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Effects of Short-term Intensive Insulin Therapy in Type 2 Diabetes Mellitus Management

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Walden University
2020

Abstract

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MSC, Georgetown University, 2018

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Diabetes is a chronic illness affecting millions of individuals in the United States and is the seventh leading cause of death. Most of the Type 2 Diabetes Mellitus (T2DM) patients manage their illness with non-insulin therapies resulting in inadequate glycemic control but there are times when they experience inadequate glycemic control and require short-term intensive insulin therapy (SIIT). Despite proven effectiveness of SIIT, there is a lack of research focusing on the effectiveness of clinical practice where providers revert their clients to non-insulin therapy after SIIT. The focus of this quality improvement (QI) project was to evaluate pre/post data and synthesize results to make a recommendation for possible practice change. The QI project utilized the theory of self-care for chronic illness and the theory of self-efficacy. By using a retrospective quantitative design, a sample of 50 QI data cases of T2DM were randomly selected and divided into two groups: those treated with SIIT (n=17) and those treated with standard therapy (STD, n=33). Consequently, the pre-QI data with Hemoglobin A1c >8% (n=17) was compared with post-QI data and analyzed against the two therapies (SIIT, n=8, STD, n=9). Findings of this QI project indicates that SIIT is more effective in treating T2DM patients with an episode of hyperglycemia compared to standard therapy. SIIT, when implemented in primary care settings, has the potential to improve health outcomes for T2DM patients struggling with uncontrolled blood sugar. Findings have the potential for contributing to positive social change leading to reduced disease burden, reduction in disease complications, improved quality of life among T2DM patients, and reduction in overall healthcare costs.

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Dedication

To my mother and my beloved children Leo, Tausi, Adiona, and Rio.

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I would like to thank my family for their encouragement and support and my professional mentor Dr. Le-Jenkins for always being a phone away no matter the distance to support me in my career endeavors. I cannot forget the assistance and support I received from Mrs. Rebecca Carter during data collection. I would also like to extend my gratitude to my DNP project committee members for their dedication and valuable feedback that made this project a success. Special thanks to my Committee chair Dr. Carolyn Sipes for her tireless guidance, advice, and motivating me to keep going even when I felt like I needed to take a break. I want you to know it was an honor to have you as my mentor and chairperson. I also would like to acknowledge Dr. Anita Manns and Dr Edna Hull for your great feedback and constructive criticism that challenged me to step up my effort and culminated in this final project. Finally, my heartfelt appreciation to Dr. Joan Hahn and Dr. Deborah Lewis for being there when we needed you to step in.

"*It had to be done*"

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Section 1: Nature of the Project

Introduction

Diabetes Mellitus is a metabolic disorder characterized by insufficient insulin secretion by the pancreas to maintain normal blood glucose levels (Handelsman et al., 2015). There are two major types of DM: Insulin-dependent or Type 1 Diabetes Mellitus (T1DM) and non-insulin dependent or Type 2 Diabetes Mellitus (T2DM). T1DM is characterized by absolute insulin deficiency and can be confirmed by the presence of antibodies, although some forms of T1DM have no evidence of antibodies (Handelsman et al., 2015). T2DM is characterized by a lack of antibodies and evidence of insulin resistance rather than absolute insulin deficiency (Handelsman et al., 2015). Diabetes is a chronic illness that affects millions of individuals in the United States and is the seventh leading cause of death with a direct and indirect estimated annual healthcare cost of $327 billion in 2017 alone (American Diabetes Association [ADA], 2019; National Diabetes Statistics Report, 2017). There are nearly 30 million people in the US with diabetes, and 95% of those have T2DM, while an additional 86 million have prediabetes (Skyler et al., 2017).

