2018

Effectiveness of Continuous Subcutaneous Insulin Infusion Therapy Education in a Clinic Setting

Kimberly Rizzo
Walden University

Walden University

College of Health Sciences

This is to certify that the doctoral study by

Kimberly Rizzo

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Janice Long, Committee Chairperson, Nursing Faculty
Dr. Lilo Fink, Committee Member, Nursing Faculty
Dr. Deborah Lewis, University Reviewer, Nursing Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2018

Abstract

Effectiveness of Continuous Subcutaneous Insulin Infusion Therapy Education in a Clinic Setting

by

Kimberly Ann Rizzo

MS, Walden University, 2015

BS, University of Michigan, 2012

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

July 2018

Abstract

Diabetes affects an estimated 29.1 million Americans, with approximately another 1/3 of Americans not yet diagnosed. Complications associated with diabetes include heart disease, stroke, hypertension, blindness, kidney disease, neuropathy and death. All of these complications can be prevented with optimal control of blood glucose levels. Advances in technology provide people living with diabetes (PLWD) a multitude of treatment options such as continuous subcutaneous insulin infusion (CSII) therapy. Unfortunately, sustained improvement in glycated hemoglobin A1c (HgA1c) is not always achieved even with this advanced therapy. The purpose of this doctoral project was to educate nurses on CSII therapy and promote improved patient compliance, knowledge and ultimately improve HgA1c control. This doctoral project is an evaluation of an Evidence-Based Quality Improvement Project (EB-QIP) that evaluated nurse-led educational sessions for PLWD using CSII therapy. The integrated theory of health behavior change was used to guide the project. The CDC process evaluation model was used to evaluate the outcomes of the education sessions. Results showed that patients who were instructed by the nurses who took part in the EB-QIP had a reduction in the overall HgA1c by an average of 1.1 points 3-months post-education. The project promotes positive social change through establishing the effectiveness of an EB-QIP that focused on the use of education on CSII therapy in improving outcomes for patients living with diabetes.

Effectiveness of Continuous Subcutaneous Insulin Infusion Therapy Education in a Clinic Setting

by

Kimberly Ann Rizzo

MS, Walden University, 2015

BS, University of Michigan, 2012

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

July 2018

Dedication

I would like to dedicate my paper to my three beautiful children. The four of us have been through many trials and tribulations in life, and it is through your love and belief in me that I was able to go from the basics of education on toward my doctorate. I love you all more than you will ever know. There is definitely no love greater than my love for the three of you.

Acknowledgments

First, I would like to thank my mom for always being in my corner and believing in me even when I felt I would never reach this level in my educational studies. I would also like to thank Paula our Medtronic Representative for providing me the education and guidance in understanding CSII therapy. Without Paula's time and effort teaching me the intricacies of CSII technology, this paper and the improved outcomes established with the participants would have never happened. With regard to the support of my committee, I would like to thank Dr. Lilo Fink, and Dr. Deborah Lewis for taking the time to help me with revisions and producing a project that I am very proud of. Lastly, I would and most important, I would like to thank Dr. Janet Long for her dedication in providing me the understanding to complete this project. Without her leadership and educational skills, guiding me through this process I would be lost. Dr. Long is a true example of what an educator is and should be. Thank you for all of your help and guidance through the last stages of my doctoral studies.

Table of Contents

List of Tables

List of Figures

Section 1: Nature of the Project

Introduction

Type 1 and Type 2 diabetes are chronic conditions that have experienced exponential growth worldwide (Rowley & Bezold, 2012). The prevalence of diabetes has increased in the United States, from 1.6 million in 1958, accounting for 0.9% of the population, to 23.4 million in 2015, accounting for 7.4% (CDC, 2017). The United States has become the epicenter of "supersized" with the explosion of fast food and subsequent rise in obesity (Spurlock & Spurlock, 2004). This, in addition to sedentary lifestyles, has led to the dramatic increase in diabetes and other associated chronic health conditions. In the United States, the prevalence of diabetes among the adult population ranges between 5.8% and 12.9%, accounting for approximately 14% of all health care expenditures, or $245 billion (McCulloch, 2016).

Type 2 diabetes (T2D) is expected to increase approximately 64%, from 19.1 to 53.1 million, by 2025 (Rowley & Bezold, 2012); worldwide T2D is expected to increase to approximately 415 million, with an annual economic impact close to $500 billion. The United States spends nearly double in health care expenses per capita compared to countries such as Germany, Canada, Denmark and France (Zhang et al., 2010). The increasing cost of treating chronic diseases such as diabetes is causing an economic crisis in the United States. The economic backlash is not only hurting the United States fiscal pocketbook but is becoming a financial hardship for individuals and families. The cost of annual health insurance premiums for the average American family ($17,545) is close to the gross yearly income of a full-time minimum wage worker, (KFF, 2015).

Without sustained HgA1c normalization, complications are likely, such as cardiovascular/cerebrovascular disease, renal impairment, retinopathy, and peripheral neuropathy (McCulloch, 2016). These complications can present silently until end-organ or vessel damage manifests. With the traditional use of multiple daily injections of insulin that are required to promote optimized glycemic control, personal compliance is critical. Multiple daily injection (MDI) therapy requires approximately 5 to 6 injections daily, along with frequent finger pricks to monitor blood glucose levels (Mayo Clinic, 2017). Also, MDI therapy brings with it a high risk of hypoglycemia, as exogenous insulin has a slower rate of absorption when compared to the normal physiology of the pancreas in a person who is nondiabetic (McCulloch, 2016).

Modern medicine, especially technological advances and treatment modalities, has experienced remarkable advances. Continuous subcutaneous insulin infusion (CSII) therapy, also known as insulin pump therapy, has greatly improved the quality of life for many people living with diabetes requiring insulin therapy. As this therapy was designed to improve glycated hemoglobin (HgA1c) levels in people living with diabetes (PLWD) requiring insulin therapy, it is becoming evident that this reduction is only short-term, as HgA1c levels over time begin to increase (Nixon, Folwell, &Pickup, 2014). The increase in HgA1c levels may be associated with knowledge deficiency, poor patient compliance with the use of this sophisticated technology, a lack of sufficient patient education focusing on CSII technology, or the interaction between the patient and health care provider (Nixon, Folwell, & Pickup, 2014). As the tasks related to CSII technology can be quite intricate, basic functions are the focus of the training when CSII therapy is

initiated, leaving PLWD lacking a more in-depth understanding of the use of their insulin delivery system. So, the decline in HgA1c levels after initiation of CSII therapy may be not be linked solely to one cause, but a combination of many causes.

The purpose of this doctoral project was to evaluate the outcomes of a quality improvement project (QIP) specific to PLWD using CSII therapy. The QIP consisted of three 45-minute education sessions to improve the knowledge and the confidence of PLWD in engaging in self-management to stabilize HgA1c levels. Secondary, deidentified data, was used to determine the effectiveness of the QIP and included aggregate serum HgA1c levels prior to initiation of the QIP and aggregate serum HgA1c levels three months post QIP.

Local Context for Gap-In-Practice

Breakthroughs in technology, such as CSII therapy, are changing how PLWD manage this disease. Although the CSII technology will not reduce the number of PLWD, the complications related to diabetes can be minimized. The research specific to the effectiveness of CSII therapy is mixed, however. Bode (2010) posits achieving maximum CSII therapy effectiveness requires continued patient education, in addition to the traditional cross-sectional and basic education received at the initiation of CSII therapy. Without tailored longitudinal guidance to learn strategies for glycemic control (Bergenstal et al., 2013), the typical PLWD will not realize the benefits offered by the CSII technology.

CSII technology provides different data entry options that are person-specific. This facilitates the insulin that mimics the function of pancreas, delivering both basal and

bolus insulin. Without understanding the basic-level options through experience and continued education, the more advanced tasks available with the CSII technology are not realized. As Bergenstal et al. (2013) explain, the knowledge deficit reduces the ability of a provider to collaborate with the PLWD to make safe clinical decisions when adjusting CSII data.

According to Bergenstal et al. (2013), analysis and visualization of pertinent standardized glucose data by providers also plays a contributing role in poor glycemic control among CSII users. Analysis of the data provided by the CSII device is critical in calculating appropriate insulin administration. This data weighs heavily on the precise computation of insulin needs, carbohydrate intake, sleep/wake cycles, and glucose levels. To program the CSII technology to deliver the correct insulin, the provider must have expert knowledge in analyzing what is visualized on the charts and graphs that are furnished with each CSII download (Medtronic, 2009). This knowledge, although not expert, should be understood by the user of the CSII technology at least minimally to recognize the importance of correct data input. This is a vital reason patient education is so relevant in optimizing glycemic control.

Local Relevance.

The State of Arizona has a population of 1,796,000, with 682,071 diagnosed with diabetes, which is 12.5% of the adult population (American Diabetes Association [ADA], 2015). Prediabetes, higher than normal blood glucose levels (70 – 100), accounts for 37.5% of the adult population, with an estimated 34,000 newly-diagnosed diabetics in Arizona yearly (ADA, 2015). Between 1995 and 2010, there was an 80% increase in

people diagnosed with diabetes in Arizona, while it is theorized that one-third remain undiagnosed (Humble & Tormala, 2011). In 2011, there were 390,000 people in Arizona reported to have diabetes (Humble & Tormala, 2011); four years later the diabetic population almost doubled to the estimated 682,071 people diagnosed with diabetes in Arizona (ADA, 2015). An estimation of those undiagnosed in the State of Arizona is 172,000 (ADA, 2016).

In 2006, there were 1,755 per 100,00 diabetes-related hospitalizations in Arizona, accounting for 170 more hospitalizations than other Western states (Humble & Tormala). The total direct medical expenses associated with treatment of diabetes in the State of Arizona was estimated at $4.9 billion in 2012, with an additional $1.5 billion for indirect costs associated with diabetes. Nationally, the total estimated cost associated with the diagnosis of diabetes in 2012 is $245 billion; $176 billion in direct medical costs and $69 billion in indirect costs. Reported costs associated with diabetes prevention and education in the State of Arizona in 2016 provided by the Division of Diabetes Translation at the Centers for Disease Control and Prevention (CDC) was $1,941,335. In 2015, the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institute of Health provided funding in the amount of $10,085,465 to be used for research projects specific to diabetes in the State of Arizona (ADA, 2016).

The Diabetes Clinic (a pseudonym) is located in a large southwestern state with a patient population consisting of Native-Americans, Hispanics, Asians, non-Hispanic Whites, and African-Americans. Diabetes statistics vary across the ethnic groups. For example, diabetes affects approximately 16.1% in the Native-American population,

followed by 12.6% of African-Americans, 8.4% Asians, 11.8% Hispanics, and 7.1% non-Hispanic whites (Humble & Tormala, 2011). According to the Center for Disease Control and Prevention (CDC) Report in 2011, the Native-American community in Arizona accounts for 5% of the population at approximately 319,600 people.

Worldwide, 415 million people have been diagnosed with diabetes, in addition to an estimated 193 million people that are either unaware of being diabetic or have not yet been diagnosed (Chatterjee, Khunti & Davies, 2017). In 2015, diabetes was placed as the sixth-leading cause of disability, creating a global economic burden estimated at $825 billion (Chatterjee, Khunti & Davies, 2017). In the United States, the economic burden of managing diabetes is approximately $245 billion yearly (CDC, 2014). Improving diabetes care with the promotion of CSII therapy in PLWD is paramount for decreasing the chronicity of diabetes and its complications.

Significance to Nursing

Health care is advancing in the United States, offering nurses more active roles in improving patient care through implementing evidence-based practices. Nurse-led education has become important in chronic disease management (Levich, 2011). Specific to diabetes, nurses can positively impact social change with respect to increasing the effectiveness of insulin therapy by reducing knowledge deficits and increasing self-management skills (Levich, 2011).

Inadequate management of diabetes can lead to increased complications, decreased quality of life, and large financial expenditures. By 2020, chronic diseases will account for an estimated three-quarters of the disease burden globally, consisting of an

estimated 60% from diabetes alone, specifically T2D and cardiovascular disease. (Day & Brown, 2014). With the chronic disease burden growing, nurses are ideally positioned in organizations and educationally prepared to provide the necessary longitudinal education to advance self-management skills by decreasing the knowledge deficit.

According to Levich (2011), nurses should lead the agenda to engage in long-term person-specific education to enhance the management of PLWD using CSII technology. This project is particularly important as nurses need to also engage in outcomes evaluations for their work. For PLWD using CSII therapy for glycemic control, a nurse-led education program can potentially increase experiential knowledge through the use of technology and increase self-management by reducing knowledge deficits. The purpose of this doctoral project was to evaluate the impact a nurse-led education program has on improving the knowledge deficit and self-management of diabetes.

Purpose Statement

Gap-in-Practice

For PLWD, CSII therapy provides a convenient, targeted, and tailored means for timely insulin infusions to rapidly respond to changes in blood glucose levels. However, there is a gap in nursing practice specific to knowledge deficits when PLWD utilize the treatment modality and achieve suboptimal reductions in HgA1c levels. Jayasekara, Munn, and Lockwood (2011) found that PLWD need continued education and training with comprehensive advice by experts to successfully use CSII therapy. Wu et al. (2013) reported that, with continued education and training by skilled professionals, PLWD had

significant reductions in HgA1c levels ($p < 0.001$), improvements in self-efficacy ($p < 0.001$), and increased self-care ($p < 0.001$).

The purpose of this doctoral project was to evaluate the impact of a nurse-led education program on glycemic control for PLWD using CSII technology. The nurse-led education program consisted of three 45-minute sessions focused on advanced technological training specific to CSII therapy, and the development of self-management skills. The hypothesis was that effective multi-session education can reduce knowledge deficits, improve self-efficacy, and promote self-management. The increased use of CSII therapy for intensive insulin treatment for PLWD is an appropriate option for many; however, not every PLWD is a good candidate for this treatment modality. With technological advancements it is imperative that the appropriate education, geared toward specific patient populations, be designed to promote the best possible outcome. Use of CSII therapy in PLWD over the next decade is expected to double, according to Saboo and Talaviya (2012). This expected growth should prompt the medical community to enhance the use of CSII therapy with extended educational sessions that promote self-management skills along with improving knowledge deficits correlated with the correct use of CSII technology.

There is inconsistent success with CSII therapy reported in the literature as demonstrated by Chamberlain and Gilgen (2014), who conducted a single-arm study that included 16 T1D and 12 T2D, concluding that patients' perceptions of the usability of CSII technology greatly affected the success of the therapy. The OpT2mise RCT study suggested that there was much greater variability in the T2D population versus the T1D

population (Aronson et al., 2014). Conget et al. (2016) performed a follow-up study that concluded suboptimal controlled T2D had significant improvement in HgA1c levels with the use of CSII therapy. Seven contributory factors were identified, including:

1. Patient tolerance and/or intolerance to insulin and therapy;
2. Biological changes to the patient resulting from age and/or gender;
3. Endocrine system function;
4. Patient lifestyle and stress levels;
5. Provider interaction and/or monitoring intervals;
6. Sensory-Augmented Pump Therapy (SAPT); and.
7. CSII technological shortfalls.

On quarterly follow-up assessments of PLWD utilizing CSII therapy at the diabetic clinic, systematic CSII (insulin pump) downloads are performed to evaluate data that is input into the insulin pump by the individual using the CSII therapy. This data is then used to calculate insulin pump settings in an effort to optimize disbursement of insulin and regulation of blood glucose levels. It has been identified, through the review of reports generated from the insulin pump download, that consistent blood glucose monitoring is suboptimal in many instances. Blood glucose monitoring should be performed a minimum of 4 times daily, however, ideal monitoring consists of 5 to 6 times daily for CSII therapy optimization (Mayo Clinic, 2017). CSII technology provides several reports generated through patient interaction with the insulin pump offering specific identifying factors that will alert the provider of inadequate use of CSII technology. Although CSII therapy promises to provide tighter glucose levels, thus

improving patient outcomes, the technology is changing so rapidly that it is theorized that PLWD and providers lack the up-to-date knowledge to optimize it.

