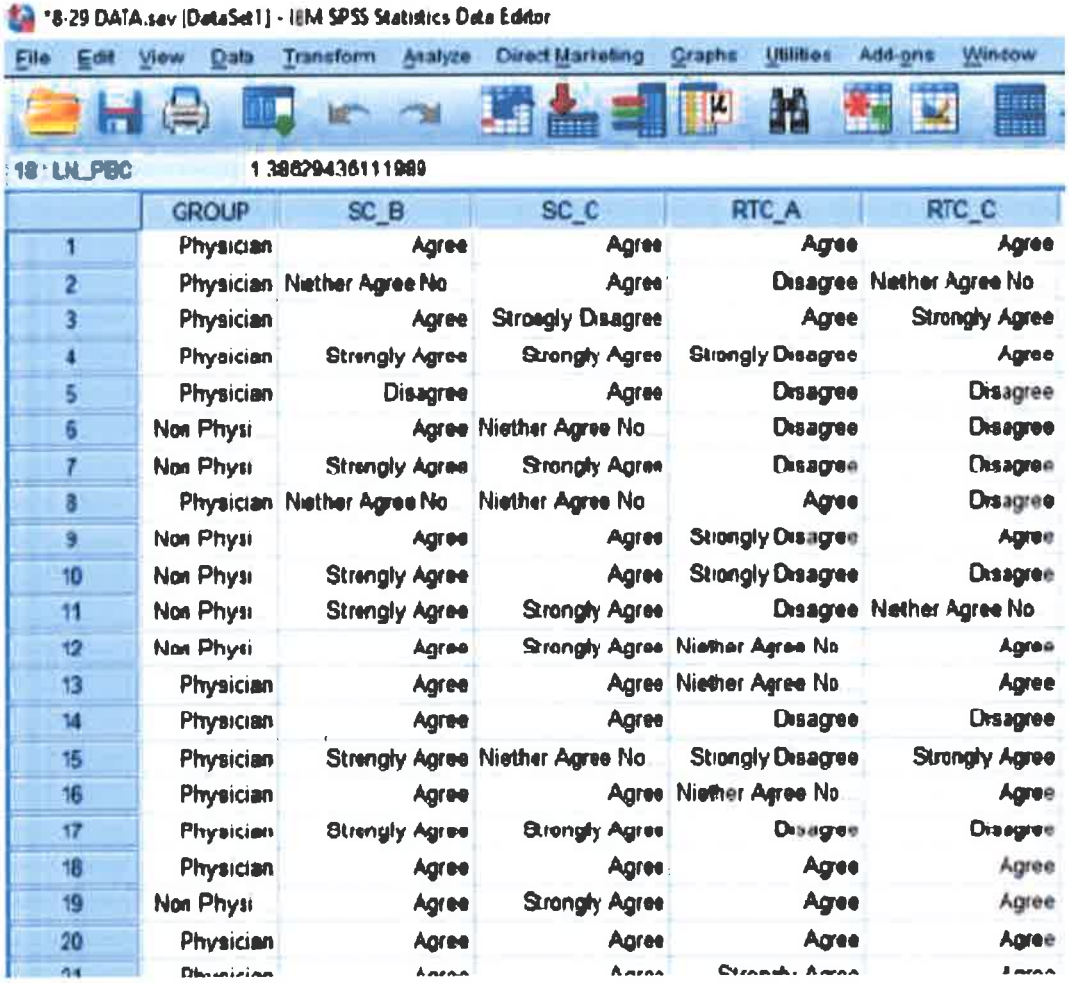
Figure 23. This is a snapshot of the sample Linkedin® post created by PI for recruitment of medical professionals on Linkedin®. This posting was linked to contacts to snowball to potential participants.

Data Coding & Analysis

Data were exported from SurveyMonkey® into Microsoft Excel. Following this was the creation of column variables and cases with eventual transfer into SPSS software version 21 (IBM, 2012) (Figure24). The conversation string variables into numeric variables was done within SurveyMonkey prior to exporting into the Excel Sheet (Figure 25). Each variable was given a label based on the survey statement for ease of viewing. Group, profession, and other demographic variables were coded as nominal. The group was coded 1 for physician and 0 for non-physician. Likert scaled

statements were coded from 1-5, based on the Answers Strongly Agree (5), Agree (4), Neutral (3), Disagree (2), Strongly Disagree (1) (Figure 26).

Perceptions of knowledge was coded Disagree (-1), Unsure (0), Agree (2). Reverse scoring was conducted to give the correct answer an appropriate score. Summations were calculated through the Tranform → Compute function in SPSS. A new variable was created with a label (e.g. knowledge_sum). Average knowledge score was calculated out of a total score of 20 through the Transform→ Compute function and the score was turned into percentage score correct. Reverse coding was also used for negative Likert scale items took place and the recoded into new variables for example, a negative statement such as "The chance of me adopting a closed-loop artificial pancreas in patient glycemic management whenever it becomes available is highly unlikely." For this process, if the respondent chose "strongly agree this would be coded a 1 instead of 5. If recoding was not done, this would affect the overall score for behavioral intent to adopt to make it reflect less favorable intention to adopt result. Reverse coding was conducted for any variable statements using negative disposition. A new column with the recoded data for this variable was created to reflect the true disposition of the statement. Scores were developed by computing the mean of all the items that constitute each theoretical dimension (Figure 27). For the behavioral intent to adopt the median score was calculated and a new variable will be created. Respondent scores above median score was coded as 1= high intent to adopt scores below the median were coded as 0= low intent to adopt (Gagnon et al., 2012; Orruno et al., 2011) (Figure 28).



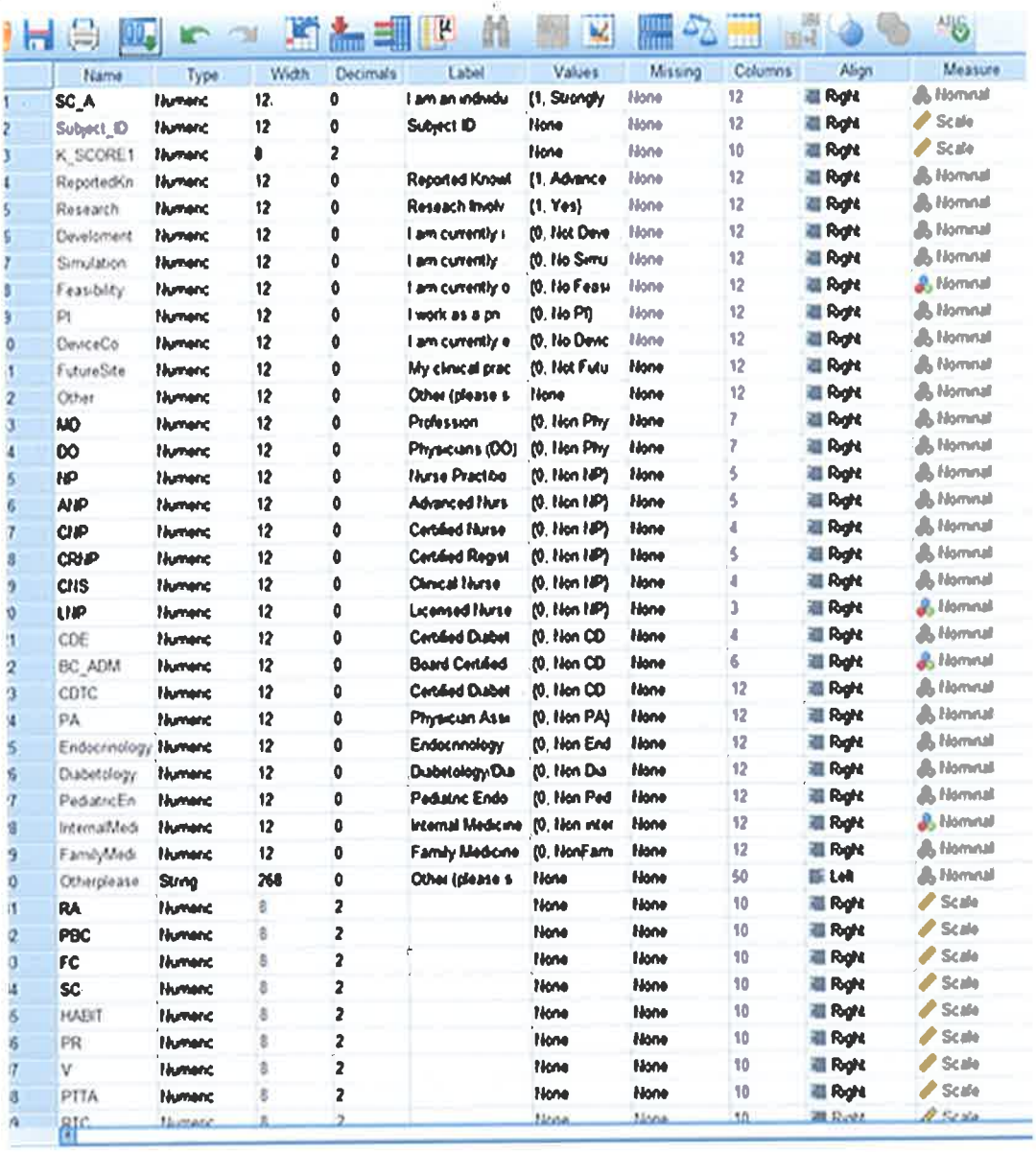
*8-29 DATA.sav [DataSet1] - IBM SPSS Statistics Data Editor

File Edit View Data Transform Analyze Direct Marketing Graphs Utilities Add-ons Window

18 : LN_PBC 1.38629436111989

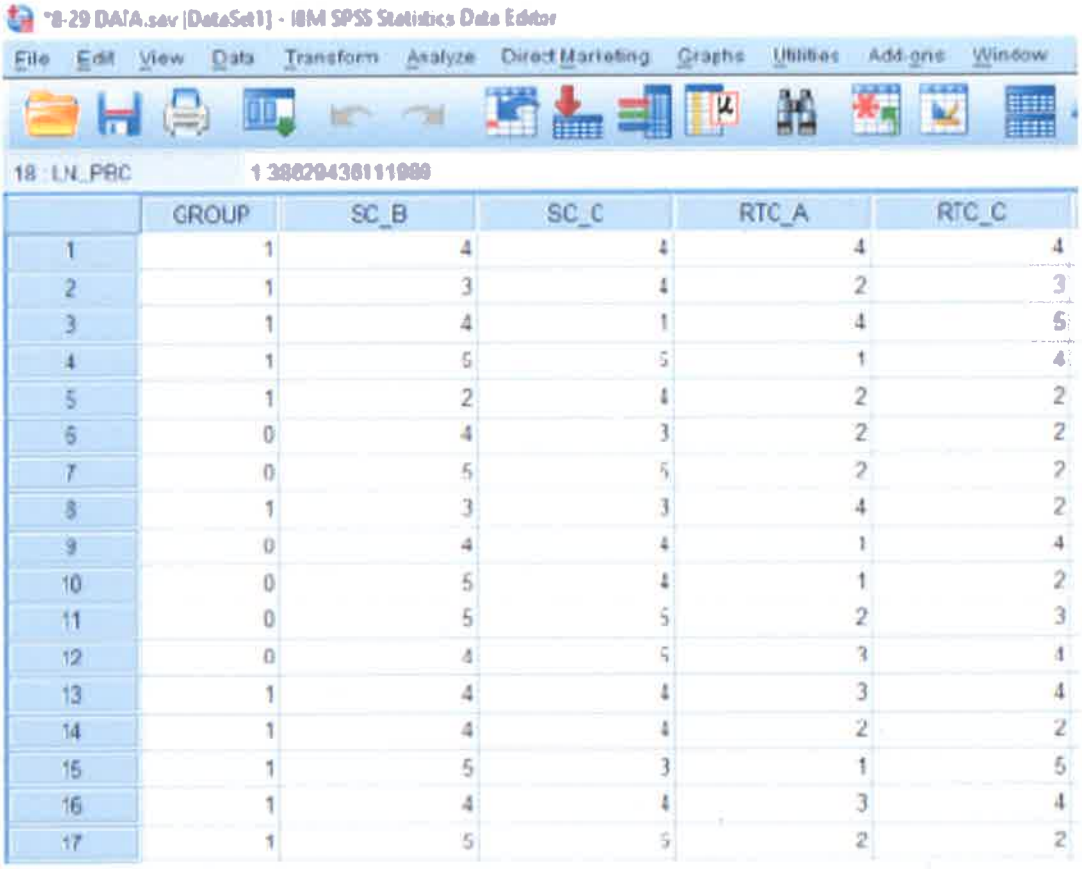
	GROUP	SC_B	SC_C	RTC_A	RTC_C
1	Physician	Agree	Agree	Agree	Agree
2	Physician	Nether Agree No	Agree	Disagree	Nether Agree No
3	Physician	Agree	Strongly Disagree	Agree	Strongly Agree
4	Physician	Strongly Agree	Strongly Agree	Strongly Disagree	Agree
5	Physician	Disagree	Agree	Disagree	Disagree
6	Non Physi	Agree	Niether Agree No	Disagree	Disagree
7	Non Physi	Strongly Agree	Strongly Agree	Disagree	Disagree
8	Physician	Nether Agree No	Niether Agree No	Agree	Disagree
9	Non Physi	Agree	Agree	Strongly Disagree	Agree
10	Non Physi	Strongly Agree	Agree	Strongly Disagree	Disagree
11	Non Physi	Strongly Agree	Strongly Agree	Disagree	Nether Agree No
12	Non Physi	Agree	Strongly Agree	Niether Agree No	Agree
13	Physician	Agree	Agree	Niether Agree No	Agree
14	Physician	Agree	Agree	Disagree	Disagree
15	Physician	Strongly Agree	Niether Agree No	Strongly Disagree	Strongly Agree
16	Physician	Agree	Agree	Niether Agree No	Agree
17	Physician	Strongly Agree	Strongly Agree	Disagree	Disagree
18	Physician	Agree	Agree	Agree	Agree
19	Non Physi	Agree	Strongly Agree	Agree	Agree
20	Physician	Agree	Agree	Agree	Agree

Figure 24. Coding of Data: Main Databased Spreadsheet. Snapshot of the main database after exportation from SurveyMonkey to Microsoft Excel and then to SPSS V.21.



	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure
1	SC_A	Numeric	12	0	I am an individu	{1, Strongly	None	12	Right	Nominal
2	Subject_ID	Numeric	12	0	Subject ID	None	None	12	Right	Scale
3	K_SCORE1	Numeric	8	2		None	None	10	Right	Scale
4	ReportedKn	Numeric	12	0	Reported Knowl	{1, Advance	None	12	Right	Nominal
5	Research	Numeric	12	0	Research Involv	{1, Yes}	None	12	Right	Nominal
6	Development	Numeric	12	0	I am currently i	{0, Not Deve	None	12	Right	Nominal
7	Simulation	Numeric	12	0	I am currently	{0, No Simu	None	12	Right	Nominal
8	Feasibility	Numeric	12	0	I am currently o	{0, No Feasi	None	12	Right	Nominal
9	PI	Numeric	12	0	I work as a pri	{0, No PI}	None	12	Right	Nominal
10	DeviceCo	Numeric	12	0	I am currently e	{0, No Devic	None	12	Right	Nominal
11	FutureSite	Numeric	12	0	My clinical prac	{0, Not Futu	None	12	Right	Nominal
12	Other	Numeric	12	0	Other (please s	None	None	12	Right	Nominal
13	MD	Numeric	12	0	Profession	{0, Non Phy	None	7	Right	Nominal
14	DO	Numeric	12	0	Physicians (DO)	{0, Non Phy	None	7	Right	Nominal
15	NP	Numeric	12	0	Nurse Practitio	{0, Non NP}	None	5	Right	Nominal
16	ANP	Numeric	12	0	Advanced Nurs	{0, Non NP}	None	5	Right	Nominal
17	CNP	Numeric	12	0	Certified Nurse	{0, Non NP}	None	4	Right	Nominal
18	CRNP	Numeric	12	0	Certified Regist	{0, Non NP}	None	5	Right	Nominal
19	CNS	Numeric	12	0	Clinical Nurse	{0, Non NP}	None	4	Right	Nominal
20	LNP	Numeric	12	0	Licensed Nurse	{0, Non NP}	None	3	Right	Nominal
21	CDE	Numeric	12	0	Certified Diabet	{0, Non CD	None	4	Right	Nominal
22	BC_ADM	Numeric	12	0	Board Certified	{0, Non CD	None	6	Right	Nominal
23	CDTC	Numeric	12	0	Certified Diabet	{0, Non CD	None	12	Right	Nominal
24	PA	Numeric	12	0	Physician Assi	{0, Non PA}	None	12	Right	Nominal
25	Endocrinology	Numeric	12	0	Endocrinology	{0, Non End	None	12	Right	Nominal
26	Diabetology	Numeric	12	0	DiabetologyDia	{0, Non Dia	None	12	Right	Nominal
27	PediatricEn	Numeric	12	0	Pediatric Endo	{0, Non Ped	None	12	Right	Nominal
28	InternalMedi	Numeric	12	0	Internal Medicine	{0, Non Inter	None	12	Right	Nominal
29	FamilyMedi	Numeric	12	0	Family Medicine	{0, NonFam	None	12	Right	Nominal
30	Otherplease	String	268	0	Other (please s	None	None	50	Left	Nominal
31	RA	Numeric	8	2		None	None	10	Right	Scale
32	PBC	Numeric	8	2		None	None	10	Right	Scale
33	FC	Numeric	8	2		None	None	10	Right	Scale
34	SC	Numeric	8	2		None	None	10	Right	Scale
35	HABIT	Numeric	8	2		None	None	10	Right	Scale
36	PR	Numeric	8	2		None	None	10	Right	Scale
37	V	Numeric	8	2		None	None	10	Right	Scale
38	PTTA	Numeric	8	2		None	None	10	Right	Scale
39	BTC	Numeric	8	2		None	None	10	Right	Scale

Figure 25 Coding of Data (Variable View). Snapshot of the conversation of string variables into numeric variables was done within SurveyMonkey prior to exporting into the Excel Sheet



	GROUP	SC_B	SC_C	RTC_A	RTC_C
1	1	4	4	4	4
2	1	3	4	2	3
3	1	4	1	4	5
4	1	5	5	1	4
5	1	2	4	2	2
6	0	4	3	2	2
7	0	5	5	2	2
8	1	3	3	4	2
9	0	4	4	1	4
10	0	5	4	1	2
11	0	5	5	2	3
12	0	4	5	3	4
13	1	4	4	3	4
14	1	4	4	2	2
15	1	5	3	1	5
16	1	4	4	3	4
17	1	5	5	2	2

Figure 26. Coding of Data: Main Databased Spreadsheet Post coding. Snapshot of the database spreadsheet coded by the PI. Coding is 0 or 1 for group and 1-5 for Likert scale items (Strongly Disagree to Strongly Agree).