T2DM is typically identified in patients who are obese, overweight, and have a family history of DM. T2DM disproportionately affects specific demographic populations. Racial/ethnic groups such as American Indians, African Americans, Hispanic/Latinos, Asians, and Pacific Islanders are disproportionately affected by T2DM (Skyler et al., 2017). T2DM also tends to be more prevalent in adults aged 65 and older and affects more males than females irrespective of age group or geographic location

(Skyler et al., 2017). The risk of developing T2DM is associated with low socioeconomic status, with low income and literacy levels having a high correlation (Skyler et al., 2017). In a survey conducted between 2007-2010 by National Health and Nutrition Examination Survey (NHANES), almost half of diabetic patients did not meet the general target of adequate glycemic control, blood pressure, and cholesterol as set by ADA and only 14% met all three measures (ADA, 2019). Failure to meet glycemic goals is associated with disease progression and complications, which are both macro and microvascular, leading to increased morbidity and mortality (ADA, 2019).

It is imperative for healthcare professionals caring for patients with T2DM to develop evidence-based treatment strategies that are effective and patient-centered. Primary care providers caring for T2DM patients should avoid therapeutic inertia, prioritize timely and appropriate intensification of both lifestyle and pharmacologic therapies for patients who have not achieved recommended glycemic control targets (ADA, 2019). According to the American Association of Clinical Endocrinologist (AACE) and the American College of Endocrinology (ACE), pharmacotherapies for T2DM should be prescribed based on suitability for the individual patient's characteristics (Handelsman et al., 2015). This is because antihyperglycemic agents vary in their impact on fasting prandial glucose (FPG), postprandial glucose (PPG), weight, and insulin secretion or sensitivity, as well as the potential for hypoglycemia and other adverse effects (Handelsman et al., 2015). Treatment guidelines for T2DM have been based on a stepwise approach with therapeutic lifestyle modifications as the first choice and insulin at the top of the ladder. Insulin is usually initiated in T2DM patients when

combination therapy with other agents fail to maintain the glycemic goal or when a patient presents with an HbA1c level >9.0% or symptomatic hyperglycemia (Handelsman et al., 2015). Short-term intensive insulin therapy (SIIT) is a treatment approach that advocates for the use of insulin intensification as the first line of choice for treating T2DM patients with persistently elevated blood glucose (Retnakaran, 2015).

Problem Statement

This quality improvement (QI) project addresses the elusive and ongoing treatment decision making challenges faced by both providers and patients in managing T2DM illness due to its chronicity and natural progression. Most of the T2DM patients, in collaboration with their providers, manage their illness with non-insulin therapies with adequate glycemic control (Sanghani, Parchwani, Palandurkar, Shah, & Dhanani, 2013). However, sometimes they may experience inadequate glycemic control and need a provider-initiated intervention that includes the use of SIIT (Cheng et al., 2016). SIIT has both short and long-term positive effects on glycemic control in newly diagnosed T2DM patients with an episode of hyperglycemia (Choi et al., 2019; Liu et al., 2018; Weng, 2017). SIIT is the use of weight-based dosage of both basal and bolus insulin with close blood glucose monitoring, insulin adjustment at appropriate intervals, intensive lifestyle modifications, and behavioral therapy with a goal of FPG of less than 110 mg/dl and HbA1c equal or less than 6.5% (Handelsman et al., 2015; Liehua Liu et al., 2018; Liu et al., 2018).

It is important to investigate the clinical significance of SIIT in T2DM management. The gap in nursing practice this quality improvement (QI) project focused

on is the lack of studies focusing on the effectiveness of SIIT on T2DM patients with the established disease who are on non-insulin therapy with an episode of hyperglycemia. Therefore, this DNP project was designed to evaluate pre/post-QI data and synthesize results to make a recommendation for possible practice change.

Purpose Statement

There is a lack of studies that focus on the effectiveness of SIIT on T2DM patients with the established disease who are on non-insulin therapy with an episode of hyperglycemia. The guiding practice-focused question for the DNP QI project was: What is the effect of short-term intensive insulin therapy intervention on non-insulin dependent T2DM patients with an episode of hyperglycemia in comparison to T2DM patients who used standard insulin therapy over 6 months? Therefore, the focus of this QI project was to evaluate pre/post-QI data and synthesize results to make a recommendation for possible practice change.