Evidence-Based Health Care

Evidence-based health care formulates and implements treatment plans based on current knowledge derived from evidence-based research and expert opinion. The intent is to deliver safe, effective care that is patient-specific and promotes positive outcomes. The evidence-based health care approach incorporates problem-solving with the most current evidence from peer-reviewed research studies, along with advice from a knowledgeable clinician, and considers values and preferences of the patient (Fineout-Overholt, Melnyk, Schultz, 2005). Through a patient-centered, evidence-based approach to the management of diabetes, Tricco et al. (2012) found improvement in the management of diabetes through quality improvement (QI) strategies. The strategies that supported the greatest improvement in HgA1c levels were patient education and the promotion of self-management skills guided by health-care professionals (Tricco et al., 2012). Tricco et al. (2012) demonstrated that, by implementing evidence-based health care in the design of interventions that focused on quality indicators, HgA1c levels improved; however, when QI strategies focused on targeting both health systems and patients, there was even greater improvement in HgA1c levels.

PICOT Process

A well-designed EB-QIP begins with recognizing a clinical problem, or situation that can be positively changed and/or be improved upon. By structuring a question that specifically defines the problem, evidence-based practice can be implemented using a

problem-solving approach to the situation (Fineout-Overholt, Melnyk, & Schultz, 2005). The PICOT question is a formula designed for nurses to easily categorize the components necessary in defining the clinical problem, allowing for strategic organization of details and the formulation of a structured problem statement. Through the PICOT process, the nurse is able to gather appropriate research evidence and evaluate the evidence before implementing it into practice. Through the evaluation process, interventions will be applied that best fit the clinical problem and the problem statement. Interventions are developed that best fit the population affected, problem identified, and place in which the intervention will be implemented. Evidence-based research is employed in this process to promote improved patient outcomes.

Guiding Practice Focused Question

How will nurse-led educational sessions for PLWD using CSII therapy impact knowledge deficit and HgA1c levels?

Response to the Gap-in-Practice

CSII therapy, otherwise known as insulin pump therapy, has been in use for over 50 years (American Association of Diabetes Educators [AADE], 2014). According to the AADE (2014), CSII therapy provides improved quality of life with a less restricted lifestyle, along with improvement in glycemic control. The success of CSII therapy is determinant on careful assessment of PLWD, including physical and psychological factors that are key features in identifying a person's ability to successfully overcome the challenges of insulin pump technology (AADE, 2014).

The technology of CSII therapy can be very intricate and difficult to understand, especially for the novice. Also, at the initiation of CSII therapy, many features of the insulin pump are reviewed, which can be daunting for many people. There appears to be a gap in the depth of knowledge and use of CSII therapy for PLWD utilizing this treatment modality. This has become evident in the reports that are generated through the database of each insulin pump at the diabetes clinic identifying noticeable gaps in data. The information provided by the insulin pump allows the clinician to view daily interaction with the insulin pump by the user, recognizing gaps in proper operation.

CSII therapy provides continuous insulin infusion that is set by a provider delivering basal insulin throughout the day (Saboo. & Talaviya, 2012). However, as recognized by the AADE (2014), patients have the responsibility of routinely checking blood glucose levels to promote glycemic control. When there is missing information, such as blood glucose levels and carbohydrate values, safe adjustments to the insulin pump cannot be made, thus poor glycemic control continues. CSII therapy is only as good as the user's ability to furnish the appropriate information and enter it into the insulin pump.

Nature of the DNP Project

Project Sources of Evidence

The evidence to support this program evaluation was derived from a secondary data analysis consisting of aggregate serum HgA1c values 3 months prior to the initiation of the QIP and 3 months after the conclusion of the QIP, along with secondary data extracted from the Adherence Reports relevant to the evaluation. This secondary data was

made available from the diabetes clinic for the evaluation of the QIP. No identifying patient information was made available to the Doctoral Student performing the evaluation.

Project Method

All participants in the QIP were PLWD requiring insulin through CSII therapy and were patients at the diabetic clinic where the QIP took place. This is an evaluation of patient educational sessions. Mandatory participation in three 45-minute educational sessions was determined to be appropriate in gathering necessary information for the evaluation. Each educational session was participant-specific, identifying areas of need for advanced training in CSII therapy through review of the participant's insulin pump download reports with each session. Behavioral data located on the Adherence Report was provided by the site to the evaluator (the DNP student) void of any participant identifying information upon evaluation of the QIP, allowing for a detailed understanding of the participant's adherence according to indices of glucose measurements, bolus events, and insulin pump activities (Medtronic, 2009).

Each session began with review of the previous sessions' learning objectives and continued with further education about each category in the Adherence Reports. This selective focus on each category provided the participants a closer observation of their own behaviors regarding the use of their insulin pump and how their behavioral data affected their blood glucose levels. Participants were provided detailed educational packets that recapped the material covered with each session. Each participant was educated on all categories of the insulin pump reports to become familiar with the data

derived from the download, and the importance of this data in the improvement of glycemic control. All participants participated in three sessions.

Project Pathway

The purpose of this doctoral project was to evaluate the outcomes of an educational program specific to PLWD using CSII therapy in a diabetic clinic, and to identify whether advanced education would provide improvement in HgA1c levels and self- management skills focal to CSII use.

Significance

Improved clinical outcomes for PLWD are achieved with stabile maintenance of normal to near-normal glycemic control (Pozzilli et al., 2016). There are many factors that affect normal to near-normal glycemic control. It was the purpose of this project to identify these factors, and to evaluate the impact of education on HgA1c and compliance. Without normalization of blood glucose levels, chronic conditions can manifest, such as diabetic peripheral neuropathy and diabetic retinopathy. Grenell and Turner (2016) estimated 47% of patients with diabetes will eventually develop peripheral neuropathy. Approximately 50% to 75% of non-traumatic amputations are related to diabetic peripheral neuropathy (Grenell & Turner, 2016). This project will analyze the outcomes of an EB-QIP aimed to increase the knowledge and skills of the PLWD in the managing glycemic control with CSII therapy.

Stakeholder Analysis

The most evident stakeholders in this process were PLWD utilizing CSII therapy; however, the director of the clinic, as well as the nurse practitioners that provide care to

the patients at the clinic were contributing stakeholders, in that their depth of understanding the technology of CSII therapy would promote improved patient outcomes. Family and friends of PLWD utilizing CSII therapy were also stakeholders, in that, through their continued support and encouragement, they could positively advocate for the advancement of knowledge needed to continue to improve lifestyle and overall health.

It is evident in the literature that, with the normalization of HgA1c and reduction in the variability of glucose levels, a decline in the complications associated with diabetes i.e., microvascular and macrovascular should be seen. The incidence of lower limb amputations is 46.1 to 9600 per 10^5 (Moxey et al., 2011); the Diabetes Control and Complications Trial DCCT/Epidemiology of Diabetes Interventions and Complications (EDIC) study found that intensive glycemic control reduced fatal and nonfatal cardiovascular disease and stroke by 57 percent (McCulloch, 2016). The reductions in these catastrophic complications would lead to less time off of work, overall improved health and wellness, and economic status for PLWD.

Quality of life for PLWD and their family members would improve with the decrease in complications associated with diabetes. Adriaanse et al. (2015) found that maintaining a good quality of life is a pertinent goal to be set with T2D, in that it improves a person's perspective about their well-being socially, physically and mentally. The complications associated with diabetes grossly determine the quality of life in PLWD (Adriaanse et al., 2015).

Family members often care for loved ones with chronic illness and, with reforms in the U.S. health care system, this is becoming more progressive over time (Lim & Zebrack, 2004). Lim & Zebrack (2004) found through a literature review that, when caregivers experienced stress caring for a family member, this equated to the caregiver appraising themselves as lacking in self-efficacy, creating high levels of caregiver depression. With reduction in HgA1c levels in PLWD, chronic conditions and complications from diabetes can be prevented, alleviating family members from caring for a chronically ill loved one.

The diabetic clinic that performed the QIP, dependent on the evaluation, may experience a positive impact from addressing this local problem. Uncontrolled diabetes, as discussed previously, is associated with a number of chronic conditions associated with the neurovascular, cardiovascular, and renal systems. An increase in patient population may be experienced related to the positive outcomes the participants experience, lending to primary care providers referring more patients to the clinic for treatment of diabetes.

Contributions to Nursing Practice

This doctoral project promotes continued evidence-based projects and translation of evidence to stimulate continued education for diabetes and chronic disease states. This project was geared to identify the gap not only in practice, but in the significance of nursing's role in the translation of evidence-based quality improvement projects into the format of education at a level that PLWD can understand and apply to their everyday lives. Technology is rapidly growing, necessitating continued hands-on training of these

variable technological gadgets to promote the optimization of the devices, therefore providing the best outcomes. Using the basic mechanisms of these intricate devices is wasting the depth of technology that is designed to enhance the quality of life, and it is a failure of the medical community when PLWD use such technology in the most basic fashion.

This doctoral project evaluated another level of education that nurses can provide to PLWD utilizing CSII technology that promotes optimization of glycemic control, reducing known complications associated with uncontrolled diabetes.

Transferability of Knowledge

Identifying the gap in practice with CSII technology and diabetic self-management skills, future nursing projects can continue identifying specialized arenas in health in which CSII technology can be used. Improving diabetic self-management skills can also parlay into other chronic conditions, educating a multitude of patient populations on self-management skills and the promotion of positive outcomes. One area of interest is applying CSII technology and the initiation of this modality in people who suffer from Addison's disease. CSII technology could be used to provide continuous cortisol through the advanced technology that CSII therapy provides. The understanding of technology, and using it to its full potential, is critical in quality of life as well as positive outcomes. Nursing research on patient safety is profoundly important, as is linking the appropriate tools to the knowledge needed to be successful.

Implications for Positive Social Change

There is limited research focusing on patient education geared toward CSII technology and future advancements associated with this therapy. It is important for PLWD who require CSII therapy to thoroughly understand the technological aspect of this treatment and acquire knowledge to promote improvement in glycemic control. It is believed that, with further education that is person-specific to diabetes and utilizing complex functions associated with CSII therapy, there will be improved compliance and a reduction in complications associated with uncontrolled diabetes. With the reduction in complications of diabetes, costs associated with treatment will be positively affected, along with quality of life, for those diagnosed with the disease.

Summary

Normalizing HgA1c levels in PLWD requiring insulin therapy promotes better patient outcomes by decreasing morbidity and mortality rates, as well as minimizing the impact of socioeconomic and quality of life issues. With normalized glycemic control, PLWD will experience a reduction in the negative effects of diabetes such as nephropathy, neuropathy, and retinopathy, along with cardiovascular problems.

Improving outcomes for PLWD with education can enhance quality of life for PLWD and family members. As I have worked with this population, it has become apparent that there is a gap in nursing and the promotion of education to improve self-management and technological skills of those PLWD utilizing CSII therapy. Upon evaluation of this QIP, I developed a clearer insight on the gap in nursing, education and normalization of HgA1c levels.

Section 2: Background and Context

Introduction

The diabetes clinic that performed the QIP estimates that over half of its patients are diabetics, and new diabetic patients are being referred to this clinic on a daily basis. It is estimated that about a quarter of the PLWD that are seen in this diabetic clinic utilize CSII therapy. When oral glycemic agents fail to control blood glucose levels in T2D, insulin therapy becomes the mainstay of treatment. For T1D, insulin is the only avenue of treatment related to the destruction of pancreatic beta cell production (McCulloch, 2016). With the administration of insulin, MDI therapy used to be the only avenue for PLWD to control blood glucose levels. MDI therapy entails correct calculation of carbohydrate intake, as well as blood glucose levels, along with the administration of insulin at specific times throughout the day based off of these calculations. Compliance with MDI therapy can become a significant barrier to the normalization of blood glucose levels associated with the multiple finger sticks required daily, averaging four to six times, to obtain accurate calculations, along with three to four daily injections of insulin daily.

In 1963, Dr. Arnold Kadish invented the first portable insulin pump; more than 10 years later, in 1976, Dean Kamen designed the first wearable insulin pump (Ghazanfar et al., 2016); also known as CSII therapy. Over the past 40 years, CSII therapy has advanced as researchers race to develop the artificial pancreas. These new technologies are proving to have an impact on glycemic control in relation to reducing the number of injections PLWD have to administer through the day with MDI therapy. CSII therapy is a

promising advancement in treatment for diabetes, reducing the complications associated with cardiovascular disease, neuropathy and nephropathy, and cholesterol profiles.

In the diabetic clinic where the QIP took place, a large majority of PLWD initiating CSII therapy experienced improvement in HgA1c levels. Unfortunately, it became evident through routine follow-up that this improvement was short-lived in many CSII users, as evidenced by declines in HgA1c levels over time. This decline may be associated with a knowledge deficit, poor patient compliance with the use of this sophisticated technology, a lack of sufficient patient education focusing on CSII technology, or the interaction between the patient and health care provider.

The objective of the evaluation of the QIP is to recognize the impact of three 45-minute educational sessions on compliance and reduction in HgA1c. As the QIP has not been evaluated, there is a gap between administration of advanced education for PLWD using CSII therapy and the outcome of that education. Normalizing HgA1c levels in PLWD requiring insulin therapy promotes better patient outcomes, decreases morbidity and mortality rates, and improves socioeconomic consequences and quality of life. With the normalization of glycemic control, PLWD will experience a reduction in negative effects of diabetes such as nephropathy, neuropathy, and retinopathy, along with cardiovascular problems.

In this section of the paper, the evidence-based model used to guide the QIP project is described in further detail, along with the project's relevance to nursing practice, and the local background and context in which the project was developed. The role of the DNP study is further outlined in this section.

Frameworks, Concepts, and Models

The use of theory in advanced practice nursing is necessary to provide a framework in directing patient care and implementation of interventions. The Integrated Theory of Health Behavior Change (ITHBC) is a framework that works to engage the patient in positive behavior changes to improve or manage chronic illness. Ryan (2009) found that approximately 50% of chronic illness is caused by personal behaviors. The promotion of health and behavior changes is critical in improved patient outcomes. The ITHBC theory was the framework used to guide the nurse-led educational sessions for the QIP as it fostered increased participant knowledge, understanding and self-management skills when using CSII therapy (Ryan, 2009). As the ITHBC promotes engagement in self-management behaviors, the desired outcome is positive long-term change (Ryan, 2009). Ryan (2009) found that self-regulation, the key component of the ITHBC, recognizes the importance of setting appropriate goals, self-monitoring, which is a critical component to success of CSII therapy, decision making, and planning for, as well as engaging in, specific behaviors needed to adequately and safely control a chronic illness. The ITHBC also engages in social facilitation understanding the impact of social influence, support and promotion of self-management skills (Ryan, 2009). All the components of the ITHBC provided the needed guidance for a successful outcome of the QIP.

The CDC Process Evaluation Model (PEM) is defined as a business process that has a specific order of activities that occur across time and place (CDC, 2004). This model is a structure that emphasizes six interlinked steps that provide the framework to

tailor an evaluation toward a specific goal that is time oriented. The CDC PEM helps to organize and summarize the important elements of the QIP. Each step in the evaluation process is reliant on the completion of the previous step, creating a focal point of completion to move forward (CDC, 2004). The CDC PEM is a representation of one or more processes and the association of these processes performed by the research team (CDC, 2004). Utilizing a model that describes activities across time and place helped to distinguish and define gaps in the QIP and optimized glycemic control. Future objectives will also be defined by the PEM, as it will recognize areas that need improvement for successful outcomes.