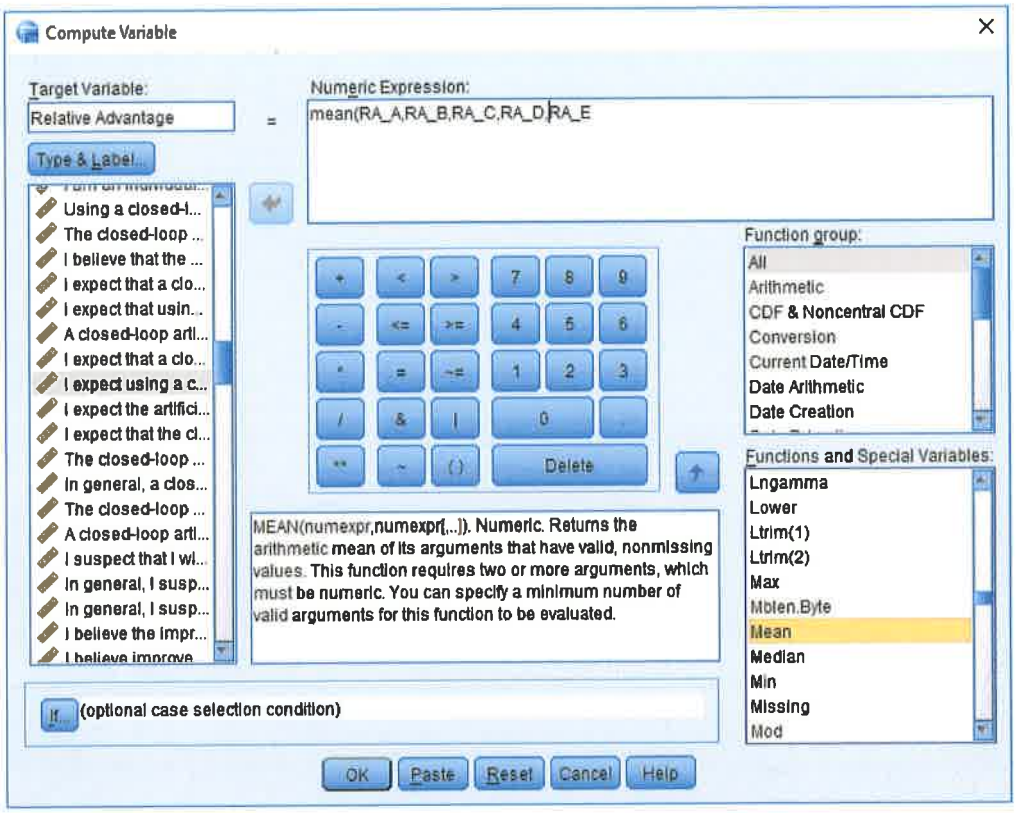
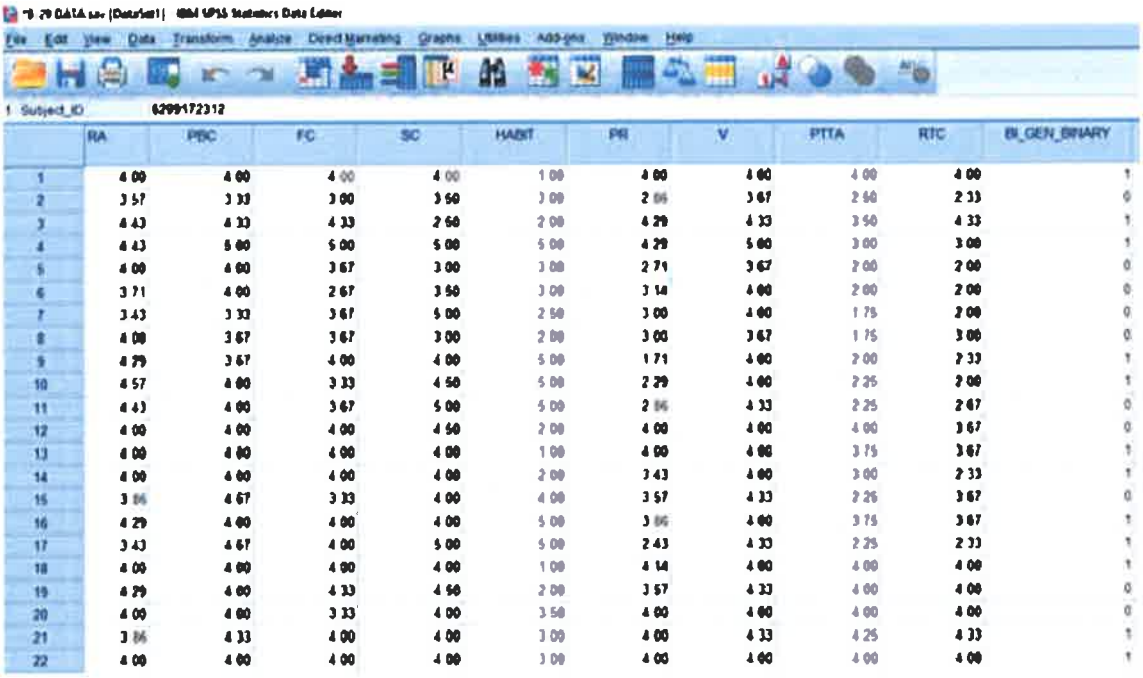


Figure 27. Coding of Data: Data Computation Function Creation of new target variable labeled (Relative_Advantage) and computed by summarizing the score of the items that measure Relative advantage and computing the mean to transform the data into a new variable. This computation was conducted for each independent variable.



	RA	PBC	FC	SC	HABIT	PR	V	PTTA	RTC	BI_GEN_BINARY
1	4.00	4.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00	1
2	3.57	3.33	3.00	3.50	3.00	2.86	3.67	2.50	2.33	0
3	4.43	4.33	4.33	2.50	2.00	4.29	4.33	3.50	4.33	1
4	4.43	5.00	5.00	5.00	5.00	4.29	5.00	3.00	3.00	1
5	4.00	4.00	3.67	3.00	3.00	2.71	3.67	2.00	2.00	0
6	3.71	4.00	2.67	3.50	3.00	3.14	4.00	2.00	2.00	0
7	3.43	3.33	3.67	5.00	2.50	3.00	4.00	1.75	2.00	0
8	4.00	3.67	3.67	3.00	2.00	3.00	3.67	1.75	3.00	0
9	4.29	3.67	4.00	4.00	5.00	1.71	4.00	2.00	2.33	1
10	4.57	4.00	3.33	4.50	5.00	2.29	4.00	2.25	2.00	1
11	4.43	4.00	3.67	5.00	5.00	2.86	4.33	2.25	2.67	0
12	4.00	4.00	4.00	4.50	2.00	4.00	4.00	4.00	3.67	0
13	4.00	4.00	4.00	4.00	1.00	4.00	4.00	3.75	3.67	1
14	4.00	4.00	4.00	4.00	2.00	3.43	4.00	3.00	2.33	1
15	3.86	4.67	3.33	4.00	4.00	3.57	4.33	2.25	3.67	0
16	4.29	4.00	4.00	4.00	5.00	3.86	4.00	3.75	3.67	1
17	3.43	4.67	4.00	5.00	5.00	2.43	4.33	2.25	2.33	1
18	4.00	4.00	4.00	4.00	1.00	4.14	4.00	4.00	4.00	1
19	4.29	4.00	4.33	4.50	2.00	3.57	4.33	4.00	4.00	0
20	4.00	4.00	3.33	4.00	3.50	4.00	4.00	4.00	4.00	0
21	3.86	4.33	4.00	4.00	3.00	4.00	4.33	4.25	4.33	1
22	4.00	4.00	4.00	4.00	3.00	4.00	4.00	4.00	4.00	1

Figure 28. Coding of Data: Final Database. This Database coded by PI representing the nine constructs making up the 9 independent variables and the binary dependent variable.

Reliability Assessment of the Tool

For the reliability assessment, a Cronbach's alpha analysis was conducted. Cronbach's alpha was used for construct validity as well as reliability purposes. The Cronbach's alpha for all factors was α.=803 (Table I) which indicates good internal consistency by George and Mallery (2011). The internal validity of the HCP-CLAPA was assessed utilizing Cronbach's alpha coefficient. Cronbach's alpha is a measure of internal consistency and is used commonly used a measure of reliability for psychometric instruments. A Cronbach's alpha score greater than 0.7 is considered to have acceptable internal consistency (George & Mallery, 2011).For the HCP-CLAPA there was 2 items removed to improve internal consistency of the survey statements.

For the construct self-concept, the statement "I am an individual who can easily adapt to new technology for patient care" was removed to improve the internal consistency of self-concept (Table II). Removing this statement improved the internal consistency for self-concept (Table III). For construct resistance to change the statement "My views about the closed-loop artificial pancreas technology are unlikely to change" was removed to improve internal consistence of the construct (Table IV). Removing this statement improved the internal consistency of resistance to change (Table V). All statistical analysis was conducted on the revised constructs.

Table I

Cronbach's Alpha Reliability for HCP-CLAPA; All Factors

Construct	Cronbach's Alpha	Total Reliability
Relative Advantage (7 Items)	.793	.803 (George& Mallory, 2011) "Good" *high upper range* N=46 items
Perceived Behavioral Control (3 Items)	.684	
Facilitating Conditions (3 Items)	.627	
Self-Concept (2 Items)	.712	
Habit (2-Items)	.677	
Perceived Risk (7 Items)	.793	
Perceived Value (12 Items)	.882	
Perceived Threat to Autonomy (4 Items)	.800	
Resistance to change (3 Items)	.721	
Behavioral Intent to Adopt (3 Items)	.708	

Table II
Total Statistic for Self- Concept with all three items.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.638	.678	3

Table III
Total Statistic for Self-Concept with improved internal consistency

Reliability Statistics

Cronbach's Alpha	*N of Items*
.712	2

Table IV.
Total Statistic for Resistance to Change with all four items.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.494	.509	4

Table V
Total Statistic for Resistance to Change with improved internal consistency.

Reliability Statistics

Cronbach's Alpha	*N of Items*
.721	3

STATISTICA ANALYSIS

The data was analyzed using a stepwise multi- iterative process of descriptive and inferential statistics, using SPSS version 21. Demographic characteristics was presented in tabular form using descriptive statistics. Non-parametric statistics are appropriate when the level of data is nominal, or ordinal, sample size is small or unequal, and the data cannot be presumed to be normally distributed (Field, 2009). The descriptive statistics include mean, medians, modes, frequencies and percentage. Descriptive data analysis helped to analyze the significance of the continuous and categorical variables in the context of the healthcare provider. Spearman's *rho* correlational coefficients was used to examine the relationship between variable's. The main research hypotheses (RQ4-RQ12) was tested using binomial logistical regression. The statistical assumptions were met such as independent observations and linearity of independent variables (Keith, 2015). These assumptions provided information on the accuracy of the predictions, it tested how well the regression model fit the data, it determined the variation in the dependent variable explained by the independent variables and it tested the hypotheses on the regression equation.

Binomial logistic regression is a common method of analysis performed in technology acceptance literature when the dependent variable has a non-normal distribution. (Gagnon et al., 2012; Orruno et al., 2011). Binomial logistic regression was also used for RQ13. This model assessed the effect of physician and non-physician groups on the dependent variable based on value.

A naturalistic approach was used to analyze the open-ended questions will be used. A Cohen's Kappa statistic was used to confirm major themes with the help of a research assistant. The data was first be organized in excel, salient themes were identified, and coded. Overarching themes were identified, and findings were confirmed with a research assistant. (Wood, 2007). Figure 30 illustrates a flowchart summary of methodology up to and including the post-IRB approval from Seton Hall University.

A Priori G* Power

An A Prior G* Power Analysis for logistic Regression to determine the sample size (Faul, Erdfelder, Lang, & Buchner, 2009) (Figure 29). This Study required a total sample size of 199 healthcare providers. The effect size was r^2 0.25 (medium effect appropriate for a binomial logistic regression, indicating the strength of the relationship between the independent and dependent variable. The alpha set at 0.05 which is the level of significance or the probability of detecting a type 1 error. The Power (1-β) is listed at .80 which is the probability of detecting aa true relationship or group difference. Logistic regression estimates the probability of an

event occurring is greater than 0.5 or greater than even odds. Statistical power is the likelihood that a study will detect an effect when there is an effect to be detected. High statistical power with reduce the probability of making a type 2 error (Portney & Watkins, 2009).

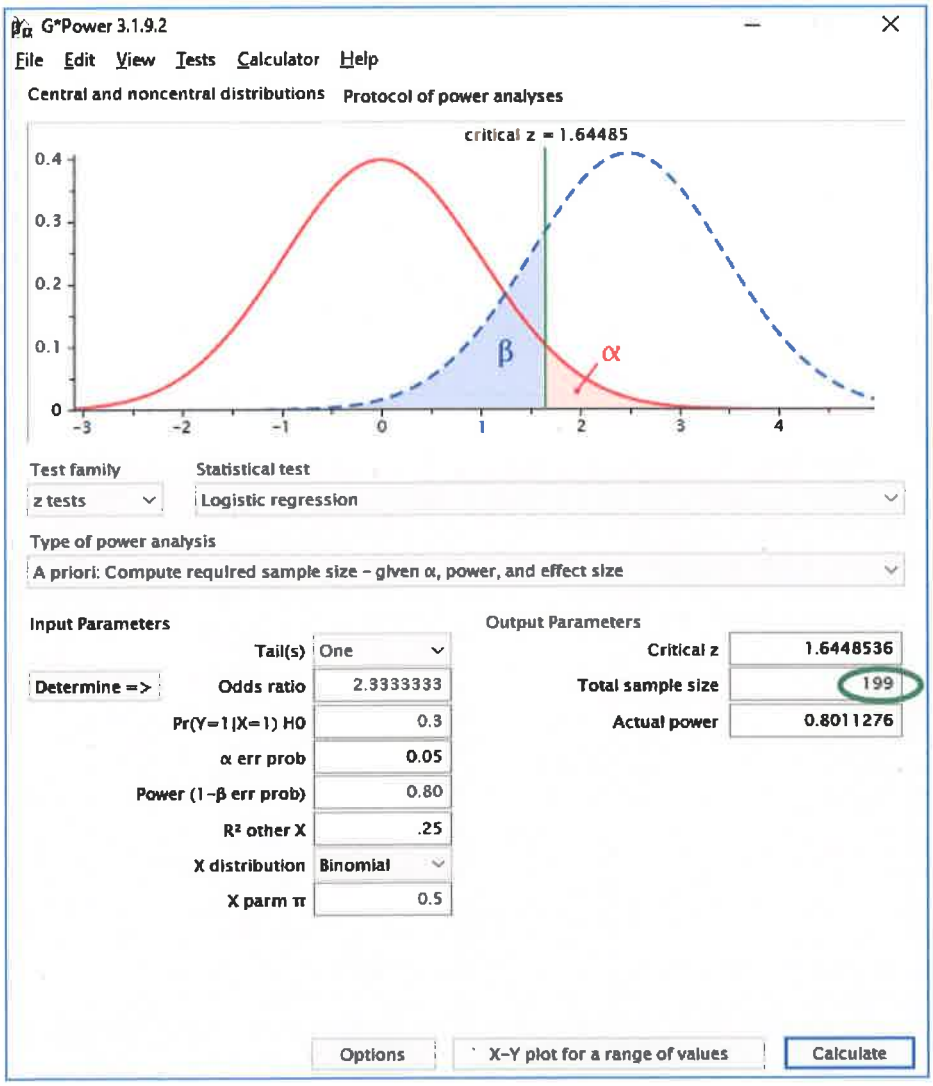


*Figure 29. A Priori G** Power analysis to determine sample size. With an effect size of r^2 0.25 appropriate for Binomial Logistic Regression, an alpha of .05, power of .80 (one tail) the total expected sample is 199 participants for the survey.

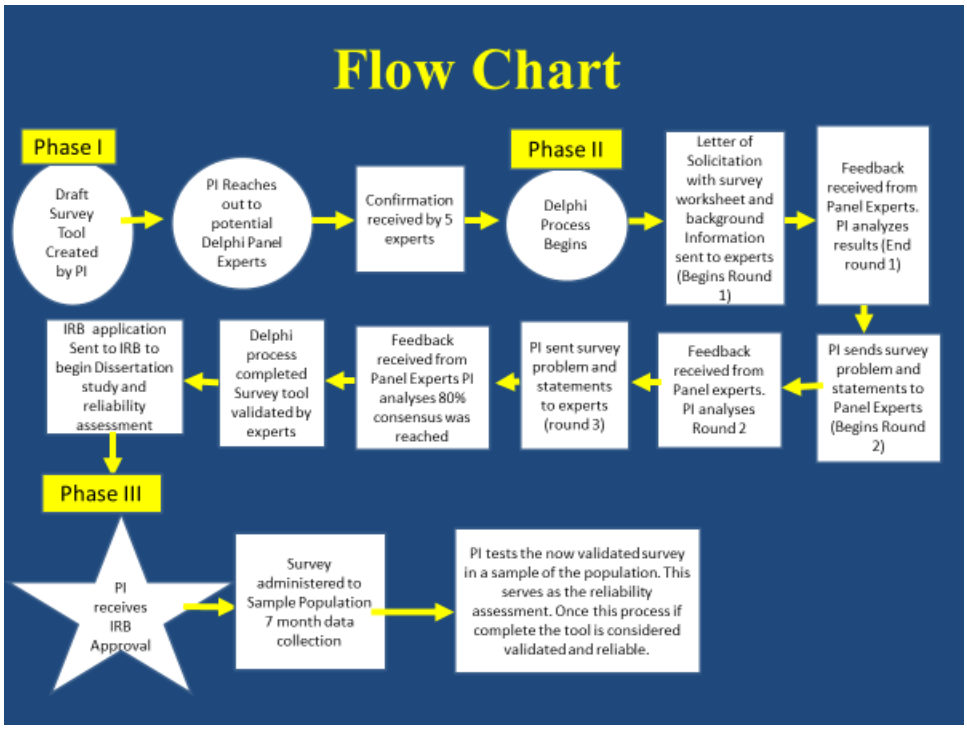


Figure 30. Flowchart summary of methodology up to and including the reliability assessment post-IRB approval from Seton Hall University.

Chapter IV

Results

Introduction

This chapter focuses on the results of the statistical test completed for this dissertation study.

Characteristic of the Sample

A total of 258 healthcare providers were recruited. Ten participants were excluded because they self-reported having no knowledge of the closed-loop artificial pancreas. An additional 15 participants were excluded because they were directly involved in either the development of or simulation testing of the closed-loop artificial pancreas. There were 26 participants that were lost to attrition. A total sample of 207 healthcare providers were included in the analysis (Figure 31).