Nature of Doctoral Project

The DNP QI project utilized the Walden University Quality Improvement Evaluation Manual. The project aimed to evaluate the effects of a SIIT clinical practice at one clinic and to propose a practice change. The project utilized de-identified T2DM patients' data provided by the authorized organization representative. The QI project involved analyzing the de-identified QI data of T2DM patients seen at the clinic for 6 months before and 6 months after QI data collection. The final results were presented as a percentage of the sample for those treated with SIIT and achieved glycemic control, and those patients treated with standard insulin therapy. The rationale for the use of this

approach is that the project has an opportunity to improve clinical practice at this clinic on how providers care for T2DM patients.

Significance of Doctoral Project

The stakeholders in this QI DNP project included T2DM patients cared for at this clinic, the healthcare providers taking care of these patients, the clinic, and the local and federal government. This project could help T2DM patients improve their self-care management of T2DM by maintaining normoglycemia, thus reducing the probability of disease complications, hospital admissions, and emergency room visits. For healthcare providers, the project has an opportunity to improve clinical practice on how they care for T2DM patients in this clinic. The clinic would benefit from the project as improved T2DM care would mean less cost of care per individual patient, thus giving healthcare providers additional time to care for patients in need. The local and federal governments would benefit as well for improved T2DM care. The improved T2DM care means fewer disease complications, leading to fewer emergency room visits and hospital admissions. This reduces the cost of T2DM management due to the reduced amount of Medicaid reimbursements for the Medicaid recipients cared for at this clinic.

The QI DNP project would benefit nursing practice in significant ways. Nurse practitioners are committed to providing patient-centered care. A patient-centered treatment plan promotes patient-provider collaboration and fosters patient autonomy and self-reliance (Bostrom, Esaksson, Lundman, Lehuluante, & Hornsten, 2014). Use of SIIT to optimize T2DM treatment when patients are experiencing persistent hyperglycemia is recognizing the chronicity of T2DM that requires adaptation over time

by both the patient and the provider (Ivers et al., 2019). Standard treatment guidelines recommend the use of insulin as a last resort for persistent hyperglycemia, which would increase the T2DM cost of care tremendously (Rodriguez-Sanchez, Feenstra, Bilo, Alessie, 2019). SIIT therapy offers an affordable and effective alternative, thereby contributing to less disease burden by reducing the risk of disease complications, hospital admission, and emergency room visits (Skyler et al., 2017). The success of this QI project in improving care for T2DM could be applied to general nursing practice and management of other chronic illnesses. SIIT therapy promotes provider-patient collaborations through shared-decision making process in identifying a patient-centered treatment plan that takes into account a patients' preferences as well at their social and cultural influences.

This DNP QI project supports the mission of Walden University, which is to produce a diverse pool of transformed professionals as scholars and practitioners so that they may contribute to a positive change to their society. This DNP QI project contributes to positive social change by evaluating the effectiveness of the T2DM SIIT treatment plan in reducing disease burden among low-income T2DM patients. The DNP project offers recommendations for implementation of SIIT as a patient-centered treatment plan, which may lead to improved compliance, reduced disease complications, and less disease burden on the family and the society at large.

Summary

Diabetes is a chronic illness that affects millions of individuals in the United States (US) and is the seventh leading cause of death (National Diabetes Statistics Report,

2017) There are nearly 30 million people in the US with diabetes, and 95% of those have T2DM, while an additional 86 million have prediabetes (Skyler et al., 2017). The progression of the disease, despite a standard stepwise treatment protocol, has continued to be a significant challenge for providers and patients alike. SIIT treatment therapy has been successful in inducing T2DM remission on newly diagnosed T2DM patients and thus helps reverse the disease progression. There is no research on the effect of SIIT therapy on T2DM patients with an established disease and an episode of hyperglycemia. The purpose of this QI project was to evaluate pre/post-QI data and synthesize results to make a recommendation for a possible practice change. The next section will evaluate the background context and theoretical basis of the DNP QI project.