Project Relevance to Nursing Practice

Nursing can provide diabetic education, especially in the early stages of T2D, as illustrated by Robertson (2012). Robertson reports clinical studies that support the positive effects of patient education and self-management, leading to better clinical outcomes. Also, according to Robertson, with well-informed patients, prevention of chronic disease will be evidenced through normalization of HgA1c levels. This, in turn, will promote improvement in quality of life and decrease in health care costs. Education is key in promoting better outcomes with PLWD requiring insulin therapy and those that require CSII therapy.

Diabetes affects 25.6 million Americans over the age of 20 (Robertson, 2012). Early diagnosis improves outcomes; however, the management and/or treatment of diabetes is paramount in the reduction of chronic disease. Nursing is pivotal in fostering patient/provider interaction along with introducing the necessary education and support

based on preventive treatment modalities along with lifestyle modifications. As nursing is patient oriented, spending more time with patients over physicians, the opportunity for education is more attainable. Robertson (2012) recognized the importance of behavioral patterns affecting lifestyle choices, along with continued patient/provider interaction; behavior and interaction are pivotal at enhancing the success of CSII therapy. Nursing has a solid role in reinforcing lifestyle changes with each encounter with a patient, reinforcing previous educational experiences. This doctoral project offers a better understanding in the gap between the use of CSII therapy, education, the normalization of glucose levels, and nursing's role in the educational process. As indicated through the researched literature, CSII therapy promotes improved HgA1c levels. However, with the necessary education and nurse/patient interaction, outcomes may improve.

Literature Review

Search Strategy

To find the most appropriate evidence-based literature associated with CSII therapy, self-care management skills, and education, multiple search sites were used. These include Medline, Cochran, ProQuest, PubMed, Cumulative Index to Nursing, Google Scholar and Allied Health Literature (CINAHL). All studies used included a full-text search with peer-reviewed articles. Keywords such *as diabetes, CSII, insulin pumps, MDI, usability, HgbA1c, type 1 diabetes, type 2 diabetes*, and *education* were used in the search for relevant evidence-based literature. The initial search, which used keywords *diabetes* and *education,* elicited 2,709,276 articles. With the addition of the other important keywords, such as *nursing* and *insulin pump therapy,* articles were narrowed

down to 861,926, with a final narrowing of the search to 25,852. Upon review of the most relevant and up-to-date literature, 176 articles were accepted for a much more thorough review, of which 10 articles were used for the literature review based on the criteria set for the project.

This literature review provided an overall understanding of CSII therapy, the technology associated with this state-of-the-art treatment, as well as diabetes education and the positive effects of these concepts in the optimization of HgA1c and glycemic control. This literature review also addressed the absence of research associated with T2D and the use of CSII therapy to optimize glycemic control, along with providing an improvement in overall quality of life for all PLWD. Health-related quality of life (HRLQ) is an essential element in the outcome of clinical trials, as well as overall health care (Varni et al., 2003). Diabetes Quality of Life (DQOL) measurement is the disease specific HRLQ used to pinpoint complications and recognize control of diabetes through educational measures, according to Varni et al. (2003). Despite new technology, therapeutic and treatment modalities, diabetes for most PLWD continues to be sub-optimally controlled. This is where additional educational approaches that focus on both the technological aspect of CSII therapy, as well as a personalized approach to diabetes education, can enhance treatment plans and promote improvement in glycemic control.

Nicolucci et al. (2013) found that most PLWD are not actively engaged with their health care providers and that education, along with psychosocial guidance, is missing in the treatment approach. In the Diabetes Attitudes, Wishes and Needs second study (DAWN2), 8596 adults with the diagnosis of diabetes in 17 countries were enrolled

(Nicolucci et al., 2013). Interestingly, as Nicolucci et al. (2013) found, no one country's outcomes were better or worse than others. Depression, using the WHO-5 Well-Being Index [(WHO-5) score ≤ 28] was 13.8%, diabetes-related distress [Problem Areas in Diabetes Scale 5 (PAID-5) score ≥ 40] was reported by 44.6% of participants, and overall quality of life was rated either 'poor' or 'very poor' by 12.2% of participants (Nicolucci et al., 2013).

Identifying personal barriers associated with diabetes is necessary in designing a personalized educational program for PLWD. This DNP student theorizes that, through the evaluation of the QIP, future nurse-led educational opportunities can be developed based off of the evaluation principles and outcomes. With a better understanding of the outcomes of this QIP through the evaluation, the promotion of future nurse-led educational opportunities can enhance positive patient outcomes in a multitude of chronic illnesses.

Education is the basis of understanding any disease process, and relieving the fear associated with the unknown. Maia, Reis and Torres (2016) found that in a longitudinal descriptive study providing self-care management education to 151 adults living with T2D aged 30-85, participants gained improvement in self-management skills ($P < 0.05$). Wu et al. (2013) also conducted a Quasi-experimental design study analyzing the efficacy of improving diabetes disease management after implementing a self-management program with people living with T2D. The study consisted of two groups, an experimental group ($n = 141$) and a control group ($n = 81$) (Wu et al., 2013). Post test scores were collected for body mass index (BMI) ($P < 0.001$), waistline circumference (*P*

< 0.01), HgA1c (*P < 0.001)* and depression/anxiety (*P < 0.001)* in the experimental group versus the control group. Post-test scores were colleceted for self-efficacy (*P < 0.001)* for the experimental group versus control (Wu et al., 2013). Both studies demonstrate that PLWD can effectively improve self-efficacy/management with educational programs that highlight specific barriers associated with optimizing diabetes control.

A significant problem associated with the use of CSII therapy is problem-solving when technology fails. This can become a major deterrent in the optimization of glycemic control. Fitzpatrick et al. (2013) demonstrated in a systematic review appraising sixteen intervention randomized controlled trials and eight quasi-experimental intervention studies, that 36% of the adult participants, along with 42% of children, displayed significant improvement in HgA1c. A systematic review performed by Wilkinson et al. (2014) focused on barriers/influences of self-management/self-care in adults with T1D and T2D. Interestingly, Wilkinson et al. (2014) found that there were barriers associated with the day-to-day management of diabetes including communication with providers and lack of educational programs providing the appropriate skills to successfully self-manage diabetes. The provision of patient-specific education is vital in the success of self-managing diabetes. It is evident in the literature that ample educational tools are either not available, or the time to deliver quality education to PLWD is lost with the quantity of patients seen in a clinic setting daily.

Much of the literature recognized that CSII therapy is superior to MDI therapy in reducing the amount of insulin used daily, the number of hypoglycemic episodes, and the

improvement in quality of life for PLWD. Unfortunately, most of the literature was geared toward T1D and the use of CSII therapy and very little was found regarding T2D. It is evident that, sooner than later, beta-cell production is restored with the use of insulin in the T2D population (Choi et al., 2013). Choi et al. (2013) found that, after 6 months of CSII therapy ($P < 0.001$), HgA1c was decreased from 8.7% at baseline to 6.3%, and during the subsequent 24 months, median HgA1c levels were maintained between 6.3% and 6.5%. C. Peptide levels also began to improve after 12 months of CSII therapy (Choi et al., 2013). Ghazanfar et al. (2016) studied that the use of CSII therapy improved the quality of life in PLWD, improved self-esteem and mood, and decreased stress and improved. Those participants in the study who were switched from MDI therapy to CSII therapy showed a significant decrease in insulin requirement ($P < 0.005$) from 1.7 ± 0.9 to 1.1 ± 0.6. This is a substantial finding, as weight gain will ensue with the increase of rapid insulin, especially in T2D (McCulloch, 2016.)

Deeb et al. (2015) studied the association of various key elements of CSII technology and the functionality of insulin pump therapy and the effects on blood glucose levels. Deeb et al. (2015) found that the frequency of blood glucose control monitoring, and the use of the Bolus Wizard feature of CSII therapy/technology, had favorable association with glycemic control. Upon review of the QIP, this DNP student theorizes that, with the provision of basic and advanced CSII technological training, along with patient-specific diabetes educational training, specifically self-management skills, improvement in glycemic control will ensue. When CSII therapy is initiated, training includes the insulin pump start with a diabetic educator from the desired insulin pump

manufacturer/company, which takes a couple of hours. Dependent on the clinic setting initiating the CSII therapy, training can include the initial start date, or can be extended out for a couple of days. This is not sufficient in providing the skills to appropriately apply the technology and sufficiently improve glycemic control. This was evidenced by a number of PLWD utilizing CSII therapy that were not controlled in the current setting of the diabetic clinic. This information then prompted the clinic to design a QIP that focused on nurse-led education and CSII therapy. As the DNP student works as a full-time nurse practitioner in this clinic setting, it was the desire of the student to then close the gap in the QIP, which was the evaluation phase to identify the outcome of the QIP educational sessions.

Reznik et al. (2014) conducted the largest study thus far for T2D utilizing CSII therapy, with 331 adult participants. This was a randomized control trial, with 168 participants started on CSII therapy and 163 on MDI therapy (Reznik et al., 2014). Baseline HgA1c was 9% for both groups, with the study being conducted over a six-month period (Reznik et al., 2014). Reznik et al. (2014) found that the CSII group reduced HgA1c by 1.1% in comparison with a 0.4% reduction in the MDI group. This study provided statistical data favoring CSII therapy use in the T2D population and the reduction and optimization of HgA1c and glycemic control. Again, a meta-analysis conducted by Weissberg-Benchell (2003), consisting of both adults and children with T1D, found that CSII therapy improved glycemic control better than when compared to MDI therapy. Finally, Li et al. (2016) conducted a randomized, parallel study comparing three groups of T2D participants using CSII therapy versus MDI therapy that consisted of

3 MDI and 4 MDI. Findings were consistent, with CSII experiencing the most improvement in glycemic control over MDI therapy (4.26 $\pm$ 1.88 days) in the CSII group versus (6.17 $\pm$ 2.36 days) MDI3 group, and (5.81 $\pm$ 2.46) in the MDI4 group; CSII group ($P < 0.05$) versus MDI3 and MDI groups (Li, et al., 2016). Li et al (2016) also found that the longstanding T2D group fared better on CSII therapy versus MDI3/4 therapy ($P < 0.05$).

Interestingly, although these studies provided insight into the problems associated with self-management and diabetes, along with the lack of studies in regard to T2D and CSII therapy, there is a barrier associated with the optimization of glycemic control and the utilization of CSII therapy in PLWD, both T1D and T2D. This is why further study is needed to discover whether the technological advancements of CSII therapy prevent PLWD from optimally controlling their HgA1c.

Evidence to Address the Gaps-in-Practice

Reviewing the literature, the gaps-in-practice regarding CSII therapy were mixed, as there were positive and negative outcomes associated with the initiation and continued use of CSII therapy. Some of the studies had a limited time exposure to the treatment, which could identify the positive outcomes; however, few of the studies focused on the nurse-led educational segment that is associated with this DNP project. Gaps-in-practice with education were very similar to what the diabetic clinic is identifying with many of the PLWD using CSII therapy. Unfortunately, the literature was focused mainly on self-management education and not strictly on person-specific education, focusing on both the promotion of self-management skills and technological training for CSII use. For these

reasons, it is very important to promote diabetic education that encompasses not only the promotion of self-management but is also geared toward the ever-changing technological aspect of medicine. A summary of this project's literature view is presented in Appendix B.

Local Background and Context

Evidence to Justify the Problem

Advances in the monitoring and controlling of HgA1c in PLWD requiring insulin therapy has improved with new technology, specifically CSII therapy. With review of existing PLWD insulin pump downloads (Trend reports) at the diabetic clinic, it has become evident that there is a gap in the use of CSII therapy and normalization of HgA1c. Even with the convenience associated with using CSII therapy, patient compliance, knowledge deficit, or patient/provider interaction may be barriers to normalization of HgA1c levels.

There is variable success with the CSII therapy reported in the literature as well (Li, et al., 2016). The initiation of CSII therapy results in a rapid HgA1c reduction, but then it begins to increase within the first year of therapy. The objective of this DNP project is to evaluate the impact of the QIP on knowledge deficits and HgA1c levels. It is theorized that the elevation in HgA1c after initiation of therapy is related to the basic education provided at the start of therapy, along with only routine quarterly follow-up visits for insulin pump adjustments, many times made by the provider (Maia, 2016). Upon evaluation of the QIP, we hope to identify whether there is a gap in nursing and patient education preventing positive outcomes associated with CSII therapy.

Institutional Context

The intended practice setting is a diabetic clinic located in large southwestern state that sees an estimated 100 adult patients daily for a number of endocrine disorders. Approximately 50 percent of these patients have diabetes. There is a large volume of diabetic patients that require oral glycemic agents, as well as MDI and CSII therapy. The DNP student's affiliation with the practice is as a full-time practicing family nurse practitioner working closely with diabetic patients.

Definition of Relevant Terms

Basal insulin: A continuous 24-hour delivery of insulin mimicking the function of the pancreas (Walsh & Roberts, 2013).

Blood glucose level: Measurement of serum blood glucose levels (Walsh & Roberts, 2013).

Carbohydrate counting: The carbohydrates in any given food (Walsh & Roberts, 2013).

Continuous subcutaneous insulin infusion (CSII): Insulin pump therapy (Conget et al., 2016).

Correction bolus: A delivery of insulin to correct a high blood glucose levels (Walsh & Roberts, 2013).

Diabetic neuropathy: Damage to nerves resulting from poor glycemic control (Walsh & Roberts, 2013).

Diabetic retinopathy: Visual problems created from damage to the small vessels in the eyes, which can cause blindness resulting from poor glycemic control (Walsh & Roberts, 2013).

Glycated Hemoglobin (HgA1c): Is the most widely used clinical test correlated with diabetes; HgA1c is the estimation of blood glucose control as red blood cells are highly permeable to glucose (McCulloch, 2016). HgA1c reflects a mean blood glucose over a period of 8 to 12 weeks (McCulloch, 2016).

Hypoglycemia: Lower than normal blood glucose levels defined as blood glucose levels <70 (Walsh, Roberts, 2013).

Hyperglycemia: Higher than usual blood glucose levels defined as blood glucose levels >100 (Walsh & Roberts, 2013).

Insulin Pump: A small device that is programmed to delivery basal/bolus insulin, replacing MDI therapy (Walsh & Roberts, 2013).

Multiple Daily Injections (MDI): Insulin delivery via multiple daily subcutaneous injections (Conget et al., 2016).

Type 1 diabetes (T1D): Destruction of pancreatic beta cells, which then leads complete insulin deficiency is the classic characteristic of T1DM (McCulloch, 2016).

Type 2 diabetes (T2D): Hyperglycemia, insulin deficiency and resistance are the classic characterizations (McCulloch, 2016); the most common type of diabetes.

Role of the DNP Student

Professional Relationship to the Project

At Walden University, the DNP student is prepared through scholastic and clinical experiences to meet the foundational elements outlined by the American Association of Colleges of Nursing (AACN). The Doctor of Nursing Practice Program (DNP) at Walden University promotes the student's understanding of what roles and responsibilities they should possess upon graduation. Through this preparation, my final requirement of this DNP program was to evaluate an EB-QIP project at my chosen practice setting prior to graduation (Walden University, n.d.). This project fulfills all criteria to formally graduate as a knowledgeable DNP and further the future of nursing through continued EB-QIPs.