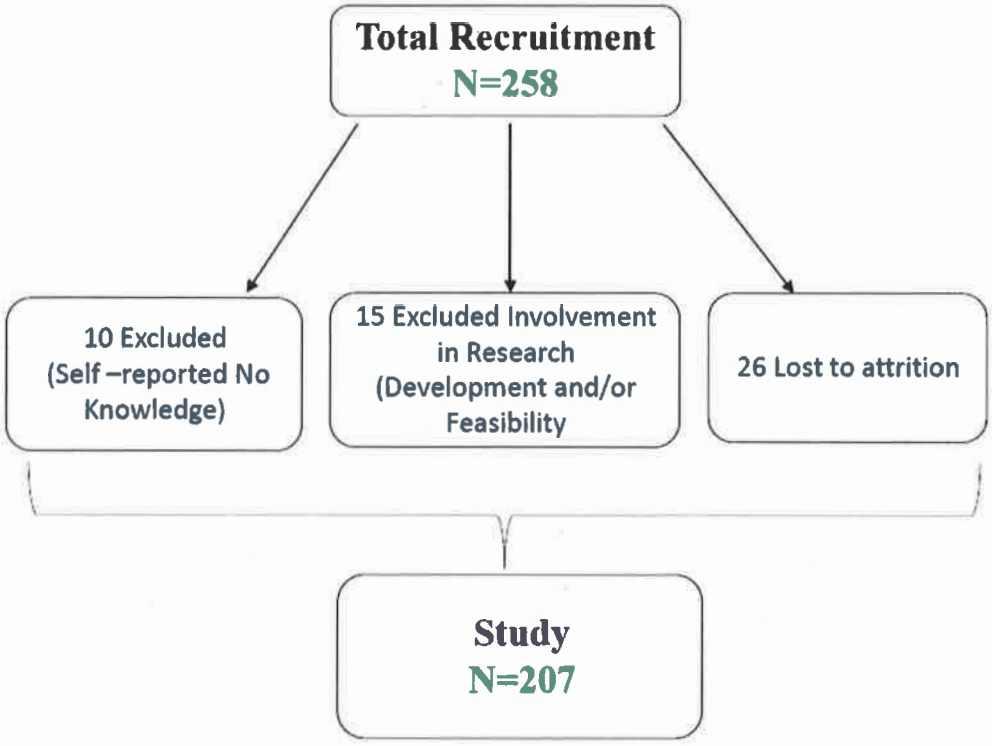


Figure 31. Flowchart indicating the total recruitment and total sample size.

Frequency of Respondents

The sample consisted of both non-physicians and physicians. One hundred and fifty-two (152) non-physicians and fifty-five (55) physicians answered the survey. The groups are not considered equal however, this will not influence the main analysis because they were not broken out by group (Table VI).

Table VI

Frequencies and percentage of the total sample size physicians and non-physicians.

Physician/Non Physician

		Frequency	*Percent*	*Valid Percent*	*Cumulative Percent*
Valid	Non Physician	152	73.4	73.4	73.4
	Physician	55	26.6	26.6	100.0
	Total	207	100.0	100.0	

U.S. Geographical Locations of Respondents According to Licensure.

Respondents of the HCP-CLAPA reveal locations were well disperced across the United States (Figure 32). PI was successful in obtaining repsonses from thirty-nine (39) states (Figure 33). Particiapnts were asked to reveal their state (s) of licensure as a healthcare practitioner. There was an option to select from one or more states. License to practice is reflected in the numbers presented in Figure 33. The result indicate that repsondents came from every state except Alabama, Alaska,

Hawaii, Idaho, Louisiana, Missouri, North Dakota, Ohio, Tenneesse, Wyoming,and West Virgina. The largest number of respondnets holding active licenses came from New York (54 licenses), Texas (13 licenses), Massachusette (13licenses), Georgia(12 licenses) and Colorado (12licenses). 30% of the respondents helf licenses in the state of New York 50% were physicians and 50% were classified as non physicians. The reason more particiapants came from NY is likely the approval from the Metropolitain New York Association of Diabetes Educators and

Snowball sampling from Novo Noridsk, INC. The American Association of Diabetes Educators and Close Concerns new letter has National dispersion. There was no other major trends interms of practitioner and license location.

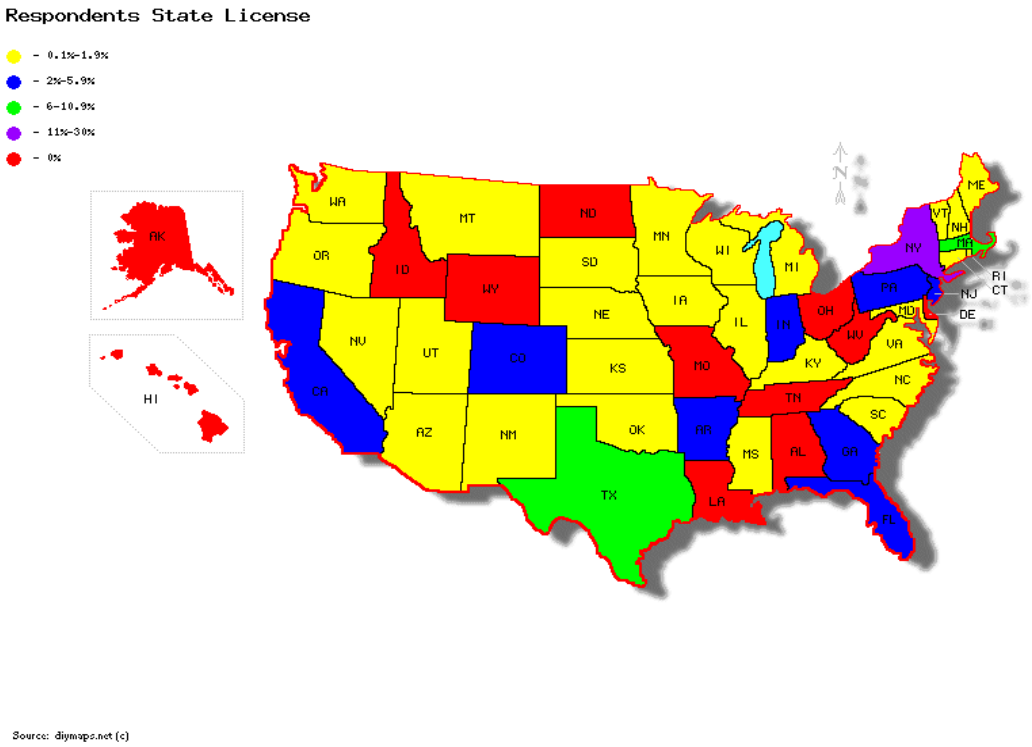
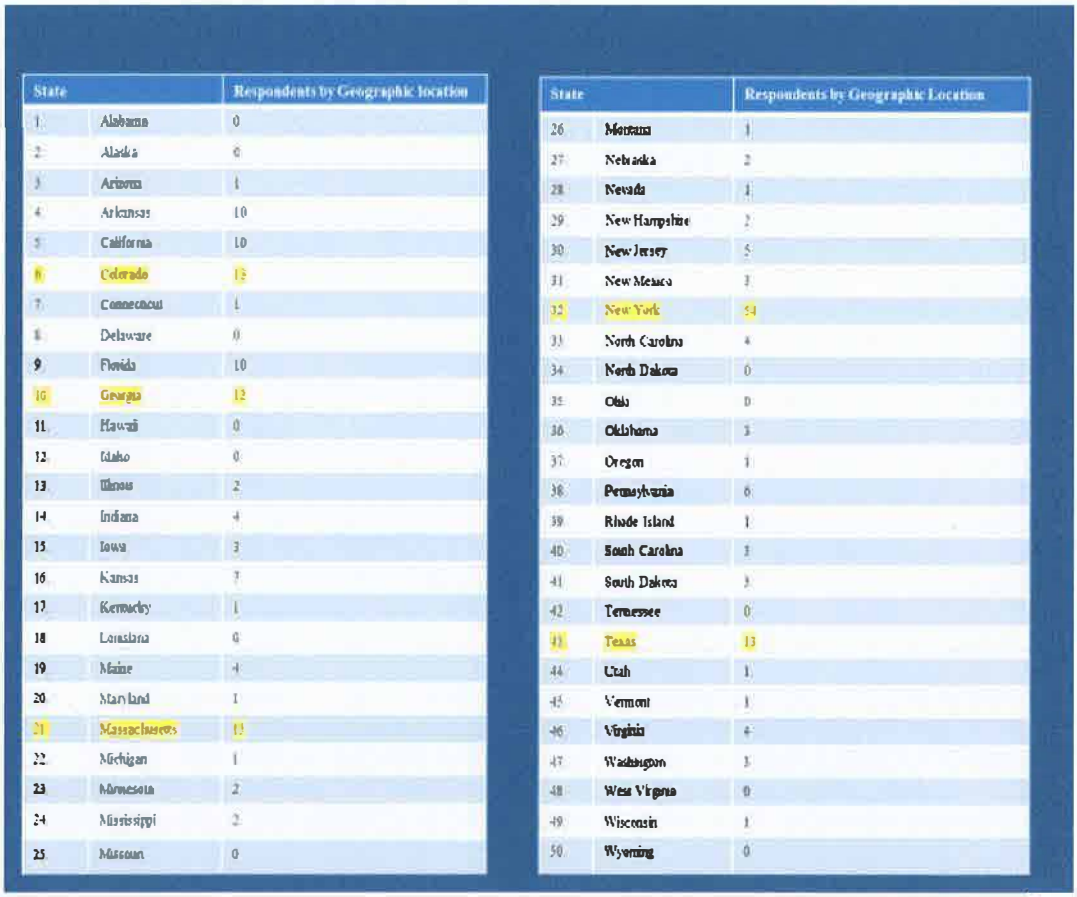


Figure 32. Distribution Map of Respondents According to Healthcare Provider Licensure in percentages.



State		Respondents by Geographic location
1	Alabama	0
2	Alaska	0
3	Arizona	1
4	Arkansas	10
5	California	10
6	Colorado	13
7	Connecticut	1
8	Delaware	0
9	Florida	10
10	Georgia	12
11	Hawaii	0
12	Idaho	0
13	Illinois	2
14	Indiana	4
15	Iowa	3
16	Kansas	7
17	Kentucky	1
18	Louisiana	0
19	Maine	4
20	Maryland	1
21	Massachusetts	13
22	Michigan	1
23	Minnesota	2
24	Mississippi	2
25	Missouri	0

State		Respondents by Geographic Location
26	Montana	1
27	Nebraska	2
28	Nevada	1
29	New Hampshire	2
30	New Jersey	5
31	New Mexico	3
32	New York	54
33	North Carolina	4
34	North Dakota	0
35	Ohio	0
36	Oklahoma	3
37	Oregon	1
38	Pennsylvania	6
39	Rhode Island	1
40	South Carolina	1
41	South Dakota	3
42	Tennessee	0
43	Texas	13
44	Utah	1
45	Vermont	1
46	Virginia	4
47	Washington	3
48	West Virginia	0
49	Wisconsin	1
50	Wyoming	0

Figure 33. Distribution Tables of Respondents According to Practitioner Licensure. Resondent by goegraphical location refers to the actaul number practitioners who are currently licenses to practice within the coorsponding state. Some respondent held licsensure in more than one state. Results show most repondents were licensed in New York, Texas, and Massachusettes, followed by Colorado and Georgia.

Gender of Respondents

More females than males took this survey. A total of 160 (77%) of the respondents were female verse 37 (17.9%) male respondents (Table VII). More non-physicians were female (137) in contrast to more male phsyicans (31) (Figure 34).

Table VII

Frequency and Percentages of Total Respondents Accordign to Gender.

Gender

		Frequency	*Percent*	*Valid Percent*	*Cumulative Percent*
Valid	MALE	37	17.9	18.8	18.8
	FEMALE	160	77.3	81.2	100.0
	Total	197	95.2	100.0	
Missing	System	10	4.8		
Total		207	100.0		

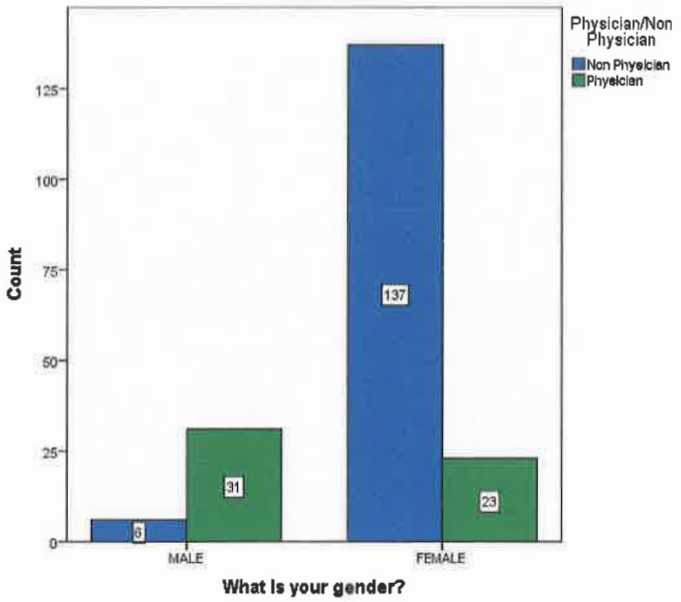


Figure 34. Bar Graph illustrating gender by professional group.

Age of Respondents

The majority of repsondents were in the middel age range, which is 41-69. The 51-60 age group had the highest number of respondents (Figure 35). Indicating that the respondants potential had more experience int their profession. The frequency of the respondants by age can be seen in Table VIII.

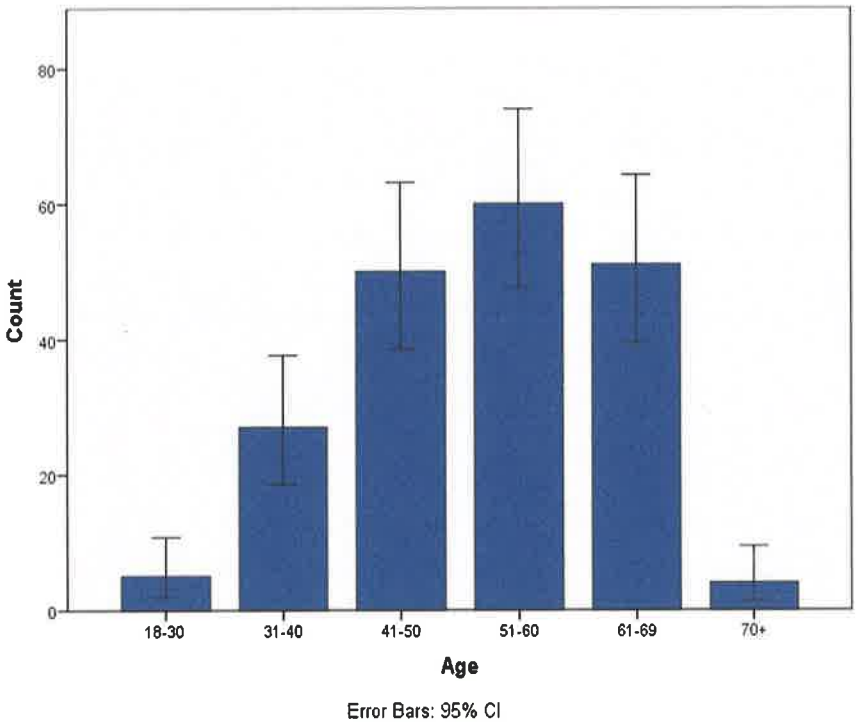


Figure 35. Bar Graph illustrating the age of respndents. The majority of respondents were in th 51-60 age range.

Table VIII
Frequencies of Total Respondents According to Age

Age

		Frequency	*Percent*	*Valid Percent*	*Cumulative Percent*
Valid	18-30	5	2.4	2.5	2.5
	31-40	27	13.0	13.7	16.2
	41-50	50	24.2	25.4	41.6
	51-60	60	29.0	30.5	72.1
	61-69	51	24.6	25.9	98.0
	70+	4	1.9	2.0	100.0
	Total	197	95.2	100.0	
Missing	System	10	4.8		
Total		207	100.0		

Respondents' Years of Experience Treating Diabetes

The majority of respondents had 11-20 years of experience treating patients with diabetes in their repsoective profession. Only one particiapnat had less than 1 year experience. Therefore the majority of respondents had experience treating patients with diabetes (Table IX). Graphical representation of respondents years of experience treating diabetes can be seen in Figure 36.

Table IX
Frequencies and Percentages of Respondents Years of Experience Treating Patients with Diabetes.

Years of Experience

		Frequency	*Percent*	*Valid Percent*	*Cumulative Percent*
Valid	<1	1	.5	.5	.5
	1-5	23	11.1	11.7	12.2
	6-10	25	12.1	12.7	24.9
	11-20	64	30.9	32.5	57.4
	21-30	49	23.7	24.9	82.2
	31+	35	16.9	17.8	100.0
	Total	197	95.2	100.0	
Missing	System	10	4.8		
Total		207	100.0		

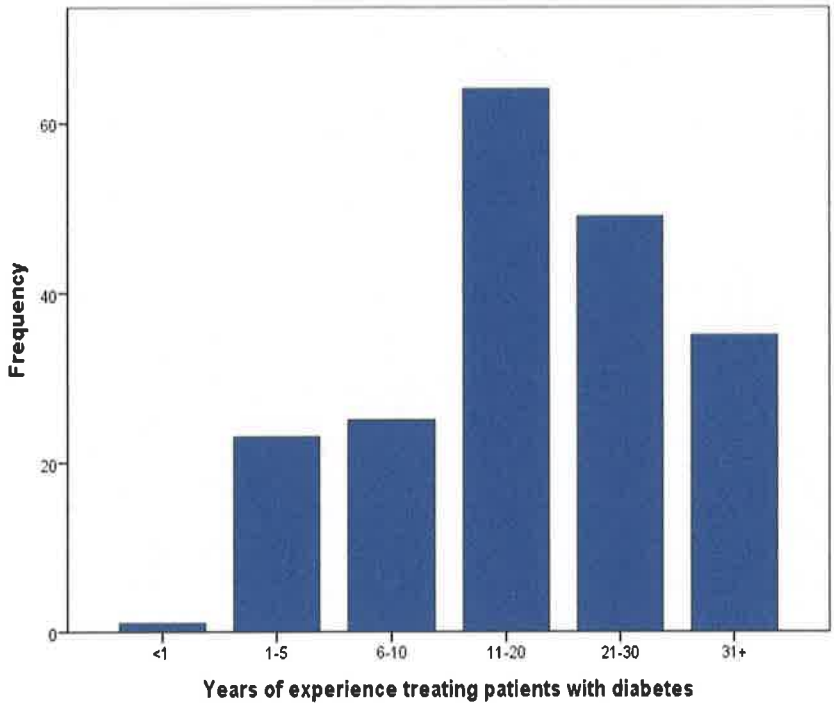


Figure 36. Bar Graph illustrating the years of experience in treating patients with diabetes.

The following results refer to research question 1. What are the physicians' and non physicians' perception of knowledge regarding the closed-loop artificial pancreas?

Perception of knowledge

Participants were asked to select the repsonse that best represented their understanding of the closed-loop aritifical pancreas. The coorsponding answers indicated no knowledge, basic knowledge, or advanced knowledge. Broken out by practitoner type a higher percentage physicians answered that they perceved their

knowledge to be advanged verses basic and a higher percentage of non-phyisicans reported that they perceived their knowledge to be basic verse advanced (Figure 37). Participants that answered that they had no knowledge were exluded from the analysis because it was imperative that the respondents had at least basic knowledge to answer the survey questions. To ensure that resondent understood the technology, there was ten questions that assessed perception of knowledge of the closed-loop artifical pancrease. Perceptions of knowledge is defined as the range of an individuals understanding or the sum of what is known (ASA, 2014). The mean knowledge score was 68% indicating that particiapants had a reasonable understanding of how this technology works (Figure 38). The majority of participants scored over 70%.