Section 2: Background and Context

Introduction

Even though extensive research has been conducted in recent years on the ability of SIIT treatment in reversing the dysfunction of beta-cells and thus improving glycemic control for newly diagnosed T2DM patients, the SIIT has not been used on non-insulin dependent T2DM patients with the established disease during an episode of hyperglycemia. The overwhelming positive patient outcomes of SIIT reversing the T2DM progression may well be beneficial if used to help T2DM patients with established illness who were previously on non-insulin therapy to regain their self-care management control of their illness. This section will discuss concepts, models, and theories to be used in this QI project, the significance of the QI project to nursing practice, and local background and context. It will later discuss the role of the DNP investigator and end with a summary of this section.

Concepts, Models, and Theories

As a chronic illness, T2DM requires the interdisciplinary approach and collaboration between the provider and the patient for an effective treatment plan (Handelsman et al., 2015). Therefore, the QI DNP project uses two theories. First, the theory of self-care of chronic illness, as described by Riegel, Jaarsma, and Stromberg (2012), may be helpful because this project addresses improving treatment compliance for SIIT treatment, as the treatment could not succeed without patient full involvement. The QI project also analyzes the application of Bandura's theory of self-efficacy. It is useful because this QI project is assessing the effectiveness of SIIT treatments which

includes patient self-determination and efficaciousness in their self-maintenance via self-care monitoring and self-care management (Bandura, 2012; Riegel, Jaarsma, Stromberg, 2012). Successful SIIT treatment requires a patient to administer insulin judiciously as instructed, monitor their blood glucose regularly, and also intensify other aspects of the disease self-care activities (Liu et al., 2018).

The theory of self-care of chronic illness was developed by Riegel, Jaarsma, and Stromberg from clinical practice for adults with heart failure (Riegel et al., 2012). According to the authors, the theory of self-care of chronic illness has three major concepts: self-care maintenance, self-care monitoring, and self-care management. Self-care maintenance is those self-care behaviors performed by patients to manage their chronic illness. Riegel et al. note that these behaviors may be recommended by healthcare providers, imposed by family members, or chosen by patients to meet their health goals. The second concept, self-care monitoring, is a routine, vigilant body monitoring or surveillance. For example, T2DM monitoring includes BG checks, calorie counting, and foot assessment. Riegel et al. state that the main goal of self-care monitoring is to be able to recognize when a change occurs due to chronic illness. The last concept in the theory, self-care management, is the process of evaluation of changes at the physical and emotional level and to determine if an intervention is needed. The authors indicate that a patient with a high level of self-care behaviors can grasp the meaning of changes and devise the best course of action to return to health stability. The theory interlinks the three concepts in managing a chronic illness via the decision-making process by the patient and

healthcare professionals . Riegel et al. state that if the link that connects the concepts of self-care is broken, patients experience adverse health outcomes.

The theory of self-efficacy was developed by Bandura (1977) to theorize how psychological procedures affect the level of self-efficacy in a patient (Bandura, 1977). The conceptual model of this theory revolves around two concepts: outcome expectation and efficacy expectation (Bandura, 1977; 1982). Outcome expectancy is the belief that an individual's given behavior will lead to a specific outcome and efficacy expectation is the belief that one can perform an expected behavior successfully to produce the desired outcome (Bandura, 1977). The expectation of personal mastery affects both the initiation and persistence of coping behavior (Bandura, 1977; 1982). The strength of an individual's conviction that they can accomplish a given task determines whether they will try to cope with a given situation or not (Bandura, 1977; 1982).