Professional Role in the Project

Currently, my professional role is working as a family nurse practitioner (FNP) in the diabetic clinic setting that is my chosen practice setting. My role in this setting for this project is also as the DNP student, working daily with PLWD who require both oral antiglycemic agents, MDI, and CSII therapy. With my current position as an FNP, I am uniquely qualified to identify the shortfalls in glycemic control with oral antiglycemic agents, as well as MDI and CSII therapy, as I work daily with PLWD and formulate treatment plans.

Participants in the QIP included patients at the clinic who had been initiated on CSII therapy. All information was provided by the diabetic clinic and was not be retrieved by the student. No patient identifiers were used in the evaluation process, as all

data was categorized by groups i.e., male/female. Upon categorizing the data, I was able to recognize trends in adherence to therapy, technological difficulties, and the effects of lifestyle on diabetes.

Motivations for the Doctoral Project

Working daily with PLWD requiring CSII therapy, the DNP student recognized a trend between the initiation and follow-up of CSII therapy, and a gap in normalizing glycemic control. It has been the DNP student's experience, through close observation and working with PLWD requiring insulin therapy, that initially there is significant improvement in HgA1c levels within a six-month period from initiation of CSII therapy; however, this improvement is not sustained. There may be a number of factors that preclude the sustainment or normalization of glycemic control. These include, but are not limited to, patient tolerance and/or intolerance to insulin and therapy; biological changes to the patient as a result of age or gender; endocrine system function; patient lifestyle and stress levels; provider interaction and/or monitoring intervals; Sensory-Augmented Pump Therapy (SAPT); and CSII technological shortfalls (Maia, 2016). It is the goal of this project to identify whether this trend is the norm, or a lack of sufficient education in both self-management skills and technological training specific to CSII therapy.

Potential Bias

The appearance of bias may be implied if the evaluator of a QIP favors a particular outcome. This could potentially cause bias toward the outcome of the evaluation, having it lean closer to the favored end. Another form of bias could be the selection of the participants in the QIP. As the QIP involved nurse-led educational

sessions, participants with high learning aptitudes could have been chosen, which could have promoted a favored outcome as well. As the DNP student did not chose the participants in the QIP, and will not be extracting data for the evaluation process, bias should not be an issue. Upon initiation of the QIP, the diabetic clinicians felt it was best to use one manufacturer for the initial training. As there are three main CSII manufacturers that the diabetic clinic works with, using one manufacturer eliminated any bias upon evaluation of the QIP, as each manufacturer has different reports to follow behavior, blood glucose levels, and administration of insulin. The use of one manufacturer allows for equal evaluation of the trend report categories.

Summary

There is variable success with CSII therapy reported in the literature. HgA1c is the gold-standard measurement of glycemic control, and affords health care providers a value in which to recognize a patient who may be noncompliant, complacent, or lacks the knowledge associated with optimizing CSII technology. It has been identified that patient-provider interaction is critical to the success of lowering HgA1c levels and optimizing the use of CSII technology. Nursing plays a pivotal role in delivering specific patient-centered education/training on CSII technology and self-management of diabetes, as evidenced by the literature.

Patient behavior impacts the longevity of CSII therapy, and can be transformed with appropriate educational approaches within the nursing context. As evidenced in the literature thus far, optimization of CSII therapy is questionable, which can be attributed to a number of reasons. This DNP project will evaluate the success of the QIP, which

consisted of three 45-minute educational sessions and their impact on improvement in HgA1c and patient compliance. It is theorized that, with the proper tools through continued education to operate CSII technology, PLWD will become more compliant in entering the correct data, in turn receiving the appropriate amount of insulin to optimize glucose levels and improve HgA1c levels.

Essential for the implementation and evaluation of any intervention employed by advanced practice nurses is to identify theories specific to the intervention and evaluation desired. The ITHBC theory was used as the framework of the QIP, along with the CDC PEM theory that was used in this DNP project as the framework to guide the evaluation of the QIP. By using a theory-based approach in nursing, time wasted in evaluating irrelevant material and the avoidance of distractions can be prevented. Also, use of a theoretical framework can foster improvement in communication among peers, patients, and other professionals. Using the CDC PEM and the ITHBC Theory, recognition of possible shortfalls in the educational process can be ascertained and adjustments to the educational program can be applied to improve health outcomes of future participants.

Section 3: Collection and Analysis of Evidence

Introduction

Quarterly follow-up visits for PLWD using CSII therapy have been routine at the diabetic clinic where the QIP took place. These routine visits include insulin pump downloads and interpretation of the data retrieved from the Adherence Report, among other reports. This interpretation helps the clinician determine any necessary changes to help optimize glycemic control. In depth education focusing on CSII technology is minimal at these visits for a number of reasons, most significantly time restraints. This has resulted in many PLWD underusing the many functions of the CSII technology. The purpose of this DNP project was to evaluate the impact the QIP had on promoting self-management skills and improving the knowledge deficit and HgA1c levels.

As identified in the literature review, Bode (2010) found that the complexity of CSII technology was a notable barrier to the compliance of PLWD, as well as optimization of HgA1c levels. Bergenstal et al. (2013) found key contributors to poor glycemic control among PLWD utilizing CSII therapy included the underutilization of glucose data, as well as inconsistent glucose data collection. This is a common occurrence in the diabetic clinic and prompted this DNP project.

This section elaborates on the study design, extraction of data, methodology and description of how the extracted data was analyzed. Specific goals and objectives are established in order to develop an appropriate research methodology to secure a positive endpoint in successfully reaching the goals and objectives identified for this DNP project. Upon completion of the evaluation of the QIP initiated at the diabetic clinic, recognition

of possible short-falls in the educational program can be identified and corrected to improve outcomes for future program participants.

Practice-Focused Question

Thanks to new technology, there have been significant advances in the monitoring and controlling of HgA1c in PLWD over the last decade. Despite these advances, PLWD requiring insulin using the most up-to-date technology, for example CSII therapy, continue to fall short in optimizing HgA1c levels. Working closely with the diabetic population in the diabetic clinic setting, through evaluation of data derived from the insulin pump Adherence/Trend Reports, I discovered that there is an apparent knowledge deficit in the correct use of the technology. This deficit, or problem, became the focus of the DNP question: How will nurse-led educational sessions for PLWD using CSII therapy impact the knowledge deficit and HgA1c levels? As Wu et al. (2013) demonstrate, continued patient education can improve self-efficacy and self-management of diabetes, promoting awareness of the importance of diligent glucose monitoring and proper use of advanced technology. Without the tools to be successful in these advanced technologies, many PLWD will be at a loss in managing the intricate applications of CSII.

Project Purpose and Method Alignment

The purpose of the DNP project was to evaluate the QIP that was implemented at the diabetic clinic that consisted of three 45-minute educational session for PLWD using CSII therapy. The data retrieved for the evaluation process was provided to me from the clinic for evaluation purposes, allowing me to recognize trends in adherence to therapy,

technological difficulties, and the effects of lifestyle and diabetes. No patient identifiers were used in the evaluation process, as all data was placed in categories appropriate for the evaluation. Also, through the evaluation, the data retrieved via the Trend reports distinguished whether or not there was improvement in compliance, understanding and usability of CSII therapy. This information is relevant, as attitudes of PLWD play a significant role in compliance and optimized HgA1c levels. Evaluation of all data, combined through Trend reports and aggregate serum laboratory HgA1c levels 3 months pre-education and 3 months post-education, served as a means of quantifying the end goal of this QIP: improved compliance and HgA1c levels.

Key Operational Definitions

Adherence Report: Reports patient behavior data for a specific period of time (normally 2 weeks). This report provides adherence through data such as glucose measurements, bolus events, and insulin pump activities (Medtronic, 2009).

Log Book Report: Presents glucose, carbohydrate levels, and insulin infused on hourly intervals (24 hours). This report recognizes glycemic control over a specific period of time (2 weeks) (Medtronic, 2009).

Device Settings Report: This report lists all insulin pump settings. This information is used as a guide in the interpretation of other reports and to make appropriate adjustments to insulin distribution based off of information obtained through the other trend reports (Medtronic, 2009).

Trend Reports: A few reports that include all function of CSII technology focusing on usage by the user. These reports are used to properly monitor and adjust treatment (Medtronic, 2009).

Statistics Table: Provides measurements including average blood glucose, number of meter glucose reading, readings above and below target settings, carbohydrate daily average, bolus daily average, basal daily average, and average total daily insulin (Medtronic, 2009).

Sources of Evidence

Archival and Operational Data

The clinic used two sources of data, current and archived. Data used for this evaluation came from the electronic medical record (EMR), as well as the CSII database. All information was provided to me by the diabetic clinic for evaluation purposes. No patient identifiers were used in the evaluation process.

Description of Data Collection

The diabetic clinic provided all data necessary for the evaluation void of patient identifiers. Data consisted of information provided from each participant's Medtronic insulin pump Trend Reports, specifically the Adherence Report. The extraction of Adherence Reports occurred at each visit at the diabetic clinic and was recorded in the patient's electronic record. The Adherence Report focuses on behavioral data that is based off of daily indices such as glucose measurements, bolus events, and other insulin pump activities (Medtronic, 2009). Aggregate serum HgA1c levels were provided to me from the diabetic clinic at 3 months pre-education and 3 months post-education and,

again, no patient identifiers were present as each data set was placed into categories for evaluation.

Participants

This EB-QIP took place at the diabetic clinic where I work as a full-time FNP, and am completing my clinical experience as a student. The participants of the EB-QIP were male and female patients at the diabetic clinic who volunteered to participate, were ≥ 18 years of age, with T1D and T2D using a CSII device (Medtronic) for glycemic control with a HgA1c ≥ 8.

Procedure

Walden University requires that an Institutional Review Board (IRB) application be completed by all DNP students for EB-QIP projects that include the collection and analysis of data concerning people, projects that are addressing gaps in practice, and all doctoral projects (Walden University, n.d.). The IRB approval ensures proper conduct from the DNP student in performing the EB-QIP, along with the evaluation of the EB-QIP devoid of any coercions to the participants of the EB-QIP (Walden University, n.d.).

As stated earlier, all data was retrieved from the diabetic clinic, void of patient identifiers, and provided to me for evaluation of the QIP. This commenced only once IRB had been approved. With the use of the categorical data, along with aggregate serum HgA1c levels pre-and post-educational sessions that were also categorized between male and female participants, trends were identified indicating success or need for educational session improvement.

Protections

Pump reliability and validity was based on approval through the Federal Food, Drug, and Cosmetic Act (FDA). This Act includes annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Safety assurance cases are provided to the FDA for pump devices, which demonstrate acceptability of risk mitigations, adequate device reliability, and adequate designs verification and validation of device specifications (HHS, 2015). Patient reliability was not guaranteed as necessary data to create sufficient information for pump download needed to be uploaded into the device by the patient.

Analysis and Synthesis

Data Systems and Procedures

Microsoft Excel was used to organize data, data sets, and variables. Maintaining control of the data collection, specific criteria must have been met prior to entering a participants' information into the project; as I was not retrieving the information, and was provided it from the diabetic clinic performing the QIP, all data was required to be void of any patient identifiers. Also, all data was placed in categories specific to the evaluation process. This information was vital to the findings and outcomes of the project.

Data Integrity

If there was any data missing from the CSII downloads, it was first determined if this information had a significant impact on the analysis. As Grove et al. (2013) explain, it may have to be excluded from the project depending on the impact of the information. During the evaluation of the EB-QIP, outliers may have been identified. According to Polit (2010) outliers are numerical values that are outside the normal range of the values

for the other data. An example of an outlier for this project would include those participants with glycemic control that appeared to be optimized by a serum HgA1c level well below 6.0. However, false appearing-optimized HgA1c could have been in relation to blood glucose variability, which can cause untoward effects on internal organs.

Significant variability in blood glucose levels can be as hazardous to the promotion of complications from diabetes as uncontrolled hyperglycemia is (Service, 2013). This variability is also a sign of knowledge deficit in the understanding/usability of CSII technology. To ascertain the accuracy of an outlier, the data needed to be scrutinized to identify where the error occurred. Errors could have occured while data was entered either by using improper values or codes as Polit (2010) explains. Also, Polit (2010) reports that outliers can be found through data cleaning; inspecting values through the frequency distribution.

Data Analysis

A simple t-test was used to compare two averages and identify differences, and as to whether those differences happened by chance. Also, a run chart was used to review the trends for each CSII download look at the progression of specific data points over time. The run chart was important, as non-statistically significant trends can be identified with multiple data points over time.

Descriptive statistics were used to summarize the sample characteristics and from this description a frequency variable was plotted based off specific variables such as HgA1c levels, number of times patients checked their blood glucose levels daily, number of times the tubing/setting was changed, and number of times BWZ and the override

function were used. IBM SPSS software was used for the statistical analysis of this project.

Summary

Medications and technology have had a profound effect on diabetes; however, with even the newest advances in technology, normalization of HgA1c with the use of CSII therapy still has its downfalls. Through evaluation of quantitative data retrieved from serum laboratory studies and data from the Trend Reports acquired from the CSII database, recognition of the gap in achieving improved glycemic control, as well as self-management skills for those PLWD utilizing CSII therapy can be achieved.

With the implementation of the three 45-minute educational sessions, and the existing data gathered pre- and post-session, the evaluation of the EB-QIP identified gaps in education, the use of CSII therapy, and the optimization of glycemic control. The population size was determined based on the criteria established by the diabetic clinic performing the QIP. All ethical principles were followed closely during the evaluation of the QIP in order to protect participant information. No personal information was used or divulged in the study.

Section 4: Findings and Recommendations

Introduction

Regardless of being given the most up-to-date treatment for T1 and T2D, using the most advanced technology in the form of CSII therapy, PLWD continue to struggle with controlling blood glucose levels. Complications associated with uncontrolled diabetes include, but are not limited to, cardiovascular/cerebrovascular disease, renal impairment, vision problems such as retinopathy, and peripheral neuropathy that can lead to amputations (McCulloch, 2016). McCulloch (2016) estimates that 14% of health care expenditures in the United States, or $245 billion, is used to treat the complications associated with uncontrolled diabetes.

Type 2 diabetes is on a swing upward in growth, with expectations of an increase to approximately 64% according to Rowley and Bezold (2012). This is an increase from 19.1 to 53.1 million by the year 2025 (Rowley & Bezold, 2012). That new treatment modalities such as oral glycemic agents, improved insulin dialogs, and updated technology do not appear to be controlling the issue at hand is concerning. T2D is expected to increase to approximately 415 million cases worldwide (Rowley & Bezold, 2012); equating to an annual economic impact of $500 billion.

Through my observation of PLWD utilizing CSII therapy in the clinic setting, it had become obvious that there was a gap between the initiation of CSII therapy in PLWD and continued education. This gap may contribute to the lack in achievement of optimal glycemic control. Through evaluation of insulin pump reports it was also apparent that that many CSII users were making use of only minimal features of the CSII technology.

As a result, the development of a quality improvement project was initiated to determine whether a nurse-led educational program would enhance the usability of the CSII technology, thus improving HgA1c levels and outcomes by reducing complications associated with T2D. The primary concentration of the practice-focused question was whether a nurse-led educational program could promote self-management skills, improve the knowledge deficit with regard to the usability of CSII technology in PLWD, and improve HgA1c levels. With the practice-focused question aligned, three 45-minute nurse-led educational sessions were performed specific to each participant. The purpose of this doctoral project was to evaluate the outcome of the educational sessions and to determine whether there was a positive impact on the participants' HgA1c levels post-education.