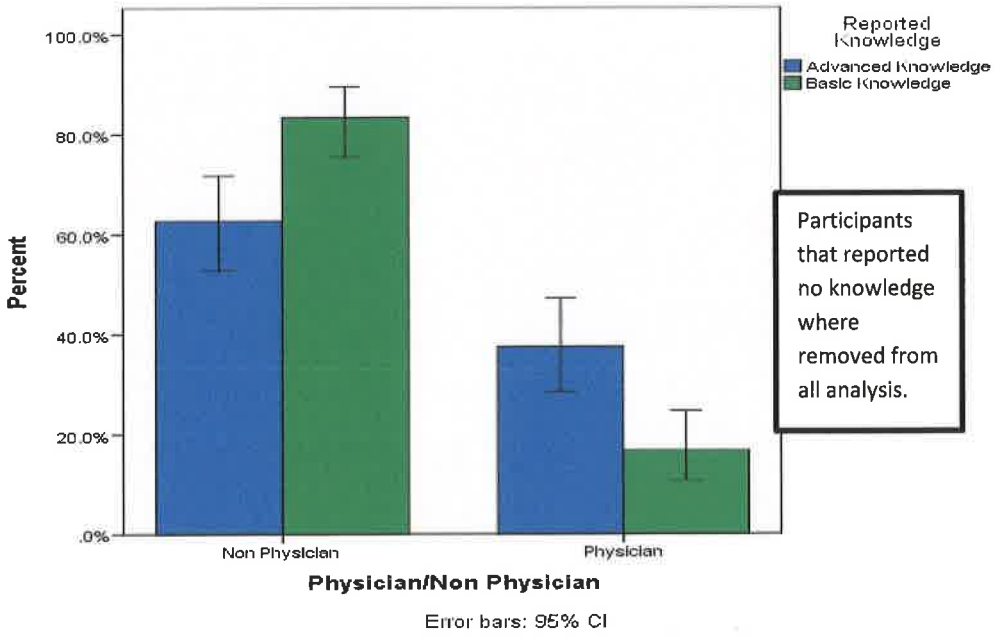


Figure 37. Cluster bar graph illustraiting physicians and non-physcians perceived reported knowledge regarding the closed-loop artifical pancreas.

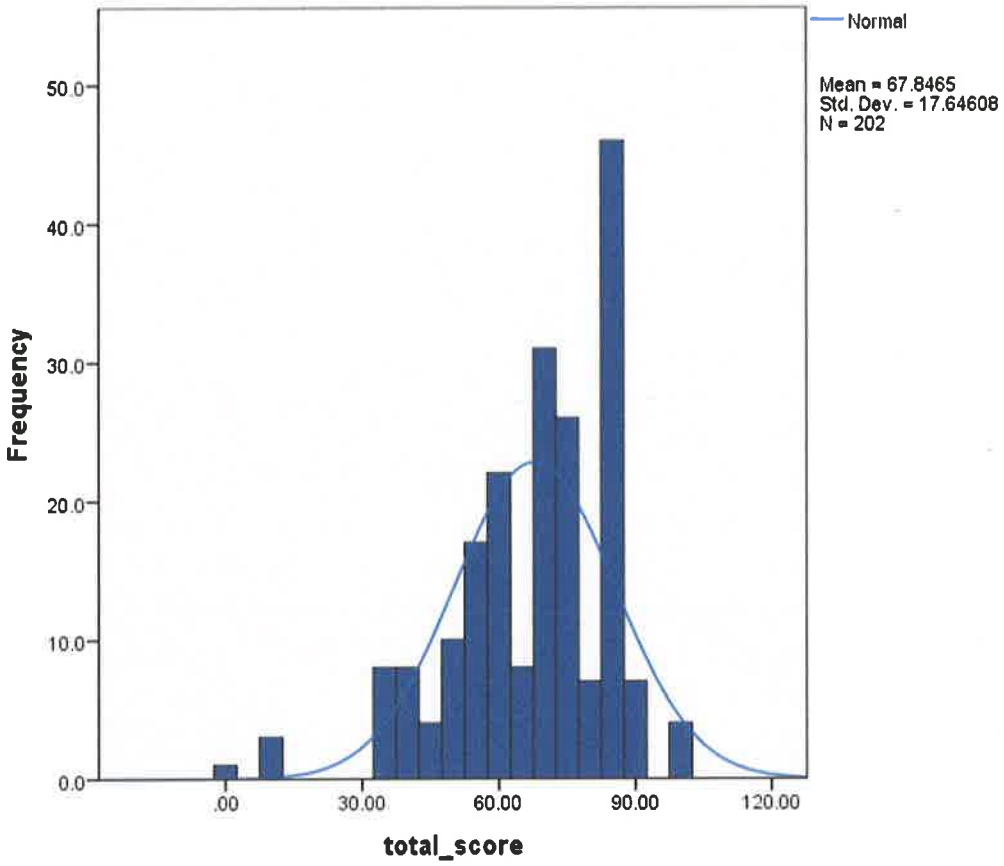


Figure 38. Histogram of the 10- question perception of knowledge score indicating respondents had a reasonable understanding of the closed-loop artificial pancreas technology.

The following results refer to research question 2. What are the physicians' and non-physicians' beliefs regarding the 9 independent variables and the dependent variable?

A Mann-Whitney *U* test was calculated examining the difference in beliefs of physicians' and non-physicians' regarding the 9 predictor variables and the dependent variable. There were significant differences between non-physicians and physicians for self- concept, perceived threat to autonomy, and resistance to change (Figure 39). However, these constructs were not significant in the main analysis meaning they did not significantly add to the model variance.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of RA is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.300	Retain the null hypothesis.
2	The distribution of PBC is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.868	Retain the null hypothesis.
3	The distribution of FC is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.773	Retain the null hypothesis.
4	The distribution of SC is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.004	Reject the null hypothesis.
5	The distribution of HABIT is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.500	Retain the null hypothesis.
6	The distribution of PR is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.139	Retain the null hypothesis.
7	The distribution of V is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.108	Retain the null hypothesis.
8	The distribution of PTTA is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.000	Reject the null hypothesis.
9	The distribution of RTC is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.000	Reject the null hypothesis.
10	The distribution of BI_GEN is the same across categories of Physician/Non Physician.	Independent-Samples Mann-Whitney U Test	.865	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Figure 39. Mann-Whitney *U* test assessing the differenced in beliefs of physicians and non-physicians regarding the 10 constructs independent variable and the dependent variable.

There were significant differences between groups for self- concept, perceived threat to autonomy, and resistance to change. For self-concept there was a higher mean rank for non-physicians m=106.92 vs physicians m=81.88, U= .004, p<0.05. For perceived threat to autonomy, there was a higher mean rank for physicians m= 130.93 vs. non-physicians 94.26, U=0.00, p<0.05. For resistance to change, there was a higher mean rank for physicians m=133.06 vs. non-physicians m=93.48, U=.000, p< 0.05.

The following results refer to research question 3. What, if any, is the association between each predictor (9) and healthcare providers' behavioral intent to adopt the closed-loop artificial pancreas systems?

Spearman rho correlations calculated the correlation between the 9 independent variables and healthcare providers intent to adopt the closed-loop artificial pancreas. Relative advantage, perceived behavioral control, self-concept, value and habit all had positive significant correlations. Perceived risk and resistance to change had negative and significant correlations. Perceived threat to autonomy had a negative and non-significant correlation to behavioral intent to adopt (Table X).

Table X

Spearman Rho Correlation coefficients for the 9 independent variables and healthcare provider intent to adopt the closed-loop artificial pancreas.

Correlations

			RA	PBC	FC	SC	HABIT	PR	V	PTTA	RTC	BI_GEN
Spearman's rho	RA	Correlation Coefficient	1.000	.405**	.372**	.310**	.339**	-.170*	.615**	-.184**	-.265**	.442**
		Sig. (1-tailed)	.	.000	.000	.000	.000	.007	.000	.004	.000	.000
		N	207	207	207	199	199	207	207	207	207	207
	PBC	Correlation Coefficient	.405**	1.000	.158*	.534**	.339**	-.152*	.578**	-.234**	-.352**	.392**
		Sig. (1-tailed)	.000	.	.012	.000	.000	.014	.000	.000	.000	.000
		N	207	207	207	199	199	207	207	207	207	207
	FC	Correlation Coefficient	.372**	.158*	1.000	.193**	.000	.012	.349**	-.123*	-.161*	.169**
		Sig. (1-tailed)	.000	.012	.	.003	.498	.431	.000	.038	.010	.007
		N	207	207	207	199	199	207	207	207	207	207
	SC	Correlation Coefficient	.310**	.534**	.193**	1.000	.310**	-.141*	.545**	-.249**	-.255**	.305**
		Sig. (1-tailed)	.000	.000	.003	.	.000	.024	.000	.000	.000	.000
		N	199	199	199	199	199	199	199	199	199	199
	HABIT	Correlation Coefficient	.339**	.339**	.000	.310**	1.000	-.355**	.323**	-.169*	-.273**	.277**
		Sig. (1-tailed)	.000	.000	.498	.000	.	.000	.000	.008	.000	.000
		N	199	199	199	199	199	199	199	199	199	199
	PR	Correlation Coefficient	-.170*	-.152*	.012	-.141*	-.355**	1.000	-.185**	.380**	.431**	-.127*
		Sig. (1-tailed)	.007	.014	.431	.024	.000	.	.004	.000	.000	.034
		N	207	207	207	199	199	207	207	207	207	207
	V	Correlation Coefficient	.615**	.578**	.349**	.545**	.323**	-.185**	1.000	-.302**	-.407**	.447**
		Sig. (1-tailed)	.000	.000	.000	.000	.000	.004	.	.000	.000	.000
		N	207	207	207	199	199	207	207	207	207	207
	PTTA	Correlation Coefficient	-.184**	-.234**	-.123*	-.249**	-.169*	.380**	-.302**	1.000	.571**	-.090
		Sig. (1-tailed)	.004	.000	.038	.000	.008	.000	.000	.	.000	.100
		N	207	207	207	199	199	207	207	207	207	207
	RTC	Correlation Coefficient	-.265**	-.352**	-.161*	-.255**	-.273**	.431**	-.407**	.571**	1.000	-.138*
		Sig. (1-tailed)	.000	.000	.010	.000	.000	.000	.000	.000	.	.023
		N	207	207	207	199	199	207	207	207	207	207
	BI_GEN	Correlation Coefficient	.442**	.392**	.169**	.305**	.277**	-.127*	.447**	-.090	-.138*	1.000
		Sig. (1-tailed)	.000	.000	.007	.000	.000	.034	.000	.100	.023	.
		N	207	207	207	199	199	207	207	207	207	207

** Correlation is significant at the 0.01 level (1-tailed).

* Correlation is significant at the 0.05 level (1-tailed).

A spearman rho correlation was calculated for the relationship between relative advantage and behavioral intent to adopt. A moderate positive and significant correlation was found (*rho* 207) =.442, $p<.001$). Indicating a higher relative advantage correlated to higher intent to adopt the closed-loop artificial pancreas. A

spearman rho correlation was calculated for the relationship between perceived behavioral control and behavioral intent to adopt. A moderate positive and significant correlation was found *(rho (*207) =.392, p<.001) Indicating a higher perceived behavioral control correlated to higher intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between facilitating conditions and behavioral intent to adopt. A weak positive and significant correlation was found *rho (*207) =.169, p=.007) Indicating a significant correlated of facilitating conditions and intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between self-concept and behavioral intent to adopt. A moderate positive and significant correlation was found (*rho (*199) =.305, p<.001). Indicating moderate and significant correlation between facilitating conditions and intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between habit and behavioral intent to adopt. A weak and positive and significant correlation was found *(rho (*199) =.277, p<.001) Indicating a higher frequency of recommending current technology correlated to higher intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between perceived risk and behavioral intent to adopt. A weak negative and significant correlation was found *rho (*207) =-.127, p=.034) Indicating a significant negative correlation of perceived risk and intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between perceived value and behavioral intent to adopt. A moderate positive and significant correlation was found (*rho (*207) =.447

$p<.001$). Indicating moderate and significant correlation between value and intent to adopt the closed-loop artificial pancreas. A spearman rho correlation was calculated for the relationship between resistance to change and behavioral intent to adopt. A weak negative correlation and significant correlation was found (*rho* (207) = -.138, $p=.023$). Indicating weak and significant negative correlation between resistance to change and intent to adopt the closed-loop artificial pancreas. Lastly, a spearman rho correlation was calculated for the relationship between perceived threat to autonomy and behavioral intent to adopt. A weak negative and non- significant correlation was found (*rho* (207) = -.090, $p=.100$). Indicating no significant correlation between perceived threat to autonomy and intent to adopt the closed-loop artificial pancreas.

The next set of results pertains to research question 4-12.What, if any, is the relationship with nine predictor variables and behavioral intent to adopt the closed-loop artificial pancreas systems. A binomial regression was conducted to assess the relationship between the 9 independent variables and behavioral intent to adopt (Gagnon et al., 2012; Orruno et al., 2011). Binomial logistic regression is used when the dependent variable is not normally distributed. In the case of behavioral intent to adopt the median number was used as cut off for intent to adopt or not to adopt. The behavioral intent to adopt the closed-loop artificial pancreas in this sample displayed a median of 3.33 Those with a response of 3.33 or higher were classified as having the behavioral intent to adopt and those with a score lower than 3.33 were classified as not having the behavioral intent to adopt. The was a total of 199 cases included in the analysis (Table XI).

Table XI

Binomial Regression Case Processing Summary for the Main Analysis.

Case Processing Summary

Unweighted Cases[a]		*N*	*Percent*
Selected Cases	Included in Analysis	199	96.1
	Missing Cases	8	3.9
	Total	207	100.0
Unselected Cases		0	.0
Total		207	100.0

a. If weight is in effect, see classification table for the total number of cases.

Assumption of No Multicollinearity

For this model the VIF values are all below 10 and the tolerance statistic are all well above 0.2 (Myers, 1990; Bowerman & O'Connell, 1990) Therefore, there is no multicollinearity with in the data (Table XII).

Table XII

Assumption of No Multicollinearity for the Main Analysis

Coefficients[a]

Model		Collinearity Statistics	
		Tolerance	*VIF*
1	RA	.472	2.119
	PBC	.614	1.628
	FC	.832	1.202
	SC	.682	1.466
	HABIT	.755	1.324
	PR	.651	1.536
	V	.393	2.545
	PTTA	.532	1.881
	RTC	.477	2.094

a. Dependent Variable: BI_GEN_BINARY

Linearity Assumption

Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box and Tidwell (1962) procedure. A Bonferroni correction was applied using all 19 terms in the model resulting in statistical significance being accepted when $p < .00026$ (Tabachnick & Fidell, 2007). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable (Table XIII).

Table XIII

Assumption Linearity of Continuous Variables for the Main Analysis

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	RA	23.666	14.539	2.650	1	.104	1.898E+10
	PBC	43.188	14.470	8.908	1	.003	5.707E+18
	FC	.545	5.502	.010	1	.921	1.725
	SC	6.323	8.112	.607	1	.436	557.020
	HABIT	-4.224	1.995	4.483	1	.034	.015
	PR	-9.769	9.285	1.107	1	.293	.000
	V	-25.590	14.689	3.035	1	.081	.000
	PTTA	-6.120	4.042	2.292	1	.130	.002
	RTC	3.854	3.432	1.261	1	.261	47.167
	LN_RA by RA	-9.448	6.187	2.332	1	.127	.000
	LN_PBC by PBC	-17.723	5.977	8.793	1	.003	.000
	FC by LN_FC	-.406	2.454	.027	1	.869	.666
	LN_SC by SC	-2.516	3.422	.541	1	.462	.081
	HABIT by LN_HABIT	2.122	.930	5.202	1	.023	8.345
	LN_PR by PR	4.710	4.359	1.168	1	.280	111.034
	LN_V by V	10.804	6.126	3.110	1	.078	49225.086
	LN_PTTA by PTTA	2.790	2.052	1.848	1	.174	16.286
	LN_RTC by RTC	-1.948	1.725	1.275	1	.259	.143
	Constant	-61.943	30.053	4.248	1	.039	.000

a. Variable(s) entered on step 1: RA, PBC, FC, SC, HABIT, PR, V, PTTA, RTC, LN_RA * RA , LN_PBC * PBC , FC * LN_FC , LN_SC * SC , HABIT * LN_HABIT , LN_PR * PR , LN_V * V , LN_PTTA * PTTA , LN_RTC * RTC .

Studentized residuals casewise list identifying outliers. There were seven cases that had studentized residuals greater than 2.5 standard deviations. However, based on cook's distance no case was greater than 1, meaning that no case significantly contributed to the model and therefore these cases were left in the analysis (Table XIV).

Table XIV

Studentized Residuals Caseswise List for the Main Analysis

Casewise List[b]

Case	Selected Status[a]	Observed BI_GEN_BINARY	Predicted	Predicted Group	Temporary Variable Resid	ZResid
31	S	N**	.933	Y	-.933	-3.733
65	S	N**	.906	Y	-.906	-3.105
90	S	N**	.886	Y	-.886	-2.783
96	S	N**	.893	Y	-.893	-2.883
138	S	N**	.878	Y	-.878	-2.683
163	S	N**	.868	Y	-.868	-2.561
222	S	N**	.917	Y	-.917	-3.317

a. S = Selected, U = Unselected cases, and ** = Misclassified cases.

b. Cases with studentized residuals greater than 2.000 are listed.

The Hosmer and Lemeshow test was conducted to assess model fit. The test is non-significant ($p = 0.106$) indicating that the model is not a poor fit (Table XV). The model summary indicates that the explained variance in the dependent variable based on the model is 24% using the Naglekerke R^2 Naglekerke R^2 is a modification of Cox & Snell R, the latter of which cannot achieve a value of 1 so for this reason Naglekerke R^2 is reported (Table XVII) (Laerd Statistic, 2015). The logistic regression model was statistically significant, $\chi 2(9) = 35.865$, p=.0001, (Table XVI).

Table XV

Hosmer and Lemeshow Test for the Main Analysis

Hosmer and Lemeshow Test

Step	*Chi-square*	*df*	*Sig.*
1	13.185	8	.106

Table XVI

Ominbus Test of Model Coefficients for the Main Analysis

Omnibus Tests of Model Coefficients

		Chi-square	*df*	*Sig.*
Step 1	Step	35.865	9	.000
	Block	35.865	9	.000
	Model	35.865	9	.000

Table XVII

Model Summary for the Main Analysis

Model Summary

Step	*-2 Log likelihood*	*Cox & Snell R Square*	*Nagelkerke R Square*
1	192.753[a]	.165	.241

a. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

The logistic regression model was statistically significant, $\chi 2(4) = 35.865$, p = .0001. The model explained 24.0% (Nagelkerke R2) of the variance in behavioral intent to adopt and correctly classified

Sensitivity and Specificity

The percent accuracy of the model now correctly classifies 78.4% of the cases overall.

31 % of participants who did not have the behavioral intent to adopt were correctly predicted in the model and 95% of participants who did have the behavioral intent to adopt were correctly predicted in the model. The sensitivity was 95% and the specificity was 31% The positive predictive value is the percentage of correctly predicted cases with the observed characteristic compared to the total number of cases predicted as having the characteristic. In this case, this is 100 x (140 ÷ (36 + 140)) which is 80%. That is, of all cases predicted as having behavioral intent to adopt, 80% were correctly predicted. The negative predictive value is the percentage of correctly predicted cases without the observed characteristic compared to the total number of cases predicted as not having the characteristic. In our case, this is 100 x (16 ÷ (16+ 7) which is 70%. That is, of all cases predicted as not having the behavioral intent to adopt, 70% were correctly predicted (Table XVIII).