Successful management of T2DM demands provider-patient collaboration where providers recommend a treatment plan, and the patients carry these plans out in self-care management (Dao, Spooner, Lo, & Harris, 2019). Care of chronic illness using the concepts of self-care maintenance, self-care monitoring, and self-care management reflects T2DM patients' self-care management as they incorporate T2DM in their lifestyle (Riegel et al., 2012). T2DM patients have to count their calories, take the prescribed medications daily, monitor their blood glucose (BG) and engage in active lifestyle (Handelsman et al., 2015). They also have to monitor their BG and make appropriate decisions when the monitoring reveals some changes in their T2DM that require additional interventions (Dao, Spooner, Lo, & Harris, 2019).

The concepts of self-efficacy and outcome expectations are crucial in SIIT therapy because the success of the T2DM treatment depends on the patients' commitment and determination to follow through with provider recommendations (Pon et al., 2019). Focusing on self-efficacy means that the provider and diabetes educator strive to instill self-confidence in patients regarding their ability to perform recommended daily self-care activities. These self-care activities include calorie counting, BG monitoring, taking insulin as prescribed, and being able to identify and report any changes in their illness (Saad et al., 2018). The goal is the achievement of competency in the performance of self-care activities leading to effective disease management (Saad et al., 2018).

In addition, when a T2DM patient performs self-care activities with efficacy, the outcome is glycemic control and improved quality of life, which further motivates T2DM patients to continue performing prescribed self-care activities (Amer, Mohamed, Elbur, Abdelaziz, & Elrayah, 2018). The use of self-care theory of chronic illness and self-efficacy in this project provided a theoretical as well as a conceptual framework to highlight the effects of SIIT treatment in T2DM patients with an episode of hyperglycemia. T2DM is a chronic illness; the success of provider-initiated treatment recommendations depends on the patients' ability to perform recommended self-care activities with efficacy and competency (Pon et al., 2019).

Relevance to Nursing Practice

The biggest challenge in T2DM management is chronicity and the natural progression of the disease despite different treatment approaches (Ivers et al., 2019). Also, the central role of self-care activities for the success of T2DM amplifies the

challenges of providers' initiated T2DM recommended treatment plan (Shrivastava, Shrivastava, & Ramasamy, 2013). Therefore, an effective T2DM treatment plan must address these two challenges.

In a clinical trial conducted by Action to Control Cardiovascular Risk in Diabetes (ACCORD), SIIT targeting an HbA1c of less than 6% recorded significantly lowered risks and progressions of diabetes microvascular complications such as retinopathy, nephropathy, and neuropathy compared with a standard treatment that target an HbA1c between 7% to 8% (Handelsman et al., 2015). The same trial also registered increased mortality with increasing HbA1c levels with high mortality noted on those subjects with persistent HbA1c greater than 7%. In a second study that sought to evaluate the effect of SIIT treatment on glucose homeostasis on newly diagnosed T2DM patients, SIIT was able to improve beta-cell function, reduce insulin resistance, and improve glucagonemia after only four weeks of therapy (Choi, Kramer, Zinman, Connelly, & Retnakaran, 2019). This shows two studies shows that SIIT is able to improve glycemic control leading to lower the risk of diease complications among T2DM patients.

SIIT is not just a process to take insulin at a different dose and frequency; it is a shared decision-making process that involves both the provider and the patient (Ivers et al., 2019). The shared decision-making approach will help augment the benefits of SIIT because it will act as an anchor of support to the patient to initiate and maintain recommended diabetes self-care activities in order to return to normoglycemia (Ivers et al., 2019). SIIT involves not only the intensification of insulin but also lifestyle modification and self-care management recommendations, which will lead to treatment

compliance, thus reducing disease complications, emergency room visits, and hospital admissions (Liu et al., 2018).