I obtained evidence for this project through the insulin pump reports downloaded with each session, using the Adherence Report, and the serum aggregate HgA1c levels of each participant three months pre-education and post-education. The Adherence Report provides information about the participant's compliance with the use of CSII technology, allowing for daily, weekly and monthly views of usability. Serum aggregate HgA1c levels are important in gauging improvement in participants' glycemic control. Subsequently, I categorized and assessed the information obtained to determine participants' improvement in CSII features. I assessed serum aggregate HgA1c levels to recognize improvement and/or failure to improve from the initiation of the program. Prior to the implementation of the project, I obtained an approval from the internal medicine

clinic's director, as well as Walden Universities Institutional Review Board (IRB); IRB approval number is 01-30-18-0410353 .

Findings and Implications

Demographics and Descriptive Data

Over a period of six months, a total of 122 patients were identified as potential participants at the diabetic clinic where the QIP was performed. Out of the 122 patients, 34 signed up to participate in the QIP, a nurse-led educational program that consisted of a series of three 45-minute educational sessions that were patient-specific. One nurse practitioner at the site performed the educational sessions and reviewed the Adherence Reports, most specifically the Trend Reports and serum aggregate HgA1c levels. This information created the guiding principles of the QIP.

Out of the 34 participants, one expired, three were lost to follow-up, and four withdrew from the program due to time restraints. PLWD (T1D and T2D) who utilized CSII therapy for the administration of insulin for one year or greater were included in the QIP. Other parameters for inclusion in the program were participants having a HgA1c ≥ 7 or significant variability in daily blood glucose levels that can falsely lower HgA1c levels within optimum range. As Hirsch (2015) found, using the HgA1c to correlate diabetes control is leaving many people, especially those with T2D, with uncontrolled diabetes in relation to glycemic variability (GV), thus creating opportunity for continued complications associated with diabetes. According to Hirsch (2015), GV should be considered as a first-line indicator of optimal diabetes control.

Upon evaluation of the QIP, patient safety and privacy were of the utmost importance. There was no identifying participant information provided to me for evaluation purposes. All data collected was provided to me by the site that the QIP was performed. I placed the data in categories using Microsoft Excel. My analysis of the categorical information commenced upon IRB approval.

Descriptive Data

The results of the evaluation involved secondary data consisting of Trend Reports from the insulin pumps, void of any participant identifying information, along with aggregate HgA1c levels provided by the site where the QIP took place. I placed all data into categories specific to the evaluation to provide a comparison from the initiation of education to completion of the educational program. The QIP consisted of 26 participants; n=12 (46%) were male, and n=14 (54%) were female. Average age of the male group was 69.8 years; average age of the female group was 54.2 years, with an overall combined average age of 61.5 years.

No oral glycemic agents or additional diabetic medications were added or removed from the participants' regimen during the QIP, negating any additional adjustments to HgA1c levels r/t new medications or changes to current treatment regimen. This was done to avoid changing any of the end results that would alter the outcome of the educational program. All participants used one CSII manufacturer, eliminating any differences in technology, use, or performance. Aggregate serum HgA1c levels of each participant were provided to me for evaluation purposes, again, void of any participant identifying information.

Results

I performed all statistical analyses using IBM SPSS version 24, with all categorical information input into Microsoft Excel. I met the goal of determining the effect of the nurse-led educational sessions over time by performing a one-tailed, paired samples t-test with the level of significance set at .05. I identified four categories allowing for the necessary statistical evaluation: serum aggregate HgA1c levels, blood glucose log use, Bolus Wizard use, and override use.

Table 1 illustrates the comparison of the pre-education and post-education categories. Table 2 illustrates each category's data.

Table 1

Comparison of Pre-Education and Post-Education Categories

Variable	Mean	Standard Deviation	P Value
Pre-Education HgA1c	8.98	1.68	-
Post-Education HgA1c	7.99	1.16	.001
Pre-Education Bolus Wizard	3.67	2.26	-
Post-Education Bolus Wizard	3.86	2.17	.246
Pre-Education Blood Glucose	3.49	1.20	-
Post-Education Blood Glucose	4.02	1.83	.081
Pre-Education Override	14.26	24.68	-
Post-Education Override	10.35	21.35	.17

Table 2

Trend Report Data Participants (n=26)

Category	Session 1	Session 2	Session 3
	Average use Blood Glucose log		
Male/Female (n=26)	3.5	3.6	4.0
Males (n=12)	3.9	3.9	4.3
Females (n=14)	3.1	3.2	3.8
	Average Bolus Wizard Use		
Male/Female (n=26)	3.6	3.8	3.8
Males (n=12)	3.5	3.8	3.8
Females (n=14)	3.8	3.7	3.9
	Average Override %		
Male/Female (n=26)	14.3	14.2	10.3
Males (n=12)	13.0	12.7	12.4
Females (n=14)	15.3	15.4	8.5

The above tables represent the four categories pre-education and post-education. The pre-education mean of serum aggregate HgA1c levels was $M = 8.98$ ($SD = 1.68$). By comparison, the mean of post-education serum aggregate HgA1c levels decreased to $M = 7.99$ ($SD = 1.66$), $t(25) = 3.8$, $p \leq .05$.

The mean of blood glucose log use, category two, was $M = 3.49$ ($SD = 1.20$) pre-education. By comparison, post-education was associated with a numerically greater blood glucose log use, $M = 4.02$ ($SD = 1.83$), $t(25) = -1.4$, $p \geq .05$.

The mean of Bolus Wizard use, category three, was $M = 3.67$ ($SD = 2.26$) pre-education. By comparison, post-education was associated with a numerically larger Bolus Wizard use, $M = 3.86$ ($SD = 2.17$), $t(25) = -70$, $p \geq .05$.

The mean of override use, category four, was $M = 14.26$ ($SD = 24.68$) pre-education. By comparison, post-education was associated with a numerically smaller use of the override function, $M = 10.35$ ($SD = 21.35$), $t(25) = 2.4$, $p \leq .05$.

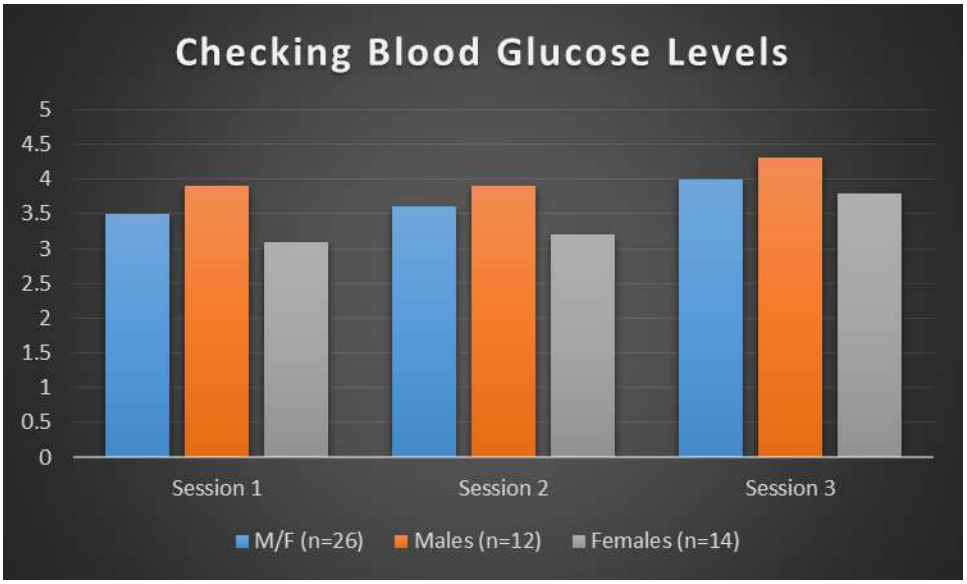

Figure 1. Blood Glucose Log

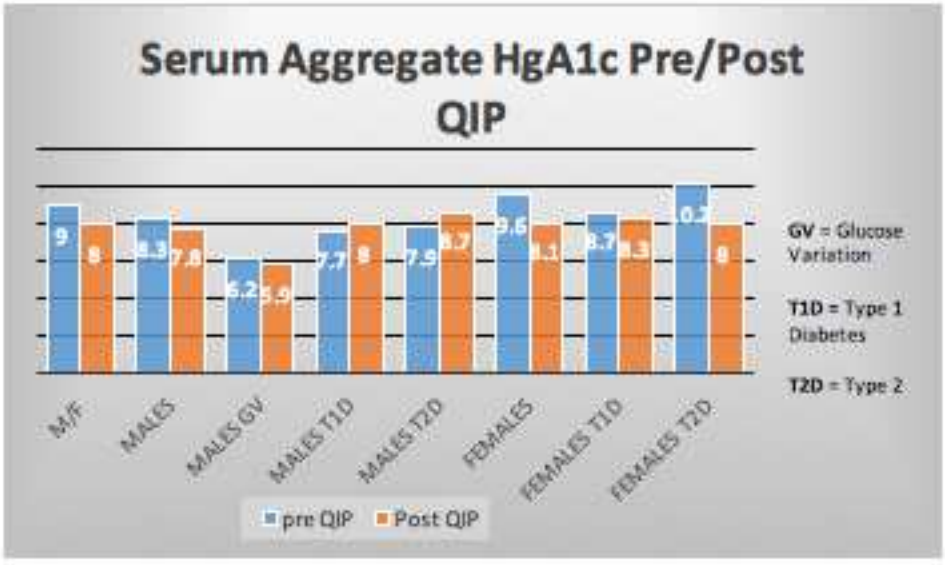

Figure 2. Serum Aggregate HgA1c Pre/Post QIP

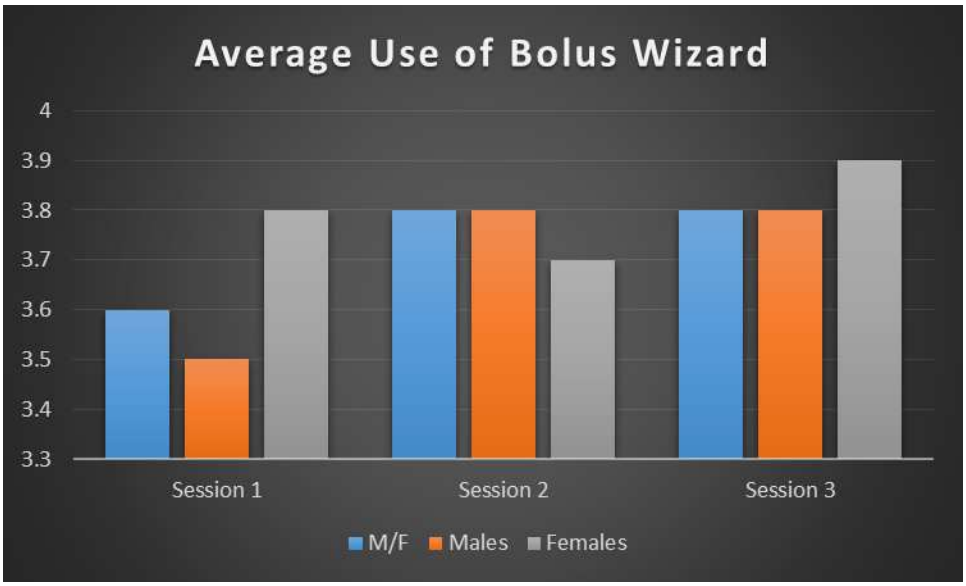

Figure 3. Average use of Bolus Wizard

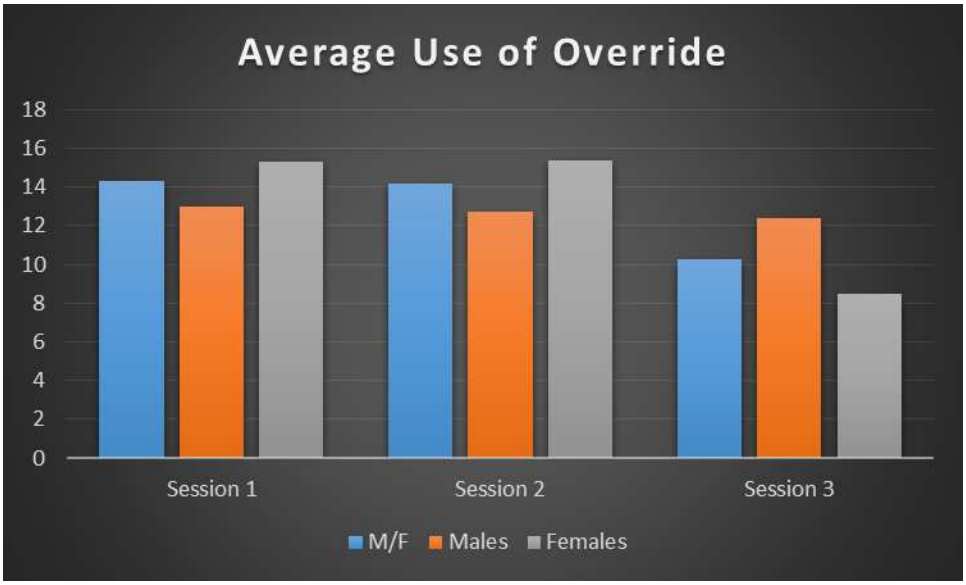

Figure 4. Average Use of Override

The above figures demonstrate the comparison between pre-education and post-education in the use of the blood glucose function, serum aggregate HgA1c levels, Bolus Wizard, and the use of the override function.

Unanticipated Limitations/Outcomes and Their Potential Impact on Findings

This project had a number of unanticipated limitations. First, the number of participants could have been larger to provide more data sets. With the small number of participants in the QIP, statistical significance in the analysis of the evaluation may have been lower than anticipated. Secondly, the turnover in medical assistant staffing within the diabetic clinic, and the need to train new staff, created issues with lost data from the insulin pump downloads, decreasing the potential for larger numbers of participants in the program. Vital information that is routinely extracted from each CSII device is to be scanned in each patient's chart at each visit. With new staff, routine processes within the clinic were neglected and vital information was lost.

As insulin pumps are the newest technology in diabetes management, technological failures were also problems associated with the analysis of the programs' success. There were a few participants who experienced technological difficulties with the insulin pumps requiring assistance from the manufacturer. In relation to lost data, two of the participants' follow-up sessions had to be rescheduled to allow for appropriate data collection prior to the upcoming session. Expanding the hours of operation may have alleviated time-restraint issues that necessitated some participants withdraw from the program.

Implications for Individuals, Communities, Institutions, and Systems

The implications of this study shed light on the importance of continued nurse-led education. Although the number of participants in the QIP was small, the results indicated improvement in all four categories with respect to number of times the

participants checked their blood glucose levels daily, the number of times the participants used the Bolus Wizard feature, and the reduction in the percentage of overrides performed by the participants. This information is critical in promoting improvement in blood glucose levels. The most telling statistic from the analysis of the data was the reduction in the overall HgA1c by an average of 1.1 post-education. This reduction in HgA1c is significant as indicated in the UKPDS study that demonstrated tight control of HgA1c levels proved decrease microvascular complications (King, Peacock & Donnelly, 1999).

The results of this project have provided keen insight as to the importance of continued diabetic education in the prevention of the complications associated with uncontrolled diabetes at this clinic. As the future of diabetes treatment continues to rapidly change, it is crucial that providers, as well as patients, continue to be educated on the state-of-the-art technological changes used for the treatment of diabetes.

The diabetic clinic where the QIP and evaluation was performed is a very busy clinic, with approximately 50% of the patient population treated for diabetes. The average time allotted for patient visits is 15 or 30 minutes. This does not leave a great deal of time for patient education. However, upon my review of the results from the evaluation of the QIP, it has become apparent that with specific time set aside for more thorough education, improvement in HgA1c levels can be achieved. Though the diabetic clinic is independent, having no association with a hospital system or additional clinics, the findings can still be shared amongst nursing peers, prompting similar clinics to institute nurse-led education focusing on diabetes and the use of advanced technologies.