Table XVIII

Classification Table for the Behavioral Intent to Use the Closed-loop Artificial Pancreas: Main Analysis

Classification Table[a]

			Predicted		
			BI_GEN_BINARY		Percentage
	Observed		No	Yes	Correct
Step 1	BI_GEN_BINARY	No	16	36	30.8
		Yes	7	140	95.2
	Overall Percentage				78.4

a. The cut value is .500

In summary, a binomial logistic regression was performed to ascertain the effects relative advantage, perceived behavioral control, facilitating conditions, self-concept, habit, perceived risk, value, perceived threat to autonomy and resistance to change on the likelihood that participants would adopt the closed-loop artificial pancreas. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell (1962) procedure. A Bonferroni correction was applied using all 19 terms in the model resulting in statistical significance being accepted when $p < .00026$ (Tabachnick & Fidell, 2007). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable. There were 7 studentized residual with a value greater than 2.5 standard deviations, which was kept in the main analysis based on the cook's distance on these cases was not greater than 1. (Cook & Weisberg,

1982) The logistic regression model was statistically significant, $\chi 2(9) = 35.865$, p = .0001. The model explained 24.0% (Nagelkerke R2) of the variance in behavioral intent to adopt and correctly classified 78.0% of cases. Sensitivity was 95%, specificity was 31%, positive predictive value was 80% and negative predictive value was 70%. Of the 9 predictor variables only 1 was statistically significant Relative Advantage (Table XIX). Relative Advantage (p=.008) added significance to the model but Perceived Behavioral Control (P=.235),Facilitating Conditions (p=.388), Self Concept (p=.477), Habit (p=.172), Perceived Risk (p=.948), Value(p=.677) Perceived Threat to Autonomy (p=.321) Resistance to change (p=.497) The odds of behavioral intent to adoption is 4.77 times greater when there is a positive relative advantage,

Table XIX

Variables in the Equation

Variables in the Equation for Healthcare Provider Intent to Use Main Analysis

							95% C.I.for EXP(B)	
		B	*S.E.*	*Wald*	*df*	*Sig.*	*Exp(B)*	*Lower*	*Upper*
Step 1[a]	RA	1.562	.585	7.133	1	.008	4.771	1.516	15.015
	PBC	.518	.436	1.410	1	.235	1.679	.714	3.950
	FC	-.291	.338	.744	1	.388	.747	.386	1.448
	SC	.256	.360	.506	1	.477	1.292	.638	2.614
	HABIT	.224	.164	1.865	1	.172	1.251	.907	1.727
	PR	-.027	.418	.004	1	.948	.973	.429	2.207
	V	.222	.534	.173	1	.677	1.249	.439	3.556
	PTTA	-.344	.346	.984	1	.321	.709	.360	1.398
	RTC	.238	.351	.461	1	.497	1.269	.638	2.527
	Constant	-8.676	2.807	9.551	1	.002	.000		

a. Variable(s) entered on step 1: RA, PBC, FC, SC, HABIT, PR, V, PTTA, RTC.

The next set of results are based on research question 13. What is the difference between Physicians' and non-Physicians' behavioral intent to adopt the artificial closed-loop systems based on value? A separate binomial logistic regression was performed assessing the interaction between healthcare provider group and value of each closed-loop artificial pancreas system on behavioral intent to adopt. Value was the only construct that asked about each of the 3-specific closed-loop types. The logistic regression was statistically significant $\chi 2(6) = 31.899$ $p=.001$ (Table XXII). Hosmer and Lemeshow test is not statistically significant ($p = .767$) indicating that the model is not a poor fit (Table XXIII). The explained variation in the dependent variable based on the model is 22% (Table XXIV).

Assumption of No Multicollinearity for the Behavioral Intent to Adopt

For this model the VIF values are all below 10 and the tolerance statistic are all well above 0.2 (Myers, 1990; Bowerman & O'Connell, 1990) (Table XX). Therefore, there is no multicollinearity with in the data.

Table XX

Assumption of No Multicollinearity for Healthcare Provider Intent to Use based on Value of each System Type.

Coefficients[a]

Model		Collinearity Statistics	
		Tolerance	*VIF*
1	VALUE24	.617	1.622
	VDUAL	.938	1.066
	VHYBRID	.635	1.576

a. Dependent Variable: BI_GEN_BINARY

Linearity Assumption

Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box and Tidwell (1962) procedure. Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable (Table XXI).

Table XXI

Assumption Linearity of Continuous Variables for Healthcare Provider Intent to Use the based on the Value of each System Type.

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	VDUAL	6.305	3.761	2.811	1	.094	547.186	.344	869233.192
	VHYBRID	-4.055	3.339	1.474	1	.225	.017	.000	12.064
	Ln_Vdual by VDUAL	-2.828	1.648	2.945	1	.086	.059	.002	1.495
	Ln_Vhybrid by VHYBRID	2.165	1.524	2.019	1	.155	8.715	.440	172.686
	LN_V24hr by VALUE24	1.018	2.555	.159	1	.690	2.768	.019	414.261
	VALUE24	-1.288	5.947	.047	1	.829	.276	.000	31851.579
	Constant	-4.819	10.959	.193	1	.660	.008		

a. Variable(s) entered on step 1: VDUAL, VHYBRID, Ln_Vdual * VDUAL , Ln_Vhybrid * VHYBRID , LN_V24hr * VALUE24 , VALUE24.

Table XXII

Omnibus Test of Model Coefficients for Healthcare Providers the Intent to Use based on Value of each System Type.

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	31.899	6	.000
	Block	31.899	6	.000
	Model	31.899	6	.000

Table XXIII

Hosmer and Lemeshow Test the Healthcare Provider Behavioral Intent to Use based on the Value of each System Type.

Hosmer and Lemeshow Test

Step	*Chi-square*	*df*	*Sig.*
1	4.916	8	.767

Table XXIV

Model Summary the Healthcare Provider Behavioral Intent to Use based on the Value of each System Type.

Model Summary

Step	*-2 Log likelihood*	*Cox & Snell R Square*	*Nagelkerke R Square*
1	197.324[a]	.147	.216

a. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

Sensitivity and Specificity

The model correctly classified 77.0% of cases. Sensitivity was 95%, specificity was 23%. Twenty-three percent (23%) of participants who did not have the behavioral intent to adopt were correctly predicted in the model and 95% of participants who did have the behavioral intent to adopt were correctly predicted in the model. The positive predictive value is the percentage of correctly predicted cases with the observed characteristic compared to the total number of cases predicted as

having the characteristic. In this case, this is 100 x (141 ÷ (40 + 141)) which is 78%. That is, of all cases predicted as having behavioral intent to adopt, 78 were correctly predicted.

The negative predictive value is the percentage of correctly predicted cases without the observed characteristic compared to the total number of cases predicted as not having the characteristic. In our case, this is 100 x (7 ÷ (12+ 7) which is 37%. That is, of all cases predicted as not to have the behavioral adopt 37% were correctly predicted (Table XXV).

Table XXV

Classification table for the Healthcare Provider Behavioral Intent to Use based on the Value of each System Type.

Classification Table[a]

			Predicted		
			BI_GEN_BINARY		Percentage
	Observed		No	Yes	Correct
Step 1	BI_GEN_BINARY	No	12	40	23.1
		Yes	7	141	95.3
	Overall Percentage				76.5

a. The cut value is .500

The interactions between healthcare provider group and each system based on value did not significant add to the model. For the interaction of physician and non-physicians, 24-hour insulin only closed-loop artificial pancreas and value was non-significant (b=-.091, *Wald* $\chi 2(1)$ =.014, p=0.905. For the interaction of physician and

non-physician, dual hormone artificial pancreas and value was non-significant (*b*=.055, *Wald* $\chi 2(1)$ =.013, *p*=0.910. Lastly, for the interaction between physician and non-physician, hybrid closed-loop artificial pancreas and value was non-significant (*b*=.066, *Wald* $\chi 2(1)$ =.010, *p*=0.922. Therefore, there was no difference in the intent to adopt the different systems based on group (physician or non-physician). However, value for the 24- hour closed-loop artificial pancreas (p=0.011) and value for the hybrid closed-loop artificial pancreas (P=0.49) did add value to the model. The value for the dual hormone closed-loop artificial pancreas did not significantly add to the model (p=0.822) (Table XXVI). The odds of adoption are 3.0 times greater when there is a positive increase in value for the 24hour closed-loop artificial pancreas and the odds of adoption is 2.1 times greater when there is a positive increase in value for the hybrid.

Table XXVI

Variables in the Equation for Behavioral Intent to Adopt each System by Value.

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	VALUE24	1.105	.436	6.440	1	.011	3.020	1.286	7.091
	VHYBRID	.753	.382	3.884	1	.049	2.122	1.004	4.486
	VDUAL	-.074	.330	.051	1	.822	.929	.487	1.772
	GROUP(1) by VALUE24	-.091	.758	.014	1	.905	.913	.207	4.033
	GROUP(1) by VDUAL	.055	.488	.013	1	.910	1.057	.406	2.749
	GROUP(1) by VHYBRID	.066	.675	.010	1	.922	1.068	.285	4.010
	Constant	-6.239	1.695	13.549	1	.000	.002		

a. Variable(s) entered on step 1: VALUE24, VHYBRID, VDUAL, GROUP * VALUE24 , GROUP * VDUAL , GROUP * VHYBRID .

Post- Hoc G* Power Analysis

The post-hoc G* Power Analysis resulted in a power of .81using a medium effect size of r^2 0.25 (Faul et al., 2009) (Figure 40). The statistical power is high and ensures the probability of making a type 11 error is low.

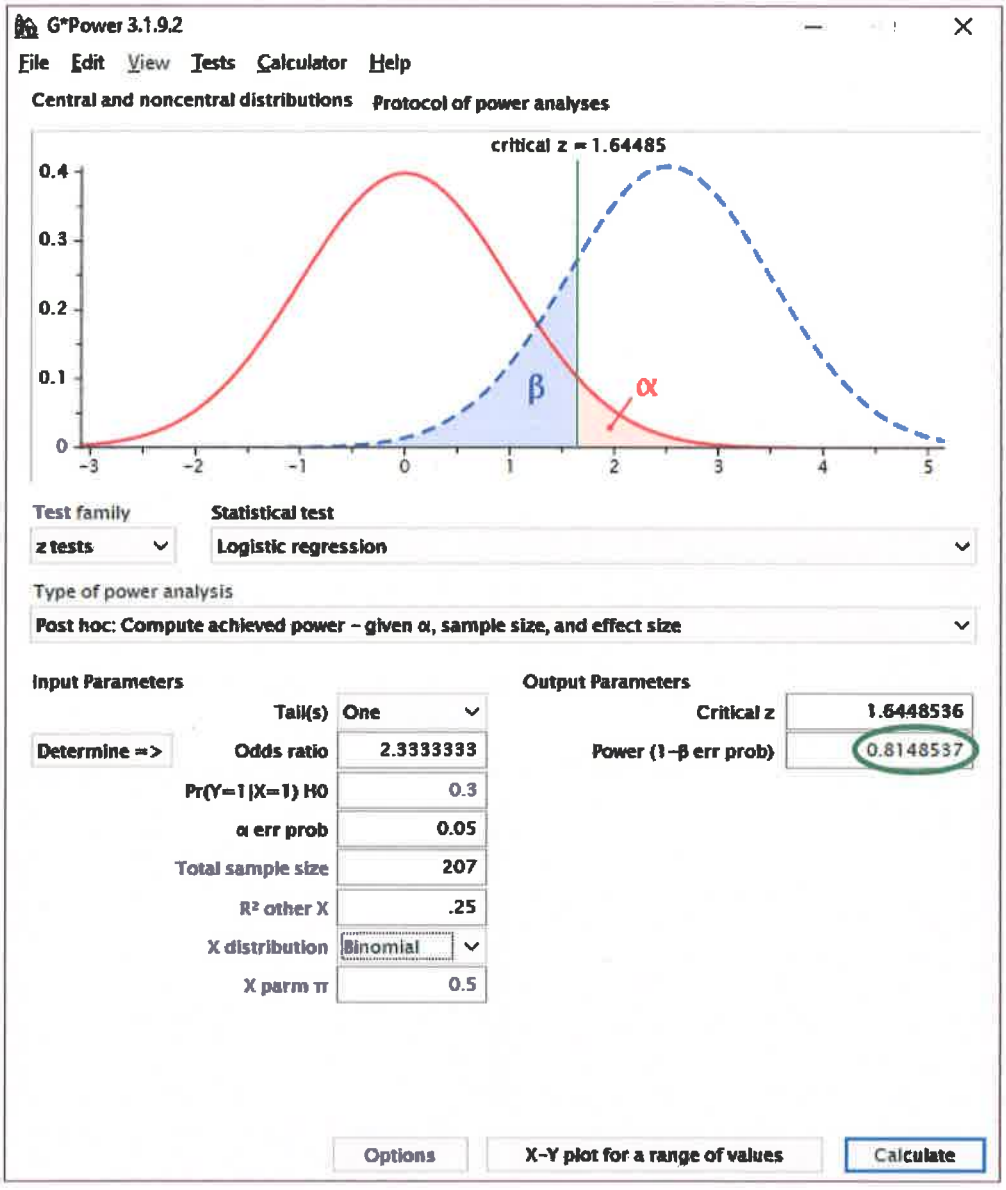


Figure 40. Post hoc G* Power Analysis. With an effect size of .25, an alpha level of 0.05, total sample size of 199, the power =81.

Summary of Quantitative Finding

To summarize, the HCP-CLAPA established a good reliability (α=.80) according to George and Mallery (2011). There were significant associations with the 9 independent variables and healthcare providers intent to use a closed-loop artificial pancreas with the exception of perceived threat to autonomy. For a summary of hypotheses test results see Table XXVII. A binomial logistic regression was performed to ascertain the effect of 9 predictor variables and behavioral intent to adopt the closed-loop artificial pancreas. A summary of hypotheses test results can be found in Table XXVIII. The model explained 24% (Nagelkerke R^2) of the variance in behavioral intent to adopt. A second binomial logistic regression was performed to ascertain the effects of value of the different systems by HCP on behavioral intent to adopt the closed loop artificial pancreas. A summary of hypotheses test results can be found in Table XXIX. The model explained 22.0% (Nagelkerke R^2) of the variance in behavioral intent to adopt. The interactions between healthcare provider group and value of each system type did not significantly add to the model. The value of the 24-hr. Closed-loop Artificial Pancreas was significant (p=0.011). The value for the Hybrid Closed-loop artificial pancreas (P=0.49) added significance to the model. However, Value for the Dual Hormone Closed-loop artificial pancreas was not significant (p=0.822).

Review of Hypothesis

Table XXVII

Summary of findings for the association of each independent variable and the healthcare providers intent to adopt the closed loop artificial pancreas.

Hypotheses Number	**Association**	**Construct**	**Alternative Hypotheses**	**Results**
$H3_a$	Positive	***relative advantage***	Accepted	(*rho*(207)=.442, *p*<.001) Moderate positive and significant relationship
$H4_b$	Positive	***perceived behavioral control***	Accepted	*rho*(207)=.392 *p*<.001) Moderate positive and significant relationship
$H4_c$.	Positive	***facilitating conditions***	Accepted	*rho*(207)=.169, *p*=.007) Weak positive correlation that was not statistically significant.
$H4_d$.	Positive	***self-concept***	Accepted	*rho*(199)=.305, *p*<.001) Moderate positive correlation that was not statistically significant.
$H4_f$.	Negative	***perceived risk***	Accepted	*rho*(207)= -.127, *p*=.034) Weak negative correlation that was not statistically significant
$H4_g$.	Positive	***perceived value***	Accepted	*rho*(207)=.447 *p*<.001) Moderate positive and significant relationship
$H4_h$.	Negative	***perceived threat to autonomy***	Rejected	*rho*(207)= -090., *p*=.100) Weak negative correlation that was not statistically significant
$H4_i$.	Negative	***resistance to change***	Accepted	*rho*(207)= -.138, *p*=.023) Weak negative correlation that was not statistically significant

We accept the alternative hypothesis for relative advantage, perceived behavioral control, facilitating conditions, self-concept, habit, perceived risk and perceived value. There is a significant and positive association between relative advantage, perceived behavioral control, self -concept, habit, perceived value and behavioral intent to use. There is a significant negative association for perceived risk and resistance to change with behavioral intent to adopt. There is a non-significant negative association with perceived threat to autonomy and behavioral intent to use. Therefore, we accept the null hypothesis for perceived threat to autonomy.

Table XXVIII

Summary of finding for the relationship between each independent variable and healthcare providers intent to use the closed-loop artificial pancreas.

Hypotheses Number	**Relationship**	**Construct**	**Alternative Hypotheses**	**Results**
H4.	Positive	***relative advantage***	Accept	(*b*=1.56, *Wald* $\chi 2(1)=7.13$,*p*=0.008 The odds of adopting the closed-loop artificial pancreas increases when there is a positive relative advantage.
H5.	Positive	***perceived behavioral control***	Reject	(*b*=.518, *Wald* $\chi 2(1)=1.41$,*p*=0.235
H6.	Positive	***facilitating conditions***	Reject	(*b*=-.291, *Wald* $\chi 2(1)=.744$, *p*=0.388
H7.	Positive	***self-concept***	Reject	(*b*=.256, *Wald* $\chi 2(1)=.506$, *p*=0.506
H8.	Positive	***habit***	Reject	(*b*=0224, *Wald* $\chi 2(1)=1.865$, *p*=0.172
H9.	Negative	***perceived risk***	Reject	(*b*=-.027, *Wald* $\chi 2(1)=.004$, *p*=0.948
H10.	Positive	***perceived value***	Reject	(*b*=.222, *Wald* $\chi 2(1)=0173$, *p*=0.677
H11.	Negative	***perceived threat to autonomy***	Reject	(*b*=-.344, *Wald* $\chi 2(1)=.984$, *p*=0.321
H12.	Negative	***resistance to change***	Reject	(*b*=.238, *Wald* $\chi 2(1)=.461$, *p*=0.002

We accept the alternative hypotheses for relative advantage and behavioral intent to adopt the closed loop artificial pancreas. The odds of adopting the closed-

loop artificial pancreas increases when there is a positive relative advantage. We accept the null hypothesis for all other independent variables.

Table XXIX

Summary of finding for the relationship between value and healthcare provider group and intent to use the closed-loop artificial pancreas by system.

Hypotheses Number	**Group**	**System**	**Alternative Hypotheses**	**Results**
H13	Physician (1)/ Non-Physician (0)	24 hr. Insulin Only	Reject	(*b*=-.091, *Wald* $\chi 2(1)$=.014, *p*=0.905
	Physician (1)/ Non-Physician(0)	Dual	Reject	(*b*=.055, *Wald* $\chi 2(1)$=.013,*p*=0.910
	Physician (1)/ Non- Physician (0)	Hybrid	Reject	(*b*=.066, *Wald* $\chi 2(1)$=.010, *p*=0.922

We accept the null hypothesis that there is no difference in HCP group and the adoption of the closed-loop artificial pancreas by systems based on Value. Qualitative themes that emerged from the open-ended questions helped to inform some of the quantitative responses.

Qualitative Themes

The following section illustrates examples of open ended responses provided by respondents based on 5 open-ended questions. These questions help add to the understanding of intent to adopt the closed-loop artificial pancreas systems by given

context to potential barriers or factors that might lead to behavioral intent to adopt. The five open ended questions were as follows:

> #1 Do you believe deskilling of the patient will occur if this technology is employed in this population? Why? Why Not? Your thoughts in this regard are appreciated.
>
> #2 Would the closed-loop artificial pancreas technology have potential use in type 2 patients? Please Explain Your Rationale:
>
> # 3 Has your current practice/organization started to develop procedures or policies on how to implement this technology into your clinical setting? Please Choose: Yes or No
> If you selected YES to the previous question, please explain what types of procedures or policies are in development.
>
> #4 Thinking about the 3 types of closed loop artificial pancreas systems (e.g., hybrid, fully automated 24-hour insulin only and the dual hormone), do you think any of system types pose more of a safety risk to the patients over the other? Please Explain Your Rationale:
>
> #5 Please comment briefly on your overall opinion(s) of closed-loop artificial pancreas
> technology:

Several Themes emerged based on the responses to these questions that are relevant to the predictors that were under investigation in this study. For question #1 regarding deskilling of patients regarding self-management skills. There were 175 participants that answered this question. The inter-rater reliability is.933 (Table XXX). The majority of healthcare providers agreed that deskilling would not occur and that more skills would be needed to use this technology and at the very minimum some basic skills would be needed. This means that healthcare providers largely do not think patients will lose self-management skills because of the automation

provided by the closed-loop artificial pancreas. A sample of responses is listed in Figure 41.

Table XXX

Cohen's Kappa for Deskilling

Symmetric Measures

		Value	*Asymp. Std. Error* [a]	*Approx. T* [b]	*Approx. Sig.*
Measure of Agreement	Kappa	.933	.022	22.980	.000
N of Valid Cases		175			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Sample Responses to the Potential Deskilling of the Patient Open ended question 1
"Probably- they may forget back up plan or basal rates if not in auto mode"
"No deskilling, certainly RESkilling"
"Yes, because it will correct for errors (in carb counting, sick day management etc) but not to the extent that their glycemic control is compromised. I would compare this to: my use of calculator technology has lessened my ability to do simple math in my head. I am not worse off because of it, but I am deskilled"
"I believe that proper candidate selection will still be a requirement for patient success. Patients will still need to understand insulin action and develop skill troubleshooting possible problems. Education of the patient will be key to patient care and success. Skill in critical thinking will be necessary and a more skilled client will be more successful"

Figure 41. Sample of open-ended healthcare provider responses to the potential deskilling of the patient due to the closed-loop artificial pancreas.

The themes that emerged for question number 2 answer a very important question regarding the use of closed-loop artificial pancreas technology for the treatment of type 2 patients. One hundred and ninety-six respondents answered this question. The inter-rater reliability was.959 (Table XXXI). The majority of respondents stated that type 2 patients who have advanced disease progression meaning that they need total insulin replacement would benefit from closed-loop artificial pancreas technology. A sample of responses is listed in Figure 42.

Table XXXI

Cohen's Kappa for Use in Type 2

Symmetric Measures

	Value	*Asymp. Std. Error*[a]	*Approx. T*[b]	*Approx. Sig.*
Measure of Agreement Kappa	.959	.023	19.700	.000
N of Valid Cases	196			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Sample Responses to the Potential Use in the Type 2 patient with diabetes Open ended question 2
"Yes, because advanced type 2 have the same if not more of a risk of for complications"
"Any therapy that assists the population of individuals living with type two diabetes an opportunity to reduce severe hypoglycemia improve quality of life and reduce both long and short-term complications is appropriate"
"There are T2 patients requiring insulin who would benefit from same technology"
"Yes, in patients who require intensive insulin therapy".

Figure 42. Sample of open-ended healthcare provider responses to the potential use of the closed-loop artificial pancreas in patients with type 2 diabetes.

Several themes that emerged from open-ended question #3 regarding policies and procedures in place for the closed-loop artificial pancreas systems. Thirty-six participants provided a response to this question. The inter-rater reliability is .855 Table (XXXII). The majority of healthcare providers reported that that they don't have a policy or procedures in place or that they are in the process of updating the policies and procedures for the new technology. This can be a result of education lagging technology advancements as reported by Caruana (2012). The hybrid closed-loop artificial pancreas has been launched and patients do have access it is only a matter of time before full automation is available. Office and institutional policies and procedures are necessary to guide education and practice standards. Only one healthcare provider stated that they have a full protocol. A sample of repsonses is listed in Figure 43.

Table XXXII

Cohen's Kappa Policies and Procedures

Symmetric Measures

		Value	Asymp. Std. Error [a]	Approx. T [b]	Approx. Sig.
Measure of Agreement	Kappa	.855	.078	7.154	.000
N of Valid Cases		36			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Sample Responses to healthcare provider progress on policies and procedures Open ended question 3
"We are working on the training of the new 670g and the pathway to get there"
"Training courses, discussions of setting patients expectations, and selection of patients for HCL system"
"full protocol"
"our patients have been placed on 670G in an incremental fashion with a few patients at a time"

Figure 43. Sample of open-ended healthcare provider responses progress on policies and procedures

The fourth open-ended question focused on safety risk of the three types of closed-loop artificial pancreas technology. This question was asked to help inform and add context to the behavioral intent to adopt each type. From the quantitative analysis, the binomial logistic regression showed that value explained a significant amount of variation in the behavioral intent to adopt the 24-hour insulin only and

hybrid closed-loop artificial pancreas however, value of the dual hormone artificial pancreas did not significantly explain the variance in the intent to adopt. This open-ended question gives content this result. One hundred and twenty-two respondents provided an answer. The inter-rater reliability was .976, p<.001 (Table XXXIII). The majority respondent stated that they need more information in order to assess risk. However, the second theme that emerged was that the dual hormone artificial pancreas technology poses more risk than the 24-hour insulin only and hybrid closed-loop artificial pancreas technology because of the instability of glucagon. Some of the statements can be seen in Figure 44.

Table XXXIII
Cohen's Kappa for Risk based on System type.

Symmetric Measures

		Value	*Asymp. Std. Error* [a]	*Approx. T* [b]	*Approx. Sig.*
Measure of Agreement	Kappa	.976	.017	18.299	.000
N of Valid Cases		122			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Sample Open-ended Healthcare Provider Responses to the Potential Safety Risk of one system over the other Open ended question 4
"Dual hormone because of stability of glucagon"
"Dual hormone because of glucagon"
"Systems that use algorithms that do not have redundancy built into them, or that do not use a dual chamber, will have significantly more risk for harm them those systems that incorporate both of these factors."
"In general, if sensor is inaccurate and system makes changes to basal delivery or suspends pump when not appropriate that could be a problem."

Figure 44. Sample of open-ended healthcare provider responses on potential safety risk of one system over another.

Lastly, open ended question 5 asked participants to provide an overall comment regarding the closed-loop artificial pancreas. One hundred and twenty-two respondents answered. The inter-rater reliability was .937, p<.001 (Table XXXIV). Overall the prevailing theme was that healthcare providers believe that the technology will be positive, and it will improve diabetes care. A sample of respondents' answers can be seen in Figure 45.

Table XXXIV
Cohen's Kappa for overall opinion of the technology.

Symmetric Measures

		Value	*Asymp. Std. Error*[a]	*Approx. T*[b]	*Approx. Sig.*
Measure of Agreement	Kappa	.937	.043	14.551	.000
N of Valid Cases		125			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Sample Open-ended Healthcare Provider Overall Comments regarding the technology Open ended question 5
"Looking forward to impact it will have on patient outcomes IF the safety and accuracy is present"
"GREAT - can hardly wait until it is standards of care"
"Positive way to decrease diabetes distress"
"Excited to learn and be trained on this new technology"
"viable option"

Figure 45. Sample of open-ended healthcare provider comments regarding the technology.

The open-ended questions provided additional context to why a healthcare provider would or would not adopt the closed-loop artificial pancreas technology. More healthcare providers believed that patient would need to acquire additional skill to use the closed -loop artificial pancreas and that deskilling would not be an issue. In addition, healthcare providers thought that this technology would be useful in the management of late stage type 2 diabetes. This is significant finding considering the number of type two patients in comparison to type 1 that this could potentially impact. The hybrid closed -loop artificial pancreas is approved for type 1 use only and other systems will probably follow suit. However, if long-term complications are reduced and cost effectiveness can be proven this indication might be made available to type 2 patients depending on the technology limitation. Healthcare professional also stated that protocols either have started or need to be updated to include the newer technology. This is an issue because education, policies, and procedures need

to be in place for offices and institutions in order to provide adequate education to healthcare providers. This often lags the technology development and in this case, it is no different. In addition, we learned that healthcare providers feel that the dual hormone artificial pancreas has the potential to put the patient more at risk than the other systems mostly due to the additional hormone glucagon. Glucagon is unstable in solution for more than 24hours. Stable forms of glucagon are currently being investigated.

Chapter V.

DISCUSSION

General Discussion of Study Finding's

The literature informs us that the US is facing an epidemic of diabetes. The economic burden for the health care system is skyrocketing from the cost associated with treatment and diabetes complications Technology for diabetes management is rapidly developing and changing (Markowitz et al., 2013). The completely automated artificial pancreas is considered the ideal treatment for type 1 diabetes (Ricotti et al., 2012). In addition, feasibility has been assessed in the type 2 diabetes population with favorable results, thereby broadening the potential scope of use of the close loop artificial pancreas (Kumareswaran et al., 2014). The healthcare provider–patient relationship is particularly challenging when it involves new treatment technology because the physician must have knowledge of the technology to be able to inform the patient however in many cases, the advancements in technology develop faster than the education required to competently use the devices which leads to a lack of competence and confidence by the practitioner (Caruana, 2012). This same issue can be seen by the results of the perceived knowledge score. Healthcare providers had an average of 68% correct on the knowledge statements showing the need for more education in regards to the technology. In addition, the decision of healthcare provider to adopt a new technology can interfere with patient access. Normally the end user decides whether to accept or reject the technology or device but in the

healthcare environment the healthcare providers play a large part of the decision-making process of whether to use a new medical device such as the closed-loop system (Schoenbeck, 2014).

The primary purpose of this study was to create, validate and test the reliability of the survey instrument. This instrument entitled "Healthcare Provider Closed-loop Artificial Pancreas Assessment (HCP-CLAPA)" addressed 10 key constructs discussed in the literature around behavioral intent to adopt technology.

The tool was successfully validated through a panel of experts in the field. The tool was then used in a sample population of interest to test for reliability. The Cronbach's alpha for the tool using all 10 constructs was an $\alpha = .803$ which is considered good by George and Mallery (2011). The individual reliability assessment for each factor were acceptable.

The secondary purpose of this study was to use this validated and reliable survey tool in the population of interest in order to identify and understand barriers to and factor leading to the behavioral intent to adopt the closed-loop artificial pancreas among healthcare providers. Relative advantage significantly contributed to the healthcare providers intent to adopt the closed-loop artificial pancreas systems. There were no differences in the intent to adopt the specific system types among healthcare providers based on value but, value did significantly lead to intent to adopt the hybrid and 24-hour insulin only closed-loop artificial pancreas system. The value of the dual hormone closed-loop artificial pancreas system did not lead to behavioral intent to

adopt. Further investigation through an open-ended question revealed that healthcare providers believe the dual hormone system may cause more risk to the patients.

The Gender Gap

There was a gap between males and females in the study. There were more females then male respondents (160 females were 77% of the total respondents and 37 males were 18% of the respondents. There were more female non-physicians 137 (70%) of the total respondent's verses 31 (16%) male-physicians. This is not unexpected as more females are non-physicians such as nurses than men (Health Resource and Service Administration, 2014). In addition, more physicians are male than female (Young, Chaudhry, Rhyne, & Dugan. 2014).

Healthcare Provider Beliefs

There was no difference in the behavioral intent to adopt the artificial pancreas by system type according to the binomial regression however, there were group differences in the overall beliefs regarding self-concept, perceived threat to autonomy and resistance to change. Non-physicians had a higher mean rank regarding self-concept than physicians. Self-concept is defined as the degree of accordance between the perception of self and the characteristics the individual associate with the realization of the behavior (Triandis, 1977). In other words, it is an assessment of one's own status with respect to one or several traits, using societal or personal norms as criteria. Non-physicians having a higher rank than physicians in regards to self-concept has been seen in the literature because physicians have been less influenced

by social and societal norms. *Social Norms* or social influence have consistent non-significant effects on behavioral intention among physicians (Holden & Karsh, 2010).

Physicians had a higher mean rank with respect *to resistance to change* and *perceived threat to autonomy* than non-physicians which again is in line with the literature. Individual differences among perspective users determine how individuals think and behave. Personality traits determine how individuals think and behave in various situations (Nov & Ye, 2008). Personality traits are often used in psychosocial research to explain beliefs and behavior. The introduction of new technology involves change for the user. Social psychological research has identified individual's dispositional inclination to resist change as a personality trait (Oreg, 2003). Resistance to change could be viewed as a possible deterrent to use of a new technology. Physicians may be viewing this technology as disruptive to some extent which would cause more resistance to changing current practices. Physicians also differ from other types of users in terms of technology acceptance (Holden & Karsh, 2010).

Physicians are medical professionals with professional autonomy. Professional autonomy is freedom to practice his/her profession in accordance to his/her knowledge and expertise (Engel, 1970; Walter & Succi-Lopez, 2008). Loss of professional autonomy may reduce the quality of services provided (Engle, 1970). The artificial closed-loop pancreas may potentially affect the professional autonomy

of a healthcare provider thus affecting the quality of patient care. These differences in the professionals' responses warrant further investigation.

Perceptions of Knowledge

Perceptions of knowledge refers to what an individual perceived to know about the subject. Knowledge is defined as the range of one's information or understanding (ASA, 2014). In this study perception of knowledge was asked as a self- reported understanding of the technology as well as reported as an overall population score. Recall that those respondents that sated no knowledge were excluded from analysis. The overall score for the 10 question perceptions of knowledge score was 68%. The results of this study with regards to perceived knowledge indicates that the respondents had reasonable knowledge of the closed-loop artificial pancreas which was necessary to appropriately respond to this survey but still warrant additional education. This was further informed by the open-ended question regarding policies and procedures, where most respondents stated that their policies and procedures where lagging behind the technology. This is consistent with the literature. Respondents also offered up information about education around the closed-loop artificial pancreas technology and many healthcare providers stated that their education needs to improve. Advancements in technology develop faster than the education required to competently use the devices which leads to a lack of competence and confidence by the practitioner (Caruana, 2012). Education/Evidence drives policies and procedures and policies and procedures drive education and

evidence-based practice (Bowen & Zwi, 2005; Caruana, 2012; Ubbink, Guyatt, Vermeulen, 2013). The hybrid artificial pancreas was approved and made available in April of 2017. The fully automated devices maybe out as soon as 2018 clearly indicating a lag in preparedness.

Discussion of Variables

As part of the preparation of the HCP-CLAPA, a thorough assessment of each construct that makes up IDT, TIB, and TBP was conducted. This assessment lead to either the inclusion or exclusion based on overlapping definitions and/or difficultly assessing the construct based on the availability of the technology. The results of the binomial regression showed that relative advantage had a significant effect on the behavioral intent to use. Relative advantage is from IDT (Rogers, 2003). *Relative advantage* is defined as the degree in which an innovation is perceived as being better than the idea it supersedes (Rogers, 2003). Diffusion scholars have found relative advantage to be one of the strongest predictors of an innovations rate of adoption. It is the ratio of the expected benefit and the cost of adoption of innovation. IDT is a theory that seeks to explain how, why, and at what rate new ideas and technology spread.

The four main elements influence the spread of a new idea: the innovation itself, communication channels, time, and a social system. The fact that the technology was not available for use at the time of this study makes it difficult to assess the full innovation diffusion model. There are four other constructs in the IDT

model. *Compatibility* is defined as the degree to which an innovation is consistent with existing values, experiences, and the needs of the adopters. This construct was originally included in the study framework but was eliminated through the Delphi panel of experts. *Complexity* is the extent to which an innovation is perceived as difficult to understand and use. This construct is similar to perceived ease of use in TAM and could not be operationalized in this study because the technology was not available for use and it would be difficult to assess complexity. *Trialability* is defined as the extent to which the innovation can be tested before a commitment from the adopter. This construct could not be assessed in this study framework because the systems were not available for testing prior to use. Lastly, *Observability* is defined the extent to which the innovation provides tangible results and demonstrability refers to the possibility to demonstrate the results of the new system. This again could not be operationalized because the technology is not available to assess results. The IDT a d its construct can be seen in Figure 46. Relative Advantage was the only construct that could be assessed and retained in new model.

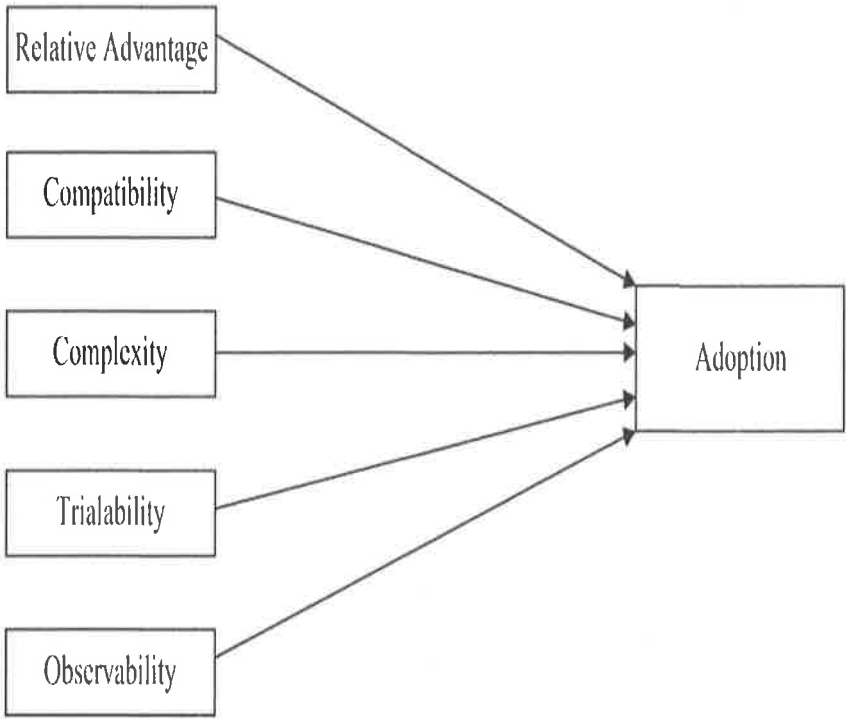


Figure 46. Adaptation of Innovation Diffusion Theory (Rogers, 2003).