Legal, Ethical and Economic Implications

Beneficence, the act of preventing harm, is critical in the treatment of diabetes or any other chronic disease state. With the provision of educational sessions for PLWD utilizing CSII therapy, a better understanding of the importance of using this technology appropriately to arrive at the best end result is achieved. With the adoption of nurse-led educational sessions that focus on the use of the advanced technology associated with CSII therapy, along with continued promotion of self-management skills, complications associated with uncontrolled diabetes can be prevented.

Diabetes has become a worldwide epidemic leading to chronic health conditions and crippling the financial welfare of the United States and many other countries through the world (McCulloch & Robertson, 2016). Screening for diabetes should be performed on all adult patients in order to identify the signs of prediabetes and provide adequate preventive treatment to reduce the complications associated with diabetes. PLWD who utilize CSII therapy need appropriate education focusing on the use of this advanced technology to optimally control HgA1c levels (Ghazanfar et al., 2016). This is an ethical dilemma in the medical community, as we are neglecting the ethical principal of 'justice' if we do not provide this life-saving education.

It is the responsibility of the entire medical community to continue developing quality improvement projects to redesign and establish protocols and provide the best evidence-based practice principles (Fitzpatrick et al., 2013). Legally, it is our responsibility to continue to update and improve old standards of operation and

implement, through research, new standards of care to promote the best possible outcomes.

Implications for Positive Social Change

There are social implications associated with this project in a number of areas: PLWD, family members, the diabetic clinic, and the nursing profession. The results of this QIP have changed the process in which PLWD utilizing CSII therapy are educated in the diabetic clinic. PLWD who use CSII therapy will be provided additional time for short educational sessions with each office visit. The director of the diabetic clinic supported the QIP and has worked closely with the nurse practitioners in this clinic to establish new policies and protocols for patient education.

Recommendations

The evaluation of the nurse-led education QIP program implemented in the diabetes clinic addressed gaps in knowledge deficits experienced by PLWD using CSII therapy for the treatment of diabetes. Formulating educational sessions that were participant-specific, and focusing on CSII technology and self-management skills, allowed a self-paced learning experience. The four categories that were the focus of the evaluation all demonstrated improvements post-education. At the start of the QIP, the average HgA1c level for the participant group was 8.98%; three months after completion of the QIP, the average HgA1c level for the participant group decreased to 7.99%.

The number of times blood glucose levels are checked throughout the day can positively influence a reduction in HgA1c over time. Looking at the blood glucose log, the average number of times the participants of the QIP checked their blood glucose

levels prior to the initiation of the QIP was 3.5 times daily. Three months post-completion of the QIP, the average number of times the participants checked their blood glucose levels increased to 4.0 times daily.

The Bolus Wizard function of the insulin pump takes into account the number of carbohydrates that are entered into the database of the CSII technology, along with blood glucose levels (Medtronic, 2009). The input of this information allows the technology to formulate an adjusted insulin administration dose based off of the data entered by the user. Prior to the initiation of the QIP, the combined average use of the BW by QIP participants was 3.6 times daily. Three months post-QIP, the combined average use of the BW by participants increased to 3.8 times daily.

The override function of the insulin pump allows for the user to change the insulin administration that the BW has suggested from the formulation of the carbohydrate and blood glucose levels the user inputs into the database. Overriding the suggestions made by BW may indicate a knowledge deficit by the user or the misunderstanding of how to properly use the CSII technology (Medtronic, 2009). Prior to the initiation of the QIP, the combined average use of the OR function was 14%. Three months post-QIP the combined participant average use of the OR function decreased to 10.3%.

Although the sample size was small, with only 26 participants in the QIP, and statistically two of the categories failed to significantly improve, the evaluation did provide proof that nurse-led education can improve patient outcomes. I recommend further study with a larger population of participants to delve deeper into the positive effects nurse-led education has on PLWD, as well as a number of other chronic illnesses.

Second, I recommended that each PLWD who is initiated on CSII therapy be provided education on the advanced technology of this treatment modality. This education can be provided in individual or group settings and should consist of multiple sessions. Upon conclusion, participants should able to demonstrate back to the instructor what was learned. By providing intensive nurse-led educational sessions, knowledge gaps PLWD may have regarding the advanced technology can be identified and closed, and overall outcomes can improve.

Strengths and Limitations of the Project

Strengths associated with this DNP project include the positive outcomes noted through the evaluation process. Although the data for two of the categories was not statistically significant, review of the Trend Report did show improvement in all three categories evaluated, along with a 1.0% average drop in HgA1c of the participants. This information allowed the diabetic clinic to improve guidelines and begin to develop new protocols that will be followed at the initiation of CSII therapy and beyond. Of course, further study with a larger sample population is needed to delve into the positive effects nurse-led education can have on patient populations with chronic illness.

Limitations associated with this DNP project are the small sample size of participants and length of the QIP. When a sample size is small, it is more difficult to discern whether improvement is due to random chance or if the improvement is related to the intervention implemented (Grove, Burns, & Gray, 2013). Also, as this diabetic clinic works with only an adult population, the QIP was only provided to people older than 18 years of age. Children, who make up a large portion of PLWD, were not evaluated.

Summary

Although the evaluation of the QIP had variable success statistically, all four categories that were evaluated demonstrated improvement post-education. The most impressive improvement was in the HgA1c levels with a reduction of 1.1. This reduction is significant as demonstrated by UKPDS study. Formulation of continued nurse-led patient education programs is critical to the success in the management and use of the advanced CSII technology and positive patient outcomes. Further study on this subject is warranted allowing for closure in knowledge deficits and clearer understanding for both the user and provider of these advanced technologies.

Section 5: Dissemination Plan

Disseminating evidence into practice involves a planned process that focuses on a target population and transfers knowledge from research into practice (Wilson, Petticrew, Calnan, & Nazareth, 2010). According to Marin-Gonzalez et al. (2017), dissemination is essential for communicating and implementing research findings, drawing focused attention to stakeholders involved in the study, and clearly displaying the research outputs. The purpose of evidence-based research is to strengthen baseline knowledge with improved guidelines and protocols through dissemination of evidence. This crucial element in research is the backbone of modern medicine and improved patient outcomes. The AACN put forth the Essentials for Doctoral Education for Advanced Nursing Practice to transform and change education required for advanced practice nursing (AACN, 2006). This education is focused on the translation of evidence into practice promoting best outcomes through the expansion of scientific knowledge (AACN, 2006).

The findings from this project will be used to better understand the behavior of the patients in the diabetic clinic that use CSII therapy. As this treatment modality continues to have technological advances, it is pertinent that patient education be at the forefront from initiation through continuation of this therapy. I discussed the findings of this project in detail with the director of the clinic, as well as the nurse practitioners and medical staff. Although the EB-QIP consisted of a small population of patients in this clinic setting, it provided great insight into the behavioral mechanisms between compliance and complacency.

The dissemination of the project's findings will be ongoing in the diabetes clinic. Discussions with educators from Medtronic have also commenced about designing new protocols for PLWD who are being considered candidates for CSII therapy. From the dissemination of the information obtained through the evaluation of the QIP, a few different protocol designs are being drafted to be presented to the director of the clinic for review. It is believed that when one of the providers in the clinic identifies a PLWD who is a candidate for CSII therapy, the candidate should be educated on the pathophysiology of diabetes, carbohydrates, dietary intake, and treatment options. It has been discussed that education sessions should be broken into multiple sessions, so as not to overwhelm the participants, and to provide a broad overview of diabetes and describe the commitment that is required from both the PLWD and the provider.

Analysis of Self

Analysis as Practitioner

This section is interesting, as it makes me look within and describe how I view myself. It is similar to looking in a mirror and examining the image that looks back at you; often criticizing shortfalls. The past 14 years have been a journey; one that I knew would end, but that end was so far in the distance I could barely see it.

My role as a practitioner is, and continues to be challenging, exciting, exhausting, frustrating, and rewarding. This position comes with many feelings that can become muddled. My daughter is completing her degree in psychology and one day was telling me about the "imposter" syndrome. This syndrome can be described as a person's inability to outwardly show their accomplishments, always in fear of being exposed as a

fraud (Sakulku & Alexander, 2011). There are many times that I have felt this 'imposter' syndrome. I am forever educating myself, but most often I feel that there is still so much to learn so I can be up-to-date on the best practice principles to provide the best care possible to my patients. I also have become very humbled in this field of medicine, as I have come to realize that I am the only resource for some of my patients. As such, I have reached the understanding that I must always continually grow and learn in my position as a practitioner.

Analysis as Scholar

My development as a scholar has been an interesting journey. I have learned so much through the development of this project. My understanding about research is much greater after having had the opportunity to develop a project from the ground up and see the difficulties and challenges that are faced. I did not go into nursing to be a researcher, but have slowly realized through this educational process that we are all scholars. It is so very important that I keep striving to learn the best possible ways to deliver care, and this can only be done through research and the development, by way of evaluation and dissemination, of best evidence-based practice principles. I definitely see myself growing as a scholar and delving deeper into nursing research. It is through the DNP role that the stage is set to apply research findings into the practice setting. Through the translation of evidence-based research, protocols can be changed and improved upon. Often the research is published, however, it is not always applied in the correct setting where it would be of greatest benefit. My future interests will involve diabetes care and nurse-led

education, developing new protocols for educating PLWD to improve the outcomes of complications related to the disease.

Analysis as Project Manager

As project manager, there were many challenges I faced. The main challenge was getting the appropriate help from the staff. This included the extraction of the de-identified data that I needed. As this is a very active diabetic clinic most days, the staff is extremely busy. Finding the time to help get me the necessary information was difficult. I did find that I would mostly rely on one or two specific staff members to help with me with this part of the project.

My ownership in the project did grow with the role of the project manager, leading to a stronger leadership role within the organization. I found that I had become very detailed in the tasks at hand and found myself directing the staff through daily goals. It is very important as a leader to respect your staff and have them respect you. I found that, even through the most stressful moments, I was stronger in leading, providing positive reinforcement, and encouraging the staff to become part of the project. This provided great initiative, and I found that many of the staff members who appeared disconnected to my needs as project lead started asking how they could help.

Challenges, Solutions, and Insights

Becoming a nurse was a goal of mine for as long as I can remember, and with this goal came many challenges. Now that I am crossing the finish line of my education, having gone as far as I can scholastically in nursing, I reflect on the many challenges I have faced, most recently through the completion of this DNP project. The first challenge

I encountered was really understanding what the DNP project was. It took me a very long time to understand ‘what’ my goals and objectives were, as I felt that there were many loose ends that needed to be tied up. However, I was unsure how to ‘tie’ them together. It was only through hours of reading and rereading my proposal that the solution to this challenge appeared. The solution to many challenges in life is reaching out for necessary guidance. As such, I am grateful to my peers and instructors who helped me understand the path of my project.

Over the past three years, I have grown immensely, finding ways to overcome significant stress and anxiety when faced with situations that were difficult to understand. I have reexamined my potential as a scholar over and over again throughout the past year, questioning my ability to truly get to the end of this project. These struggles have made me stronger, knowing that as long as I set your sights on what is most important, I can accomplish whatever I set my mind to.

In many ways, I look at the completion of my doctoral studies and my DNP project as finishing a marathon. I have had the pleasure of running two full marathons in my life. The start of the marathon is exhilarating; wondering if you can accomplish such a feat. The moment you cross the finish line, worn down emotionally and physically, the emotions that you feel are indescribable. You are overcome with a feeling of great accomplishment, both physically and mentally, along with the feeling of overwhelming joy and gratitude that your body and mind carried you through. This is the same indescribable feeling I have about completing this DNP project and completing my

doctoral studies. It has been a marathon to complete these past three years, and my feeling of accomplishment cannot be described in words.

The success of this project, however, was only achieved with the help of many others. I learned very quickly that attempting anything alone is never as fulfilling as having others work with you. Without the guidance of my committee chair and members, my project would not be where it is today. My committee chair has been my advocate and educator, teaching me the important steps in becoming a true scholar. Without her and every person involved in this project, I would not be where I am today. The main lesson learned has been understanding the importance of each person involved and knowing when to ask questions.

Summary

Diabetes continues to be a growing problem in the United States and worldwide, affecting 415 million people. It is the sixth leading cause of disability (Chatterjee, Khunti, & Davies, 2017). The global economic burden, according to Chatterjee, Khunti, & Davies (2017), is estimated at $825 billion. There are numerous treatment options available for PLWD including oral glycemic agents, MDI therapy, and CSII therapy. The technological aspects of CSII therapy are advancing so rapidly, providing the most state-of-the-art options for the treatment of diabetes, that PLWD and providers are left scrambling to keep up.

Literature suggests that CSII therapy is superior to MDI therapy in reducing the amount of daily insulin use, hypoglycemic episodes, and improving quality of life for PLWD. The literature, however, did not provide substantial evidence about advanced

technological education provided to PLWD and the use of CSII therapy. Deeb et al. (2015) did, however, find that frequent use of the Bolus Wizard and blood glucose log features of the insulin pump did have a favorable effect associated with glycemic control. Much of the literature suggested that nurse-led education focusing on self-management skills demonstrated an improvement in self-efficacy/management for PLWD.

The purpose of this DNP project was to evaluate the impact of a nurse-led educational program on glycemic control. This program was designed to identify whether or not the provision of advanced technological training for CSII therapy provided improvement in the understanding of the CSII technology for PLWD. It was the premise of the QIP project to improve technological understanding, thereby improving HgA1c levels of the participants post-education.

Upon evaluation of the statistical data, it was evident that all four categories that were evaluated improved. Although this QIP project had a small number of participants (N=26), it did show that, with additional education, there was improvement in the usability of the CSII technology. Through these observations, the diabetic clinic is working closely with the representatives from the insulin pump manufacturers that are used most frequently in the clinic to develop an educational protocol for the initiation of CSII therapy, along with continued nurse-led education for PLWD.

It is, however, recommended that this specialized arena of nurse-led diabetes education be further studied with a larger population of PLWD. With the advancements in technology, it is a failure of the medical community if providers, and users of these advance technological modalities to treat chronic illness, are not thoroughly trained on

the functionality of the technology. To continue to develop advanced treatment options for PLWD and not offer appropriate education on the operation of the equipment, effective glycemic control will be lost in confusion and the treatment will continue to be misunderstood.