There are several subdimensions of relative advantage that influence the rate of adoption. Economic factors include the initial cost of an innovation may affect its rate of adoption. Social Prestige cam influence adoption. People seek an innovation to boost their social status, but once other members adopt the same innovation it loses its prestige. Overadoption is the adoption of an innovation by an individual when experts feel that he/she should reject it. This happens when one aspect of the innovation is so attractive that is supersedes everything else. Since the closed loop-artificial pancreas is not currently available, cost is unknown and may vary by system. The closed-loop artificial pancreas system may decrease discomfort for the patient by reducing the number of injection and or also be time and effort saving so it

these subdimensions that were investigated in this study under the value construct. There were many sub dimensions that could not be assessed because the device was not available for use. As a medical device it is unlikely that social prestige would be a factor. This is a preventative innovation so the immediacy of one of the rewards potential reduced compilations may not occur or be seen for some time. Individuals adopt in-order to lower the probability of some unwanted future event. Closed-loop artificial pancreas may prevent diabetes related complications which is the future event. Delayed reward is a non-event or absence of something that otherwise might not happen, so it is associated with a slow rate of adoption. This causes questioning the reward, for example is the technology necessary to get the reward? It is a delayed reward verse immediate reward. Given these complex difficulties in perceiving the relative advantage of preventative innovations it is understandable that individuals don't adopt currently available diabetes related technology. However, preventative technology can be a motivating factor to adoption. As can be seen with preventative health campaigns which have been carried out successfully which resulted in lifestyle changes that prevent chronic illnesses drug abuse, smoking, and HIV/AIDS prevention (Rogers, 2003).

In terms of healthcare, value has been described as the total benefits received minus the cost (Ettinger, 1998; Lee & Larsen, 2009; Lapierre, 2000). In this study it was operationalized-as time, effort/energy and cost in the context of perceived patient outcomes indicating value. Value significantly contributed to the model based on system type. However, it was only significant for the 24hr closed-loop artificial

pancreas and the hybrid system. Qualitative themes suggest that the dual hormone system could potentially pose more risk to the patient. This potentially reveals that a more sophisticated system does not lead to the behavioral intent to use a technology if more features and attributes add complexity or risk. According to this study, the odds of adoption are 3.2 times greater when there is a positive increase in value for the 24hr closed- loop artificial pancreas and the odds of adoption were 2.1 times greater when there was a positive increase in value for the hybrid closed-loop artificial pancreas. Value did not influence the intent to adopt the dual hormone artificial pancreas. The total benefit in terms of perceived patient outcomes minus the cost of time, effort, and energy did improve the behavioral intent to adopt certain systems.

Theoretical Framework Revisited

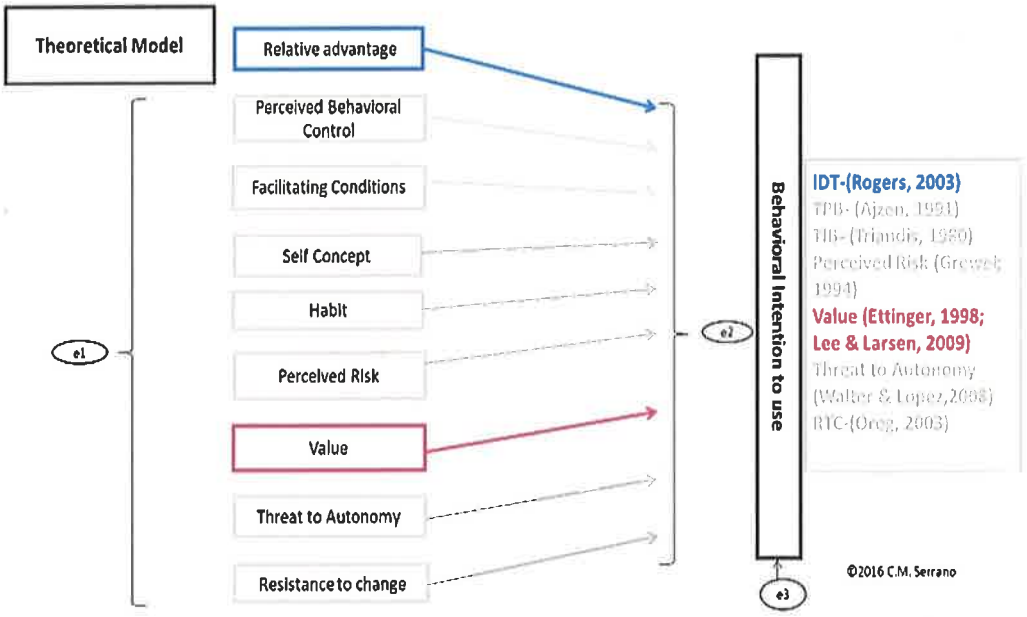


Figure 47. Theoretical model highlighting significant constructs.

The original framework had nine independent variables that potentially influenced behavioral intent to use the closed-loop artificial pancreas. The result of this study analysis revealed that relative advantage and value were the only constructs that improved behavioral intent to use this technology. Although both regression models resulted in statistically significant results, there was a significant amount of variance left unexplained. This leads to question other potential influencing factors.

Qualitative Themes

More HCP's believe that additional skills will be needed to use the closed-loop artificial pancreas and that deskilling would not occur. I find this surprising considering that deskilling is defined as the loss of skills due to automation of technology. If we consider GPS and how that has cause so many to rely on the technology and lose the capability to remember how to get to a location or even reduce map reading skills. In addition, it is well documented that healthcare providers are becoming more reliant on technology for obtaining patient information, making diagnoses and in carrying out treatments. Evidence has shown that technology can negatively affect doctor-patient communications, physical examination skills, and development of clinical knowledge (Lu, 2016). This should be a concern for patients with diabetes as well because diabetes management largely relies on self-management skills. It would be a natural progression to rely on the automated insulin delivery which may potentially lead to deskilling of some kind. This is worth further investigation as this technology becomes more mainstream.

More healthcare providers believed this technology would be useful in the type 2 diabetes population who have more advanced disease progression. This is interesting because the hybrid closed-loop artificial pancreas has not been approved for type 2 use and most studies are conducted in the type 1 population. Feasibility studies have been conducted in this area but this technology has been focused largely on the type 1 diabetes patient. Most likely do to the differences in the algorithms for insulin delivery in a type 2 patient with some endogenous insulin production verses a

type 1. Nevertheless, manufactures of should consider potential use in type 2 patients and the challenges that this would provide.

Most HCPs stated that protocols need to be updated and implemented to include the new technology. Very few HCPs answered this question which in itself speaks volumes of the potential lack of thought in this area. The hybrid closed-loop artificial pancreas is on the market already the other two types of systems should be available in the next two years and very little thought has gone into preparation for these systems. This echo's the literature in which education lags the technology advancement. Education, policies and procedures are lagging behind the technology. This is consistent with the literature. Education and evidence drives policies and procedures and policies and procedures drive education and evidence-based practice (Bowen & Zwi, 2005; Caruana, 2012; Ubbink et al., 2017). Therefore, a call to action on education around these devices as well as policy development is needed now. It's also important to note that healthcare providers made judgements about this technology with minimal knowledge showing a very early behavioral intention which would need to be investigated further once there is more exposure to this technology.

Lastly, when asked about risk, healthcare providers agreed that they need more information to assess potential risk of one system over the other, but the second emerging theme was the notion that the dual hormone technology may potential cause more risk to the patient than the other system types due to the glucagon instability. This theme informed the PI the potential reason the quantitative analysis did not show

that value influenced the behavioral intent to adopt the closed-loop artificial pancreas and warrants further investigation once the system is available.

Barriers exist regarding what determines healthcare providers' intent to use/adopt a closed-loop artificial pancreas system for diabetes patient management. The purpose of this study was to understand the factors that affect the intent to adopt this technology which may help shape healthcare provider educational processes and procedures. It's is important to understand what leads to healthcare provider technology adoption when the technology is used by the patient for disease management and the healthcare provider plays a significant role in the decision-making process. This study found that among healthcare providers if the technology can be considered better than the technology that it supersedes it will have a higher chance of adoption. Healthcare providers are behind in developing education strategies and policies and procedures.

Practical Implications

Education/ policies and procedures are lagging-behind technology advancement. This is consistent with the literature. This technology is here now therefore, at a minimum healthcare providers need to invest in advancing their knowledge regarding this technology and institutions/ practices needs to update policies and procedures to incorporate the closed loop artificial pancreas technology.

Study Limitations

Measuring perceived characteristics of an innovation cross-sectional may provide only a partial picture of the relationship especially if the innovation is not available for current use. A longer longitudinal study, where a cohort of healthcare providers followed to see if their behavioral intent to adopt changed, may prove more beneficial.

Self-reported finding

Respondents may have answered according to their own perceptions of what the primary investigator may have wanted as answers.

Sampling

Participants were recruited from either snowball sampling though social media and through Novo Nordisk inc. or one of the association or professional groups (MNYADE, AADE, and Close Concerns the Diabetes Q&A the Research co.). This was a sampling of convenience and could bias the results. Although the population was very specific because the respondents needed to know about the technology under investigation as well as have experience with patients with diabetes

Lack of incentive to individuals in the survey may have resulted in attrition or lack of survey participation. If a monetary or gifted incentive was offered in the Letter of Solicitation (Appendix F), there may have been a higher chance of participation.

Study Design

Unequal groups of physicians and non-physicians making it difficult to assess differences in acceptance. The statistical methods of use were also a limitation. The dependent variable was asked on a Likert scale to enable future analysis. However, this study used a binary dependent variable. The median response was used to determine acceptance and non-acceptance therefore, data was lost. Lastly, although necessary, this study may have been a bit premature because many constructs could not be assessed due to the technology which is still largely under investigation and not available for use. Survey fatigue could have been a major limiting factor with this study. The average time spent was 16 minutes therefore, participants may not have answer honestly or stopped the survey prematurely leading to attraction. Recall that there was 26 survey's that were incomplete.

Generalizability

The results of this study are only generalizable to those who took the survey. Results are not generalizable to the profession. More research is necessary to confirm if these results hold true across the medical professions presented in this study.

Voluntary Participation

Participants who volunteer to respond to a study may have different characteristics than those who do not respond (Burns & Grove, 2001). For example, participants who responded may have an interest in the closed-loop artificial pancreas technology or technology acceptance research which may be in contrast to those that did not respond.

Chapter VI

CONCLUSION

Overall Conclusion

The main analysis indicated that intent to adopt would increase if there was *a relative advantage* to current therapies. This is in-line with other research indicating that relative advantage is a significant predictor of the behavioral intent to adopt. Therefore, because these systems are viewed as better than the current technology it will drive adoption The *value* of the hybrid and 24-hour insulin only closed-loop artificial pancreas significantly influenced the intent to adopt this technology. This is echoed on the thematic analysis. Where the *value* of the dual hormone artificial pancreas did not impact intent to adopt. The thematic analysis indicted that dual hormone systems are perceived as potentially cause more risk to the patient that the other systems.

Future Research

This study was conducted because there was no available tool to address the technology acceptance of the closed-loop artificial pancreas among healthcare providers. Future research could include, investigate the differences in actual adoption among equal groups of physicians and non-physicians. Although the interaction of the groups on value of the different types of closed-loop artificial pancreas systems did not differ, there were differences seen in the responses to self-concept, perceived threat to autonomy, and resistance to change. It would be interesting to see if equal groups enhance these differences in anyway.

Future research could investigate the diffusion of the closed-loop artificial pancreas and the actual adoption of the technology by the patient once the technology is on the market and in use. Ultimately, it is the patient using this technology. It is important to look at factors that lead to and barriers to the adoption of the closed-loop artificial pancreas. Focusing on system type and patient demographics.

It is important to investigate the long-term benefits of the technology. This technology appears to help patients gain better glycemic control than what is available, indicating the possibility to reduce both short term and long-term complications of diabetes. Studies should focus on the short-term and long-term benefits of using this technology specifically focusing on health economic outcomes research. The results of which could inform both the healthcare community and insurance companies which would impact the viability of this technology.

Future research needs to focus on the curricula of healthcare providers as well as their access to continuing educations on new technologies for patient care. Education informs procedures and policies which, impacts technology adoption. Often the technology advancements lead the education required to adequately implement the technology. Quicker response time to technology advancement is paramount to the acceptance and diffusion of technology.

Research could focus on qualitative themes that were presented earlier. Specifically, around patient deskilling. It was interesting to note that most healthcare providers believed that deskilling would not occur with the automation of insulin. Undoubtedly, progress in medical technologies has improved the delivery of health

care and the quality of life (OECD, 2014). However, there are indications that deskilling does occur in day to day life when automation is used. Healthcare providers are becoming more reliant on technology for obtaining patient information, making diagnoses and in carrying out treatments. Evidence has shown that technology can negatively affect doctor-patient communications, physical examination skills, and development of clinical knowledge (Lu, 2016). However, as work is offloaded to machines, humans can focus in higher level cognitive skills such as the social and emotional aspects of medicine. This notion of deskilling vs upskilling for patients and healthcare providers may be important as patient treatment becomes more automated

Dissertation Significance and Conclusion

Diabetes is increasing annually worldwide. The economic burden for the healthcare system is skyrocketing from costs associated with treatment and diabetes complications. All patients with Type 1 patients and some patients with type 2 need insulin replacement. There is a high treatment burden among patients with diabetes. Technological advancement has made the closed-loop artificial pancreas possible. Healthcare providers play a large role in patient treatment decisions. For, the closed-loop artificial pancreas to get to the patient as a treatment option the technology must first be accepted by the healthcare provider. This was the first study that investigated commonly used technology acceptance constructs from the Theory of Planned Behavior, Theory of Interpersonal Behavior, and the Innovation Diffusion Theory as

well as value and barriers. The results reveled that relative advantage and value added to healthcare provider acceptance of the technology. Therefore, the closed loop artificial pancreas was perceived as a technology that is better than the technology that it supersedes. The construct of value added to the healthcare providers intent to adopt specific systems. Qualitative analysis revealed that systems with more features or attributes may not improve the intent to adopt the technology if the systems attributes adds complexity or risk for the patient.

The study provides an understanding of factors that influence behavioral intent to use. Intent to use would increase if there is a positive relative advantage above current therapies. Value of a system is based on system attributes. This study did not identify barriers to adoption. However, we know that this technology is not right for everyone considering the complexity of the device. This technology is not right for every patient due to the complexity. It requires the right practitioner, right technology type, and right patient. The technology is not generalizable to every patient and, therefore, needs more research is needed as discussed previously. Healthcare provider education needs to occur earlier and be maintained as these devices become available and to ensure appropriate use in patient care.

More research is imperative. Research focusing on patient technology adoption as well as health economics outcome research is necessary to better understand the adoption of this type of technology. Because closed-loop artificial pancreas technology is new, more evidence-based research is necessary. It's vital to understanding technology adoption among healthcare providers because healthcare

providers influence patient access to treatment and ultimately can influence patient outcomes.

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APPENDIX A

Delphi Expert Panelist Letter of Solicitation

SETON HALL UNIVERSITY
1 8 5 6

July 31, 2016

Dear Expert Panelist,

Thank you for agreeing to provide your expert opinion on the **Healthcare Provider Closed Loop Artificial Pancreas Adoption (HCP-CLAPA)** instrument. You have been asked to provide your feedback, based on your specific expertise, which has been identified as subject matter that is highly relevant to the tool. Your feedback will be used to refine and improve the questionnaire, so any insight you have will be greatly appreciated ***and used for this purpose***. Your input will be integrated along **with other Expert Panelists' Reponses through a Modified Delphi** process **to** achieve face and content validity for this instrument. Please note that it is not necessary for you to be familiar with the technology assessed in this survey in order to serve as an expert on this panel because some of the panelists will be serving different expert roles in the evolution of this survey.

The purpose of this instrument **once it is review and revised by the expert panelist and distributed to survey participants** is to examine *the determinants of healthcare provider's intent to adopt the closed loop artificial pancreas* to help address a gap in the current literature and a growing concern regarding the

utilization and sustainability of this technology. The survey instrument utilizes theories often used in technology adoption which are the Roger's (2003) innovation diffusion theory (IDT), Triandis (1980) Theory of Interpersonal Behavior (TIB) and Theory of Planned Behavior (TPB) along with other identified constructs of interest. The questions in the survey have been written to reflect themes in the literature in the context of technology adoption related to the healthcare provider.

Please review each question and the related construct or factor associated with the question. You will be asked to determine if the question measures the construct or factor described. Please insert "Y" for Yes or "N" for No into each slot provided per question for each variable under the construct. If you have comments or questions in any of the categories, you may then use the comments box to provide suggestions for refinement or improvement in that specific category. Your comments for this first round of the Delphi are requested within (14) days of receipt.

The survey tool will then be modified based on the responses that are received from the expert panel. Please feel free to provide commentary pertaining to any question for each variable. Also, please feel free to provide any additional questions that you believe will enhance the quality of this survey instrument. If additional questions should be added, please indicate the exact wording of the questions you suggest and into which construct the question should be placed. Also, if possible, please provide a brief explanation as to why this additional question (s) is/are needed so that the PI can better understand. Use as much space as needed to

indicate the reason why this/ these question (s)should be added. Also, for each round regarding recommendations to keep or eliminate a question based on the panelist responses, there is a small possibility that I (along with my research committee) may decide to keep or eliminate a particular question despite attaining 80% consensus from the panel. If this should happen, this will be noted in the subsequent round to the Delphi panel with a rationale.

A consensus of 80% by the expert panel is sought to complete each round of this Delphi process (Hasson, 2000). If consensus is not met in the first round you will be asked to participate in a second round, but only specific to those questions that did not reach consensus. For the second round you will be asked to provide your comments within (7) days of receipt. If consensus is not met following the second round, then a third and final round will be conducted to reconcile these disagreements. Further instructions will be provided to you at that time. Majority panel recommendations will be followed for each round. A majority is represented by agreement between 80% or more of the panel (Hasson, 2000).

Following the survey worksheet, please continue to the Demographic questionnaire. There is a table of contents listing all documents that are attached for your review. The survey worksheet has the questions listed by construct. The questions are numbered according to finalized questionnaire. If you need further clarification, please don't hesitate to contact via email listed below or (cell) [redacted]

Your anticipated support in this project is greatly appreciated! Thank you so much!

Kind Regards,

Carolyn Serrano

Doctoral student, Seton Hall School of Health and Medical Sciences
Carolyn.flynn@student.shu.edu

APPENDIX B

Delphi Round 1 Survey Worksheet

B-1 Instructions to Delphi Panelist

B-2 First page preview of Worksheet

B-3 Preview of Demographic Survey Worksheet

For the complete survey worksheet and/or any questions or further information regarding the HCP-CLAPA, please contact the PI at carolyn.serrano.07@gmail.com

Health Care Provider Closed-loop Artificial Pancreas Adoption (HCP-CLAPA) Instrument

Survey Worksheet for DELPHI PANEL

Note: This survey will be administered to prescribing health care professionals electronically

Closed-Loop Artificial Pancreas:

A closed-loop artificial pancreas involves the use of a mechanical system that consists of a continuous glucose monitor, continuous subcutaneous insulin pump, and a control algorithm for calculating rates of insulin delivery, and rapid acting insulin analogs (Kowalski, 2015). Ideally, these systems would perform without human interventions operating as a closed process (Kudva, 2014). The literature uses a wide variety of terminology such as artificial pancreas, bionic pancreas, closed-loop, automated insulin delivery, and treat to target system (Kowalski, 2015). Hybrid closed-loop, fully automated closed-loop, and dual hormone systems are under development at various stages of testing (Florenza, 2015).