References

Adriaanse, M. C., Drewes, H. W., Van der Heide, I., Struijs, J. N., & Baan, C. A. (2016). The impact of comorbid chronic conditions on quality of life in type 2 diabetes patients. *Quality of Life Research*, *25*, 175-182. http://doi.org/10.1007/s11136-015-1061-0

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced nursing practice*. Washington, DC: Author. Retrieved from http://www.aacn.nche.edu/dnp/Essentials.pdf

American Association of Diabetes Educators. (2014, June 6). *Continuous subcutaneous insulin infusion (CSII)* [White Paper]. Retrieved from https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/publications/csii_pentulimate.pdf?sfvrsn=2

Bergenstal, R. M., Ahmann, A. J., Bailey, T., Beck, R. W., Bissen, J., Buckingham, B., . . . Wesley, D. M. (2013). Recommendations for standardizing glucose reporting and analysis to optimize clinical decision making in diabetes: The ambulatory glucose profile. *Journal of Diabetes Science and Technology*, *7*(2), 562-578. http://doi.org/10.1177/193229681300700234

Blood sugar testing: why, when and how. (2017). Retrieved from http://www.mayoclinic.org/diseases-conditions/diabetes/-indepth/blood-sugar/art-20046628Bode, B. W. (2010). Insulin pump use in type 2 diabetes. *Diabetes Technology and Therapeutics*, *12*(Suppl 1), S17-S21. http://doi.org/10.1089/dia.2009.0192

Brennan, M. B., Allen, G. O., Ferguson, P. D., McBride, J. A., Crnich, C. J., & Smith, M. A. (2017). The association between geographic density of infectious disease physicians and limb preservation in patients with diabetic foot ulcers. *Open Forum Infectious Diseases*, *4*(1), 1-8. http://doi.org/10.1093/ofid/ofx015

Carelink pro therapy management software for diabetes. (2009). Retrieved from http://www.professional.medtronicdiabetes.com/carelink-system

Carroll, J. K., Fiscella, K., Epstein, R. M., Sanders, M. R., & Williams, G. C. (2012). A 5a's communication intervention to promote physical activity in underserved populations. *BMC Health Services Research, 12*(374). http://doi.org/10.1186/1472-6963-12-374

Centers for Disease Control and Prevention. (1999). *Overview of the framework for program evaluation.* http:www.cdc.gov/eval

Centers for Disease Control and Prevention. (2011, January 14). CDC health disparities and inequalities report-United states 2011. *Morbidity and Mortality Weekly Report, 60S*. Retrieved from https://www.cdc.gov/mmwr/pdf/other/su6001.pdf

Centers for Disease Control and Prevention. (2013). *CDC health disparities and inequalities report - United States 2013.* (2013). Retrieved from https://www.cdc.gov/mmwr/pdf/other/su6001.pdf

Chamberlain, J., & Gilgen, E. (2015). Do perceptions of insulin pump usability impact attitudes toward insulin pump therapy? A pilot study of individuals with type 1 and insulin-treated type 2 diabetes. *Journal of Diabetes Science and Technology*, *9*(1), 105-110. http://doi.org/10.1177/1932296814552822

Chatterjee, S., Khunti, K., & Davies, M. J. (2017). Type 2 diabetes. *The Lancet*, *389*(10085), 2239-2251. http://doi.org/10.1016/S0140-6736(17)30058-2

Chen, S., Feng, L., Rickels, M., Peleckis, A., Sokolsky, O., & Lee, I. (2015). *A data-driven behavior modeling and analysis framework for diabetic patients on insulin pumps*. Paper presented at the IEEE International Conference on Healthcare Informatics 2015. Retrieved from http://repository.upenn.edu/cis_papers/791

Choi, S., Lee, J., Lee, J., Kim, S., Han, S., Kim, I., & Noh, Y. (2013). Improvement of b-cell function after achievement of optimal glycemic control via long-term continuous subcutaneous insulin infusion therapy in non-newly diagnosed type 2 diabetic patients with suboptimal glycemic control. *Diabetes/Metabolism Research and Reviews*, *29*, 473-482. http://doi.org/10.1002/dmrr.2416

Conget, I., Castaneda, J., Petrovski, G., Guerci, B., Racault, A. S., Reznik, Y., ... Aronson, R. (2016). The impact of insulin pump therapy on glycemic profiles in patients with type 2 diabetes: Data from the opt2mise study. *Diabetes Technology & Therapeutics*, *18*(1), 22-28. http://doi.org/10.1089/dia.2015.0159

Cryer, P. E. (2016). *Management of hypoglycemia during treatment of diabetes mellitus.* Retrieved from http://www.uptodate.com/contents/management-of-hypoglycemia-during-treatment-of-diabetes-mellitus

DNP project process guide. (n.d.). Retrieved from Center for Research Quality: http://academicguides.waldenu.edu/researchcenter

Day, G., E., & Brownie, S. (2014) Rising to the challenge: Nursing leadership via nurse-led service provision for chronic disease management and prevention. *Nursing*

and Health 2(2), 30-34. http://doi.org/10.13189/nh.2014.020202.

Deeb, A., Abu-Awad, S., Abood, S., El-Abiary, M., Al-Jubeh, J., Yousef, H., ... Mustafa, H. (2015). Important determinants of diabetes control in insulin pump therapy in patients with type 1 diabetes mellitus. *Diabetes Technology & Therapeutics*, *17*(3), 1-5. http://dx.doi.org/10.1089/dia.2014.0224

Dickinson, J., Lipman, R., & O'Brian, C. (2015). Diabetes education as a career choice. *The Diabetes EDUCATOR*, *41*(6), 665-676. http://doi.org/10.1177/0145721715608952

Driver, V. R., Fabbi, M., Lavery, L. A., & Gibbons, G. (2010). The costs of diabetic foot: The economic case for the limb salvage team. *Journal of Vascular Surgery*, *52*(12S), 17-22. http://doi.org/10.1016/j.jvs.2010.06.003

Employer health benefit 2015 annual survey. (2015). Retrieved from The Kaiser Family Foundation: https://www.kff.org/report-section/ehbs-2015-summary-of-findings/Farid, D., Haidar, A., & Rabasa-Lhoret, R. (2013). Is insulin pump therapy a treatment option for some type 2 diabetes patient requiring intensified insulin regimen. *Canadian Journal of Diabetes*, *37*, 139-142. http://doi.org/10.1016/j.jcjd.2013.03.021

Fineout-Overholt, E., Melnyk, B. M., & Schultz, A. (2005). Transforming health care from the inside out: advancing evidence based practice in the 21st century. *Journal of Professional Nursing*, *21*(6), 335-344. https://doi.org/10.1016/j.profnurs.2005.10.005

Fitzpatrick, S. L., Schumann, K. P., & Hill-Briggs, F. (2013). Problem solving

interventions for diabetes self-management and control: A systematic review of literature. *Diabetes Research and Clinical Practice*, *100*, 145-161. http://doi.org/10.1016/j.diabres.2012.12.016

Franklin, H., Rajan, M., Tseng, C. L., Pogach, L., & Sinha, A. (2014). Cost of lower-limb amputation in US veterans with diabetes using health services data in fiscal years 2004 and 2010. *Journal of Rehabilitation Research & Development*, *51*(8), 1325-1330. http://doi.org/10.1682/JRRD.2013.11.0249

Ghazanfar, H., Rizvi, S. W., Khurram, A., Orooj, F., & Qaiser, I. (2016). Impact of insulin pump on quality of life of diabetic patients. *Indian Journal of Endocrinology and Metabolism*, *20*(4), 506-511. http://doi.org/10.4103/2230-8210.183472

Gonder-Frederick, L., Shepard, J., & Peterson, N. (2011). Closed-loop glucose control: Psychological and behavioral considerations. *Journal of Diabetes Science and Technology*, *5*(6), 1387-1395. http://doi.org/10.1177/193229681100500610

Grenell, J. A., & Turner, A. E. (2016, November 10). Diabetic peripheral neuropathy: An overview. *The Clinical Advisor*, 12-16. Retrieved from http://www.clinicaladvisor.com/diabetes-resource-center/diabetic-peripheral-neuropathy/article/571729/

Grove, S., Burns, N., & Gray, J. (2013). *The practice of nursing research. Appraisal, synthesis, and generation of evidence.* (seventh ed.). St. Louis, MS: Elsevier.

Gucciardi, E., Wing-Sheung Chan, V., Manuel, L., & Sidani, S. (2013). A systematic

literature review of diabetes self-management education features to improve diabetes education in women of black African/Caribbean and Hispanic/Latin American ethnicity. *Patient Education and Counseling*, *92*(2013), 235-254. http://doi.org/10.1016/j.pec.2013.03.007

Hirsch, I. B. (2015). Glycemic variability and diabetes complications: Does it matter? Of course it does? *Diabetes Care*, *38*, 1610-1614. https://doi.org/10.2337/dc14-2898

Humble, W., & Tormala, W. (2011). *Arizona diabetes burden report: 2011*. Retrieved from http://www.azdhs.gov/documents/.../diabetes/reports-data/AZ-Diabete-Burden-Report--2011.pdf

King, P., Peacock, I., & Donnelly, R. (1999). The UK prospective diabetes study (UKPDS): Clinical and therapeutic implications for type 2 diabetes. *The British Journal of Clinical Pharmacology*, *4*(5), 643-648. https://doi.org/10.1046/j.13565.2125.1999.00092.x

Levich, B., R. (2011). Diabetes management: Optimizing roles for nurses in insulin initiation. *Journal of Multidisciplinary Healthcare 4*, 15-24. http://www.doi.org/10-2147//JMDH.S16451

Liberman, A., Buckingham, B., & Phillip, M. (2014). Diabetes technology and the human factor. *Diabetes Technology & Therapeutics 16,* 110-117. http://www.doi.org/10.1089/dia.2014.1513

Li, F., Fu, L., Zhang, W., Su, X., Wu, J., Sun, J., & Ma, J. (2016). Blood glucose fluctuations in type 2 diabetes patients treated with multiple daily injections. *Journal of Diabetes Research*, *2016*. http://doi.org/10.1155/2016/1028945

Lim, J., & Zebrack, B. (2004). Caring for family members with chronic physical illness: A critical review of caregiver literature. *Health and Quality of Life Outcomes*, *2*(50). http://doi.org/10.1186/1477-7525-2-50

Long-term trends in diabetes. (2017). Retrieved from http://www.cdc.gov/diabetes/data

Maia, M. A., Reis, I. A., & Torres, H. D. (2016). Relationship between the users' contact time in educational programs on diabetes mellitus and self-care skills and knowledge. *Journal of Nursing*, *50*(1), 59-64. http://doi.org/10.1590/S0080-623420160000100008

Maindal, H. T., Skriver, M. V., Kirkevold, M., Lauritzen, T., & Sandbaek, A. (2011). Comorbidity and lack of education countered participation in a diabetes prevention self-management program. Nursing and Healthcare of Chronic Illness, *3*(3), 293-301. http://doi.org/10.1111/j.1752-9824.2011.01103.x

Marin-Gonzalez, E., Malmusi, D., Camprubi, L., & Borrell, C. (2017). The role of dissemination as a fundamental part of a research project. *International Journal of Health Services*, *47*(2), 258-276. https://doi.org/10.1177/0020731416676227

Medical devices. (2015). Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

McCulloch, D. K. (2016A). *Management of persistent hyperglycemia in type 2 diabetes mellitus.* Retrieved from http://www.uptodate.com/content/management-of-peristent-hyperglycemia.

McCulloch, D. K. (2016B). *Classification of diabetes mellitus and genetic diabetic*

syndromes. Retrieved from http://www.uptodatelcom/contents/classification-of-diabetes-mellitus-and-genetic-diabetic-syndrome

McCulloch, D., & Robertson, R. (2016). *Risk factors for type 2 diabetes mellitus.* Retrieved from https://www.uptodate.com/contents/risk-factors-for-type-2-diabetes-mellitus

Moxey, P. W., Gogalniceanu, P., Hinchliffe, R. J., Loftus, I. M., Jones, K. J., Thompson, M. M., & Holt, P. J. (2011). Lower extremity amputations - A review of global variability in incidence. *Diabetic Medicine*, *28*, 1144-1153. http://doi.org/10.1111/j.1464-5491.2011.03279x

Nicolucci, A., Burns, K. K., Holt, R. I., Comaschi, M., Hermanns, N., Ishii, H., ... Peyrot, M. (2013). Diabetes attitudes, wishes and needs second study (DAWN2): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabetic Medicine*, *30*, 767-777. http://org/10.1111/dme.12245

Nixon, R., Folwell, R., & Pickup, J. (2014). Variation in the quality and sustainability in long-term glycemic control with continuous subcutaneous insulin infusion. *Diabetic Medicine*, *31*, 1174-1177. http://doi.org/10.1111/dme.12486

Pozzilli, P., Battelino, T., Danne, T., Hovorka, R., Jarosz-Chobot, P., & Renard, E. (2016). Continuous subcutaneous insulin infusion in diabetes: Patient populations, safety, efficacy, and pharmacoeconomics. *Diabetes/Metabolism Research and Reviews*, *32*(1), 21-39. http://doi.org/10.1002/dmrr.2653

Reznik, Y., & Cohen, O. (2013). Insulin pump for type 2 diabetes. *Diabetes Care*. http://doi.org/10.2337/dcS13-2027

Reznik, Y., Cohen, O., Aronson, R., Conget, I., Runzis, S., Castaneda, J., & Lee, S. (2014). Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): A randomized open-label controlled trial. *Lancet*, *384*, 1265-72. http://dx.doi.org/10.1016/S0140-6736(14)61037-0

Robertson, C. (2012). The role of the nurse practitioner in the diagnosis and early management of type 2 diabetes. *Journal of the American Academy of Nurse Practitioners*, *24*, 225-233. http://doi.org/10.1111/j.1745-7599.2012.00719.x

Rowley, W. R., & Bezold, C. (2012). Creating public awareness: State 2025 diabetes forecasts. *Population Health Management*, *15*(4), 194-200. http://doi.org/10.1089/pop.2011.0053

Ryan, P. (2009). Integrated theory of health behavior change: Background and intervention development. *Clinical Nurse Specialist*, *23*(3), 161-172. https://doi.org/10.1097/NURS.0b013e3181a42373

Saboo, B. D., & Talaviya, P. A. (2012). Continuous subcutaneous insulin infusion: practical issues. *Indian Journal of Endocrinology and Metabolism*, *16*(2), 269-262. http://doi.org/10.4103/2230-8210.104055

Sakulku, J., & Alexander, J. (2011). The imposter syndrome. *International Journal of Behavioral Science*, *6*(1), 73-92. https://doi.org/10.14456/ijbs.2011.6

Service, J., F. (2013). Glucose variability. *Diabetes 62,* 1398-1404. http://www.doi.org/10.2337/db12-1396

Smide, B., & Nygren, U. (2013). A pilot study to determine levels of diabetes knowledge among health care workers in nursing homes. *European Diabetes Nursing*, *10*(1),

13-18. http://doi.org/10.1002/edn.218

Spurlock, M. (Director), & Spurlock, M. (Writer). (2004). *Supersize me* [DVD]. Retrieved from http://www.imbd.com/title/tt0390521/Tingen, M. S., Burnett, A. H., Murchison, R. B., & Zhu, H. (2009). The importance of nursing research. *The Journal of Nursing Education*, *48*(3), 167-170. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3677814

Tricco, T. C., Ivers, N. M., Grimshaw, J. M., Moher, D., Turner, L., Galipeau, J., . . . Shojania, K. (2012). Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. *Lancet*, *379*, 2252-2261. http://doi.org/10.1016/S0140-6736(12)60480-2

Varni, J. W., Gottschalk, M., Burwinkle, T. M., Kaufman, F., Jacobs, J. R., & Jones, K. L. (2003). The pedsql tm in type 1 and pet 2 diabetes. *Diabetes Care*, *26*(3), 631-637. http://doi.org/10.2337/diacare.26.3.631

Walsh, J., & Roberts, R. (Eds.). (2013). *Pumping insulin. Everything you need to succeed on an insulin pump*. San Diego, CA: Torrey Pines Press.

Weissberg-Benchell, J., Antisdel-Lomaglio, J., & Seshadri, R. (2003). Insulin pump therapy. *Diabetes Care, 26,* 1079-1083. http://dx.doi.org/10.2337/diacare.264.1079

Weng, J., Li, Y., Shi, L., Zhang, Q., Zhu, D., Xlan, Y., . . . Cheng, H. (2008). Effect of intensive insulin therapy on beta-cell function and glycemic control in patients with newly diagnosed type 2 diabetes: A multicentre randomised parallel-group trial. *Lancet*, *371*(9626), 1753-1760. http://doi.org/10.1016/S0140-6736 908

060762-X

Wilkinson, A., Whitehead, L., & Ritchie, L. (2014). Factors influencing the ability to self-manage diabetes for adults living with type 1 and type 2 diabetes. *International Journal of Nursing Studies*, *51*, 111-122. http://doi.org/10.1016/j.ijnurstu.2013.01.006.