Directions:

For the purposed of this research I am employing the definition of a closed-loop pancreas that includes a Nighttime only closed-loop which is likely to be one of the first generation hybrid closed-loop pumps, 24-hour fully automated insulin only closed-loop artificial pancreas and/or dual hormone systems including insulin +glucagon or insulin + glucagon suppressors(Glp-1/pramlintide). When answering the questions, you will be given specific instructions when to consider specific systems.

Understanding that the closed-loop artificial pancreas does not exist on the market for patient use and is not expected to be available on the market within the next two years, please answer the questions based on ***your best perception of how this technology will affect the following*** when it does become available.

Please Note: Some questions appear to be repetitive but they are capturing each of the 4 different technologies (hybrid closed-loop pumps, 24-hour fully automated insulin only closed-loop artificial pancreas, and both dual hormone systems) and therefore need to be measured independently.

Unless otherwise indicated *please DO NOT consider patient access and cost* when answering these questions.

Unless otherwise indicated *please DO consider all possible forms of the closed-loop* when answering these questions (hybrid- nighttime only, insulin only 24-hour and both dual hormone systems).

For construct definitions please see ITEM E- Construct Definition Chart.

Questions 1-10 (the knowledge and demographic questions) are listed at the end of the worksheet.

Item/ Variable	Does it measure the concept?	Is it clear?	Is it double barreled?	Is it biased through socially desirable response?	Comment
Construct No.**1 Relative Advantage**-The degree in which an innovation is perceived as being better than the idea it supersedes, in other words the new technology is better than the old (Rogers, 2003).					
10. I expect the closed-loop pancreas will help patients get into faster control than current treatments.					
89. I expect the artificial pancreas will offer more durable glycemic control for patients over current regimes.					
56. I expect using the artificial closed-loop pancreas will make patient management easier than current treatments.					
13. I expect that the closed-loop artificial pancreas will reduce long term complications (i.e. kidney damage) more effectively than current treatments.					
33. I expect that the closed-loop artificial pancreas will reduce short term complications (i.e. hypoglycemia) more effect than current treatments.					
34. I expect using the artificial closed-loop pancreas can improve patient outcomes.					

Demographics: Please provide the following demographic information:

2. Are you currently involved in research involving the closed loop artificial pancreas?

□ Yes □ No

If Yes check all that apply:

□ I was or I am involved in the development of a closed loop artificial pancreas.

□ I work or have worked in simulation testing of a closed loop artificial pancreas.

□ I work or have worked on feasibility testing of a closed loop artificial pancreas.

□ I work as a Primary investigator in clinical trials for a closed loop artificial pancreas.

□ My clinical practice is under consideration as a site for current or future testing for a closed loop artificial pancreas.

Comments from the Experts:

---

3. What is your gender?

□ Male □ Female

Comments from the Experts:

---

4. What is your age?

□ 18- 30 years

□ 31-40 years

APPENDIX C

Delphi Round 2 Survey Worksheet preview page 1

For the complete survey worksheet and/or any questions or further information regarding the HCP-CLAPA, please contact the PI at carolyn.serrano.07@gmail.com

EXPERT PANEL: Thank you very much for your input on Round 1 of the survey.

In the second round of the Delphi process, you will find the following concerns/recommendations made by at least (1) Expert Panel member. I am now proposing each recommendation made about a given statement/question for your review to gain 80% consensus.

Please Check /Mark with an X whether the change should be made or if the original statement/question should be left as is. This will suffice as round 2 of the Delphi process. Please note that if a simple grammatical change(s) was/were recommended for more clarity to a statement/ question, that/those change(s) are being made. Thank you.

1. It was suggested by an expert that the following question:

   10. I expect the closed-loop pancreas will help patients get into faster control than current treatments.

   1) This item should be removed because it is similar to question 89 and less specific. (89.I expect the artificial pancreas will offer more durable glycemic control for patients over current regimes).

Make change as per expert (s)' recommendation _____

Leave this statement/question as originally proposed _____

Additional comments:

_____

_____

_____

2) Change the word "faster" to "expedited" so that the statement reads:

10. I expect the closed-loop pancreas will help patients get into <u>expedited</u> control compared to current treatments.

Make change as per expert (s)' recommendation _____

Leave this statement/question as originally proposed _____

Additional comments:

_____

_____

_____

APPENDIX D

Delphi Round 3 Survey Worksheet preview page 1

For the complete survey worksheet and/or any questions or further information regarding the HCP-CLAPA, please contact the PI at carolyn.serrano.07@gmail.com

EXPERT PANEL: Thank you very much for your input on Round 2 of the survey.

Consensus was reached on the majority of questions. There are a few questions that need further expert consideration.

On the following two question since consensus was not achieved, I am making new suggestions. Please provide your expert opinion. This will suffice as round 3 of the Delphi process for your review to gain 80% consensus. Please note that if a simple grammatical change(s) was/were recommended for more clarity to a statement/ question, that/those change(s) are being made. Thank you.

1. Consensus was not achieved however, as the PI I am interested in the particular aspect of "deskilling of the patient". I am posing to you the original question as it was written for Rounds 1 and 2 as a reminder. I am then providing my suggestions below and asking for your commentary and critique.

   81. Consider the definition of deskilling as the loss of a skill set due to technology; and with this in mind, consider the following: I believe using the closed-loop artificial pancreas will cause a deskilling of the patient with type 1 diabetes to occur.

   42. Consider the definition of deskilling as the loss of a skill set of due to technology; and with this in mind, consider the following: I believe using the closed-loop artificial pancreas will cause a deskilling of the patient with type 2 diabetes to occur.

Remember consensus was not achieved on this question in Round 1 and Round 2 therefore I am making the following recommendation.

Recommendation #1

Proposed Rewrite:

For both questions # 81 and 42: I am proposing these questions as open ended question allowing the participant to give their professional opinion on deskilling of a patient using the artificial pancreas technology. Therefore, the questions are posed as follows: (Note: the numbering has changed in the survey 81 is now 78)

78. For the following question the terminology "deskilling of the patient" is being used. Consider the definition of deskilling as the loss of a skill set due to technology. With this in mind, please provide your thoughts regarding using the closed-loop artificial pancreas technology in a patient with Type 1 diabetes. Do you believe deskilling of the patient will occur if this technology is employed in this population? Why? Why Not? Your thought in this regard are appreciated.

APPENDIX E

Seton Hall University

Institutional Review Board (IRB) Approvals

E-1: [01/25/17] Letter from Seton Hall IRB approving research study

E-2: "PI's Request for Approval of Research, Demonstration or Related Activities Involving Human Subjects" Form Signed by IRB Director [1/25/17] and Academic Advisor [11/16/17]

E3: [06/14/17] Approval of 1st IRB Amendment

E4 [08/29/17] Approval of 2nd IRB Amendment

January 25, 2017

Carolyn M. Serrano
[redacted]

Dear Ms. Serrano,

The Seton Hall University Institutional Review Board has reviewed the information you have submitted addressing the concerns for your proposal entitled "Determinants of Behavioral Intent to Adopt the Closed-Loop Artificial Pancreas Among Diabetes Healthcare Providers". Your research protocol is hereby accepted as revised **for three sites only** and is categorized as exempt. The three sites are:

1. The American Association of Diabetes Educators;
2. The Metropolitan New York Association of Diabetes Educators;
3. the public domain on the internet using sources such as physicians' office websites, hospitals, and/or universities that provide this information online.

Please note that, where applicable, subjects must sign and must be given a copy of the Seton Hall University current stamped Letter of Solicitation or Consent Form before the subjects' participation. All data, as well as the investigator's copies of the signed Consent Forms, must be retained by the principal investigator for a period of at least three years following the termination of the project.

Should you wish to make changes to the IRB approved procedures, the following materials must be submitted for IRB review and be approved by the IRB prior to being instituted:

- Description of proposed revisions;
- *If applicable*, any new or revised materials, such as recruitment fliers, letters to subjects, or consent documents; and
- *If applicable*, updated letters of approval from cooperating institutions and IRBs.

At the present time, there is no need for further action on your part with the IRB.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

All material must be typed.

PROJECT TITLE: Determinants of behavioral intent to adopt the closed-loop artificial pancreas among health care providers

CERTIFICATION STATEMENT:

In making **this application,** I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects. I (we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Director of the Institutional Review Board, Seton Hall University, South Orange, NJ 07079.

Carolyn. M Serrano — 11/16/2016
RESEARCHER(S) — DATE

Please print or type out names of **all researchers below signature.
Use separate sheet of paper, if necessary.**

My signature indicates that I have reviewed the attached materials of my student advisee and consider them to meet IRB standards.

Dr. Deborah DeLuca — 11/16/2016
RESEARCHER'S FACULTY ADVISOR **[for student researchers only]** — DATE

Please print or type out name below signature

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research at the Jan 2017 meeting.

The application was approved ✓ not approved ___ by the Committee. Special conditions were ____ were not ✓ set by the IRB. (Any special conditions are described on the reverse side.)

Nancy J. Ruzicka, Ph.D — 1/25/17
DIRECTOR, — DATE
SETON HALL UNIVERSITY INSTITUTIONAL
REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

SETON HALL UNIVERSITY
1 8 5 6

June 14, 2017

Carolyn Serrano
[redacted]

Dear Ms. Serrano,

The IRB hereby approves the requested amendment to your research protocol, "Determinants of Behavioral Intent to Adopt the Closed-Loop Artificial Pancreas Among Diabetes Healthcare Providers" to add Novo Nordisk Inc. and Close Concerns as research performance sites.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca

Please review Seton Hall University IRB's Policies and Procedures on website (http://www.provost.shu.edu/IRB) for more information. Please note the following requirements:

Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Amendments: If you wish to change **any** aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.

Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.

Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Renewal: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your initial approval anniversary date. **Note:** No research may be conducted (except to prevent immediate hazards to subjects), no data collected, nor any subjects enrolled after the expiration date.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Prof. Deborah DeLuca

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SETON HALL UNIVERSITY
1 8 5 6

August 29, 2017

Carolyn M. Serrano
[redacted]

Dear Ms. Serrano,

The IRB hereby approves the requested amendment to your research protocol, "Determinants of Behavioral Intent to Adopt the Closed-Loop Artificial Pancreas Among Diabetes Healthcare Providers" to add Carol Hamersky as the new interrater coder.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca

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APPENDIX F

Letter of Solicitation to Survey Participants

SETON HALL UNIVERSITY
1 8 5 6

Dear Healthcare Provider,

My name is Carolyn Serrano. I am a Ph.D. student at the School of Health and Medical Sciences at Seton Hall University. I am conducting this research study as part of my doctoral dissertation.

What is the purpose of the study?
You are invited to participate in this survey study. You are invited to participate because you may be a healthcare provider that works with patients that have diabetes. Research in the field of diabetes technology has grown. Studies have shown that some factors may either prevent or promote technology adoption among health care providers. Healthcare provider technology adoption can influence the accessibility of technology to the patient. The purpose of this study is to understand key factors leaded to adoption and the potential barriers to adoption of the closed-loop artificial pancreas technology. It will also help determine the differences in adoption of the closed-loop artificial pancreas system, among physician's and non-physicians

What is the study procedure?
Please complete the survey if you fit the requirements. The requirements are: being a physician (e.g. endocrinologist, diabetologist, internal medicine, primary care) or non – physician (e.g. licensed, registered, or certified nurse practitioner, advanced practice registered nurse, clinical nurse specialist, certified diabetes educator or physician assistant) who is involved in the care of patients with diabetes. You can complete the survey by clicking on the link below. This study will also use a recruitment technique known as chain-referral or snow-ball sampling. This means that you can forward this email to anyone that you think meets the requirements. Anyone who fits the requirements can participate in this study. They can complete the study even if you don't. This allows the survey to reach a greater audience. The attached link is not unique to you. It can be forwarded to anyone. No record will be kept of the person you forwarded this to. Completing the survey will take about 15 minutes. You can take as much time as you would like to complete this survey.

Is participation voluntary?

Your participation in this research study is voluntary. You can decide not to participate at any time. If you don't participate, you will not be penalized or lose any benefits to which you are otherwise entitled. By clicking the link below, you are providing your consent to participate in this study.

Is the survey anonymous?
Your identity will not be collected as part of this study. Your name, address, or other personal identifying information will not be collected. Only general demographic information will be collected. There will be no records identifying you. Your answers are anonymous. There will be no way to contact you or link your answers to you. If you forward the survey to others, no identifying information will be collected from them. The research data may be published at the end of the study. If it is, it will not identify any participant. Please also note that although the Survey Monkey® website is secure, as there is with anything online, there is a remote risk of hacking. When you complete the survey, please submit the survey by clicking on the "Submit" radio button. By doing this, your browser should automatically close but to be safe, please close your browser manually after you click the submit radio button.

What will happen to the study data?
The study data will be kept confidential to protect its integrity. The data will be stored on a USB drive. The USB drive will be stored in a locked cabinet in the office of the principal investigator. The principal investigator, Carolyn Serrano, will have access to all the data for a period of three years. After three years, the research data will be destroyed.

Risk and Benefit to participating.
There is no foreseeable risk or discomfort anticipated by your participating in this research study. There are no proposed or foreseeable direct benefits to you by participating in this research study. However, by participation in this survey research you may be facilitating the education for future practitioners about the adoption of diabetes technology.
Can I request further information?
If you have an interest in learning more about this topic or study please feel free to contact me through the office of Dr. Deborah DeLuca Chair in the Department of Interprofessional Health Sciences and Health Administration in the Seton Hall University School of Health and Medical Sciences, at 973-275-2842, Deborah.deluca@shu.edu. Should you have any questions about your rights as a participant in this research study, you may contact Dr. Mary Ruzicka, Director, Institutional Review Board in the Office of the IRB at Seton Hall University may be reached at 973-313-6314. You may send questions about subjects' rights as human subjects in a research study by email to: irb@shu.edu.

Ways to participate in this study.
Please feel free to ask other professionals that you know to participate in this survey. Additionally, if you choose not to answer the survey questions, but know colleagues that

might be eligible or interested, please pass this survey link onto them. The survey is available on Survey Monkey® electronic survey.

The survey link to my study is:

Link will be placed here.

By accessing and completing the HCP-CLAPA and demographic profile through the link listed here, you are conveying your informed consent to participate in the study.

Thank you for taking the time to read this. I appreciate your consideration in participating in this study.

Best Regards,
Carolyn Serrano

APPENDIX G

Principal Investigator Created Tool:

The Healthcare Provider Closed-Loop Artificial Pancreas Assessment

(HCP-CLAPA)

[Initial pages preview of the HCP-CLAPA]

For the full tool and/or any questions or further information regarding the HCP-CLAPA, please contact the PI at carolyn.serrano.07@gmail.com

Healthcare Providers Closed- Loop Artificial Pancreas Adoption Instrument

HCP-CLAPA INSTRUMENT

Dear Respondent: Please take a moment to complete this brief survey. Be assured all information is strictly confidential and no individual respondent information will be identified.

Closed-Loop Artificial Pancreas:

*1. Please select the response that best represents your **knowledge** of the closed-loop artificial pancreas.

□. I consider my understanding in the area of the closed-loop artificial pancreas technology to be advanced

□. I consider my understanding in the area of the closed- loop artificial pancreas technology to be basic.

□ I have no knowledge of closed-loop artificial pancreas technology.

Demographics: Please provide the following demographic information:

*2. Are you currently involved in research involving the closed-loop artificial pancreas?

□ Yes □ No

If Yes check all that apply:

□ I am currently or I have been involved directly in the development of a closed-loop artificial pancreas.

□ I am currently working or have worked in simulation testing of a closed-loop artificial pancreas.

□ I am currently or have worked on feasibility testing of a closed-loop artificial pancreas.

□ I work as a primary investigator in clinical trials for a closed-loop artificial pancreas.

□ I am currently employed at a device company that is directly involved in research and development of a closed- loop artificial pancreas.

□ My clinical practice is under consideration as a site for current or future research studies for a closed-loop artificial pancreas system/s.

3.*What is your profession?

□Physician
If Physician, MD or DO?

□ MD □DO

□ NP Nurse Practitioner
□APRN Advanced Practice Registered Nurse

- ▢ANP: Advanced Nurse Practitioner
- ▢CNP: Certified Nurse Practitioner
- ▢CRNP: Certified Registered Nurse Practitioner
- ▢ CNS Clinical Nurse Specialist
- ▢LNP: Licensed Nurse Practitioner

▢ Physician Assistant

▢ Certified Diabetes Educator

- ▢ Board Certified Advanced Diabetes Management
- ▢ Certified Diabetes Technology Clinician

▢Other _____

4.* What is your specialty?

- ▢ Endocrinology
- ▢ Diabetology/Diabetologist
- ▢ Pediatric Endocrinology
- ▢ Internal Medicine
- ▢ Family Medicine
- ▢ Other _____

Directions:

For the purpose, of this research I am employing the definition of a closed-loop artificial pancreas that includes the hybrid closed-loop, 24-hour fully automated insulin only, **and** dual hormone systems **including *insulin +glucagon* or *insulin + glucagon suppressors*(Glp-1/pramlintide) systems. When answering the questions, you will be given specific instructions when to consider specific systems.**

Directions: Understanding that the only closed-loop artificial pancreas that is FDA approved for use is the Medtronic's MiniMed®® 670G System, which is a first-generation hybrid closed-loop system and is currently only FDA approved for treatment of type 1 diabetes, and not currently expected to be on the Market until Spring 2017. Acknowledging that the other closed- loop systems are not FDA approved and are not expected to be marketed within the next two years, please answer the questions based on ***your best perception of how this technology will affect the following*** when it DOES become available.

Unless otherwise indicated, *please DO NOT consider patient access and cost* when answering these questions.

Unless otherwise indicated, *please DO consider all possible forms of the closed-loop* when answering these questions (hybrid, insulin only 24-hour and both dual hormone systems).

Please respond to the following statements using the scale to the right of the statement and indicate how much you agree or disagree with each statement using the scale below:

Scale

①-Strongly Disagree (SD)
②-Disagree (D)
③-Neither Agree nor Disagree (N)
④-Agree (A)
⑤-Strongly Agree (SA)

Variable ←Strongly Disagree--------- Strongly Agree →					
Variable	**←Strongly Disagree------Strongly Agree →**				
5. I am an individual who can easily adapt to new technology for patient care.	①	②	③	④	⑤
6. Using a closed-loop artificial pancreas system to manage patients seems like a hassle to me.	①	②	③	④	⑤
7. I expect that a closed-loop artificial pancreas system will reduce long term complications (i.e. kidney damage) more effectively than current treatments.	①	②	③	④	⑤
8. The closed-loop artificial pancreas system could pose a risk to glycemic control of a patient due to malfunctioning.	①	②	③	④	⑤
Directions: The next set of questions deals with a 24 hour fully automated **insulin only** closed-loop artificial pancreas technology. Please answer the questions based on your beliefs regarding the 24 hour fully automated **insulin only** hormone closed-loop systems.					
9. I believe the improved patient outcomes will be worth the time necessary for training on a 24-hour fully automated insulin only closed-loop artificial pancreas system.	①	②	③	④	⑤
10. I intend to use a 24-hour fully automated insulin only closed-loop artificial pancreas system for patient glycemic management as often as needed when it becomes available.	①	②	③	④	⑤
11. I believe improved patient outcomes from a 24-hour fully automated **insulin only** closed-loop artificial pancreas systems will be worth the effort it	①	②	③	④	⑤