Wilson, P. M., Petticrew, M., Calnan, M. W., & Nazareth, I. (2010). Disseminating research findings: what should researchers do? A systematic scoping review of conceptual framework. *Implementation Science*, *5*(91), 1-16. Retrieved from http://www.implementationscience.com/content/5/1/91

Wu, S. V., Liang, S., Lee, M., Yu, N., & Kao, M. (2013). The efficacy of self-management programme for people with diabetes, after special training programme for healthcare workers in taiwan: A quasi-experimental design. *Journal of Clinical Nursing*, *23*, 2515-2524. http://dx.doi.org/10.1111/jocn.12440

Zhang, P., Zhang, X., Brown, J., Vistisen, D., Sicree, R., Shaw, J., & Nichols, G. (2010). Global healthcare expenditure on diabetes for 2010 and 2030. *Diabetes Research and Clinical Practice*, *87*, 293-301. https://doi.org/10.1016/j.diabres.2010.01.026

Appendix A: Summary of Educational Sessions

Self-Management/CSII (Insulin Pump) Patient Education	
Session 1/Day 1 - Introduction	• Introduction to the program. • Download Insulin Pump • Review most recent serum lab values with participant (HgA1c, C. Peptide, Fasting insulin/blood glucose) • Review categories of Trend Reports (Adherence report, Logbook report, Device settings report, Daily detail report) • Review Adherence report with participant. • Correlate serum lab values with data entries in Trend reports.
Session 2/Day 2	• Review previous session's discussion and answer questions. • Review insulin pump download and Trend report categories ~ Review Logbook report in detail. • Discuss self-management skills to improve compliance with Logbook entries i.e., carbohydrates/blood glucose levels. • Discuss carbohydrate in greater detail. • Discuss physical activity and nutrition and their effect on blood glucose levels. • Answer questions/concerns from the participant

Session 3/Day 3	• Download Insulin Pump ~ review most recent lab values with participant. • Review categories of Trend Reports ~ focus on reports from the download that participant has questions on. • Review self-management skills that the participant is struggling with. • Provide educational reference material that was discussed at previous sessions with the participant at the end of the session.

Appendix B: Summary of Literature Review

Author, Title, Journal	Year	Purpose	Findings	Population	Type of Study	Primary or Secondary	How does this help understand the Topic
Ghazanfar, H., Rizvi, S. W., Khurram, A., Orooj, F., & Qaiser, I. (2016). Impact of insulin pump on quality of life of diabetic patients. *Indian Journal of Endocrinology and Metabolism*, *20*(4), 506-511. http://dx.doi.org/10.4103/2230-8210.183472	2015	Identifying the impact of continuous subcutaneous insulin infusion (CSII) therapy on the quality of life in patient with type 2 diabetes mellitus (T2DM) and compare it to the quality of life of patient with T2DM using multiple daily injection (MDI) therapy.	The use of CSII therapy improved quality of life such as self-esteem, decreased stress and overall improved mood. Also, it improved physical health, flexibility in mealtime, as well as ease of travel. Those patients who shifted from MDI therapy to CSII therapy showed a significant ($P<0.005$) decrease in insulin requirement from 1.7 ± 0.9 to 1.1 ± 0.6 U/kg/day. Hypoglycemic episodes were also reduced in 81.1% of the participants, which may be accounted for in the reduction of insulin requirement.	Male/Female age >50, with T2DM diagnosis >6 months requiring use of insulin therapy	Case-control study	**Primary** **Key Words:** Insulin, quality of life, T2 DM, insulin pump, multiple daily injection therapy **Grade** Level III; Well-designed case control not randomized	This study identifies the importance of utilizing advanced technology to optimize glycemic control. With glycemic control the development of complications associated with diabetes mellitus can be reduced. Also, with the use of CSII therapy it was found that the participants in the study experienced fewer episodes of hypoglycemia, improving overall quality of life.

Choi, S., Lee, J., Lee, J., Kim, S., Han, S., Kim, I., & Noh, Y. (2013). Improvement of b-cell function after achievement of optimal glycemic control via long-term continuous subcutaneous insulin infusion therapy in non-newly diagnosed type 2 diabetic patients with suboptimal glycemic control . *Diabetes/Metabolism Research and Reviews*, *29*, 473-482. http://dx.doi.org/10.1002/dmrr.2416	2013	Identify the efficacy of B-cell restoration in with the use of CSII therapy in non-newly diagnosed T2DM	In non-newly diagnosed T2DM there was noted to be significant improvement in B-cell production with achieving optimal glycemic control with CSII therapy. After 6 months of CSII therapy (*P<0.001*) glycated hemoglobin A1c (HbA1c) was decreased from 8.7% at baseline to 6.3%, and during the subsequent 24 months median HbA1c levels were maintained between 6.3% and 6.5%. C. Peptide levels also began to raise after 12 months of CSII therapy.	Patients with T2DM diagnosed >1 year, with HbA2c level of ≥7% despite previous treatment, absence of renal impairment prior to CSII therapy, and available for follow-up for at least 6 months after initiation of CSII therapy.	Retrospective Study ~ Case Report **Grade** Level IV; No groups to compare	**Primary**	This study provides insight into the promotion of improved B-cell function in T2DM with the utilization of CSII therapy and improvement of glycemic control. With a reduction of HbA1c levels from baseline of 8.7% to 6.3%, it was found that the C. Peptide levels also improved within a 12-month period.
Deeb, A., Abu-Awad, S., Abood, S., El-Abiary, M., Al-Jubeh,	2015	This study was designed to assess the association of various key elements of	The frequency of blood glucose control monitoring and the use of	T1DM consisting of children with median age of 12 and adults	RCT	**Secondary** Key words: T1DM, CSII	This study provides significant information regarding the use of key features of CSII technology

J., Yousef, H., ... Mustafa, H. (2015). Important determinants of diabetes control in insulin pump therapy in patients with type 1 diabetes mellitus. *Diabetes Technology & Therapeutics*, *17*(3), 1-5. http://dx.doi.org/10.1089/dia.2014.0224		insulin pump functions and their effect on blood glucose control	the Bolus Wizard had favorable association with glycemic control, which was more significant in the children's groups. More significant, however, those patients who used the bolus feature of the CSII technology had better glycemic control.	with a median age of 27.5.	**Grade** Level II; Well-designed RCT	therapy, insulin pump, bolus, glycemic control	and the improvement in glycemic control. It also identifies that human behavior has a significant role in the use of CSII therapy and glycemic control outcome.
Reznik, Y., Cohen, O., Aronson, R., Conget, I., Runzis, S., Castaneda, J., & Lee, S. (2014). Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise	2014	This study was comparing the difference between MDI and CSII therapy and the optimization of glycemic control. The OpT2mise study was designed to define the specific role CSII therapy had on T2DM and to define safety, rate of hypoglycemia, patient adherence, and patient	495 patients were entered into the run-in phase of the study, with 331 participants randomized. 168 participants were started on CSII therapy, whereas 163 were continued on MDI therapy. Baseline HbA1c was 9% for both groups. The study was	T2DM patients with poor glycemic control despite MDI therapy, age 30-75, male and female ~ Exclusion pregnancy or a maximum daily dose of insulin 220 units.	RCT **Grade** Level II; Well-designed RCT	**Primary**	This study provided significant statistical data proving that optimization of glycemic control can be obtained through the use of CSII therapy safely in T2DM patients, with a reduction in TDD of insulin.

): a randomized open-label controlled trial. *Lancet*, *384*, 1265-72. http://dx.doi.org/10.1016/S0140-6736(14)61037-0		satisfaction.	conducted over a 6-month period after which the CSII group had a reduction in HbA1c of 1.1% in comparison to the MDI group which had a reduction of 0.4%; the mean difference between the two groups was 07%. The CSII group used a mean total daily dose (TDD) of insulin of 97 units, where the MDI group used a mean TDD of 122 units of insulin (*P<0.0001*). There was no significant body weight difference between the groups.				
Weissberg-Benchell, J., Antisdel-Lomaglio, J., & Seshadri, R. (2003). Insulin pump therapy. *Diabetes Care*, *26*, 1079-1083.	2003	This study was conducted to identify the metabolic and psychosocial impact on children and adults with the use of CSII therapy.	The study findings proved that CSII therapy was associated with improved glycemic control when compared to MDI therapy. Also, it was found that the utilization of CSII therapy was not associated with any adverse	As this was a meta-analysis there were 52 studies included in the analysis with a total of 1,557 subjects with T1DM, adult and pediatric.	Meta-analysis **Grade** Level I; Evidence from a systematic review	Primary Key Words: T1DM, T2DM, CSII therapy, MDI therapy, glycemic control, hypoglycemia, insulin resistance, psychosocial,	Conclusions exhibited through this study was that CSII therapy is correlated with improvement in glycemic control, thus providing additional support in preventing chronic conditions associated with diabetes.

http://dx.doi.org/10.2337/diacare.264.1079			outcomes			behavior.	
Li, F., Fu, L., Zhang, W., Su, X., Wu, J., Sun, J., ... Ma, J. (2016). Blood glucose fluctuations in type 2 diabetes patients treated with multiple daily injections. *Journal of Diabetes Research*, *2016*. http://dx.doi.org/10.1155/2016/1028945	2016	This study was conducted to compare fluctuations in blood glucose levels in T2DM participants treated with three different therapies; CSII therapy, MDI3 (3 injections daily), and MDI4 (4 injections daily).	CSII therapy proved to promote the most improved glycemic control faster than MDI therapy (4.26 ± 1.88 days) in the CSII group versus (6.17 ± 2.36 days) MDI3 group, and (581 ± 2.46 days) MDI4 group. CSII group ($P < 0.05$) versus MDI3 and MDI4 groups. Also, the longstanding T2DM group fared better on CSII therapy versus MDI3/4 therapy ($P < 0.05$) for CSII group.	T2DM patients newly diagnosed and longstanding T2DM, age 18-80, with HbA1c of 12%, male/female.	Randomized, parallel group trial. **Grade** Level II; Well-designed RCT	**Secondary** **Key words:** MDI therapy, CSII therapy, Insulin pump, Behavior, T2DM, T1DM, glycemic control	This study focuses on the improvement in glycemic control with the use of CSII therapy in T2DM patients who are not controlled on MDI therapy. Unfortunately, further study is needed to examine the risks of CSII therapy focusing on the psychological impact of utilizing this technology, along with future advancements associated with the technology and patient adherence
Maia, M. A., Reis, I. A., & Torres, H. D. (2016). Relationship between the users' contact time in educational programs on diabetes mellitus and self-care skills	2016	This study was performed to identify the relationship between users' contact hours in educational program and self-care knowledge variables in the relation to diabetes mellitus.	A final group of 151 users were included in the study. It was found that there was significant improvement in self-care scores ($P<0.05$) for those users during the educational interventions, which	Type 2 DM patients, male/female, ages 30-85.	Longitudinal descriptive study **Grade** Level VI; Evidence from a single descriptive study	**Secondary** **Keywords:** Health education, diabetes mellitus, knowledge, self-care, nursing.	This study highlights the benefits of patient education and the promotion of self-care and knowledge enhancement and understanding of diabetes. It is interesting to note that the 151 participants in this study gained improvement in both self-care qualities ($P<0.05$), as well as baseline knowledge at the conclusion of the educational program.

and knowledge. *Journal of Nursing*, *50*(1), 59-64. http://dx.doi.org/10.1590/S0080-62342016000100008			consisted of 8 hours. Knowledge base also increased for the users.				
Wu, S. V., Liang, S., Lee, M., Yu, N., & Kao, M. (2013). The efficacy of self-management programme for people with diabetes, after special training programme for healthcare workers in taiwan: a quasi-experimental design. *Journal of Clinical Nursing*, *23*, 2515-2524. http://dx.doi.org/10.1111/jocn.12440	2013	This study was performed to analyze the efficacy of improving disease management after implementing a self-management program for people with T2DM.	There were (*n = 147*) participants in the experimental group and (*n = 81)* in the control group. Post test scores of BMI (*P < 0.01*), waistline circumference (*P< 0.01)*, Hba1c (*P<0.001)* and depression/anxiety (*P<0.001)*in the experimental group versus the control group. Post-test scores for self-efficacy (*P,0.001)* for the experimental group.	T2DM, male/female, > 20 years of age.	Quasi-experimental design **<u>Grade</u>** Level III	**Secondary** **Keywords:** T2DM, self-management, self-care, education,	This study highlights that people living with diabetes can effectively improve self-efficacy with planned implementation of self-management training programs with trained healthcare workers. This illustrates that with continued diabetes education promoting self-care habits and understanding, improvement in factors associated with diabetes and the chronicity of the disease can be reduced, thus reducing risk factors for multiple other complications associated with diabetes.
Fitzpatrick, S. L., Schumann, K. P., &	2013	The purpose of this study was to examine the published	There was a large variance in the studies and their	Sixteen intervention randomized controlled	Systematic Review	**Secondary**	This systematic review focused on educational

Hill-Briggs, F. (2013). Problem solving interventions for diabetes self-management and control: A systematic review of the literature. *Diabetes Research and Clinical Practice*, *100*, 145-161. http://dx.doi.org/10.1016/j.diabres.2012.12.016		literature on the effect of problem-solving interventions on diabetes self-management and disease control.	approaches to problem-solving in patient education. It was found, however, that with education regarding problem-solving interventions 36% of the adults who participate in the study and 42% of children who participated in the study showed significant improvement in HbA1c. Psychosocial outcomes have been more promising.	trials (11 adults, 5 children/adolescent) and 8 intervention studies that were quasi-experimental designs (6 adult, 2 children/adolescent) consisting of T1DM/T2DM, Male/female	**Grade** Level I	**Keywords:** Diabetes mellitus, problem-solving, problem focus, decision making, self-management, education, self-care	interventions and the positive aspects associated with the use of patient education as a positive intervention in improving glycemic control, and promoting self-management/self-care attributes. With continued patient education, chronic conditions associated with uncontrolled diabetes can be reduced, allowing patients to feel empowered over the course of their diagnosis of diabetes.
Wilkinson, A., Whitehead, L., & Ritchie, L. (2014). Factors influencing the ability to self-manage diabetes for adults living with type 1 or 2 diabetes. *International Journal of Nursing Studies*, *51*, 111-112. http://dx.do	2014	This study was looking at barriers/influences that influence self-management/self-care for adults with types 1 and 2 diabetes mellitus	In this systematic review there were multiple barriers that were associated with the day-to-day management of diabetes. The key issues related to communication, education, personal factors, providers' issues. Interestingly, communication with	Adults living with types 1 and 2 diabetes mellitus.	Systematic Review **Grade** Level I	**Secondary** Keywords**:** Barrier, T1DM, T2DM, facilitators qualitative research, self-care, systematic review	This study focuses on the importance of diabetes education concentrating on self-care. It also highlights the importance of communication between provider and patient, as well as the provision of culturally sensitive care. With good communication between the provider and patient, patient compliance will improve It is important to understand that this study also find that community support played a significant role in patient's ability to self-manage their diabetes, as there are many issues patients face day-to-day, compounded with vulnerability increasing

i.org/10.1016/j.inurstu.2013.01.006			providers, along with educational programs that provided appropriate skills to be successful in self-care was a significant barrier, along with the provision of culturally sensitive care				situational, cultural and social issues. Diabetes is variable, affecting each person differently and as such, self-care needs to be individually addressed meeting each persons' life experiences.