The proven effectiveness of SIIT to achieve glycemic control and arrest the T2DM progression can significantly improve the quality of life among T2DM patients. Persistent inadequate glycemic control is likely to weigh heavily on a patient (Li, Ji, Scott, & Dunbar-Jacob, 2019). T2DM requires patients to invest their time and resources in self-care activities in order to maintain adequate glycemic control, failure of which has been seen to contribute to psychological symptoms such as depression and anxiety (Li et al., 2019). On the other hand, the presence of psychological symptoms negatively affects patient's diabetes self-management behaviors leading to disease deterioration and low quality of life (Kayar et al., 2017).

Nurse practitioners are committed to providing patient-centered care. A patient-centered treatment plan promotes patient-provider collaboration, foster patient autonomy, and self-reliance (Boström, Isaksson, Lundman, Lehuluante, & Hörnsten, 2014). Use of SIIT to optimize T2DM treatment when patients are experiencing persistent hyperglycemia is recognizing the chronicity of T2DM that require adaptation over time by both the patient and the provider (Ivers et al., 2019). Standard treatment guidelines would suggest the use of insulin as a last resort for persistent hyperglycemia, which will increase the T2DM cost of care tremendously (Rodriguez-Sanchez, Feenstra, Bilo, Alessie, 2019). SIIT therapy offers an affordable and effective alternative, thereby contributing to less disease burden by reducing the risk of disease complications, hospital admission, and emergency room visits (Skyler et al., 2017).

Local Background and Context

Diabetes continues to be a major health issue in the United States and around the globe. It is the seventh leading cause of death in the United States and sixth globally (National Diabetes Statistics Report, 2017; World, Health Organization, 2016). World Health Organization (WHO) (2016) ranked diabetes second in terms of morbidity only surpassed by cancer. Although the prevalence of diabetes was found to be approximately equal for both lower and upper social, economic groups, lower and middle social, economic groups experience a higher burden of the disease due to the high cost of managing diabetes (Fritz, 2017; WHO, 2016)

Therefore, while many T2DM risk factors are preventable, being a member of a low-income population, uninsured, or from a minority group increases the prevalence of T2DM complications such as hyperglycemia, micro and macrovascular complications including death (Fritz, 2017). Many patients with T2DM continue to experience disease progression despite the use of a stepwise treatment protocol (Liu et al., 2018). SIIT therapy has shown promising positive outcomes when used on newly diagnosed T2DM patients (Liu et al., 2018). This QI DNP project evaluated the effect of SIIT therapy for T2DM patients with an episode of hyperglycemia (Qingfeng et al., 2015). SIIT therapy has been able to reduce HbA1c to normoglycemia within a few weeks of therapy (Weng, 2017). If this result is replicated in the QI project, it will allow T2DM patients to resume previous non-insulin therapy, which is affordable and manageable, thus increasing treatment compliance and reduction of disease complications in the targeted local population.

The DNP QI project was conducted at a primary care clinic, serving a large metropolitan area in the eastern part of the United States. The clinic is one of nine clinics operated by a non-profit organization, and is certified as a Federally Qualified Health Center (FQHC) dedicated to providing primary care services to low-income, uninsured, and Medicaid-enrolled patients. Therefore, SIIT therapy would help T2DM patients with an episode of hyperglycemia regain control of their self-care management and resume low-cost non-insulin therapies such as lifestyle modifications and some oral anti-glycemic medications. Low-cost non-insulin therapy would be beneficial to both the patient and this clinic as it strives to provide free and subsidized healthcare to this population.

Definition of Terms and Acronyms

Blood glucose (BG): Blood glucose is the level of circulating glucose in the blood (Handelsman et al., 2015).

Fasting prandial glucose (FPG): Fasting prandial glucose is measured in the morning after overnight fasting and before taking any meal (Handelsman et al., 2015).

Postprandial glucose (PPG): Postprandial glucose is measured at a specified time after a meal (Handelsman et al., 2015).

Hemoglobin A1c (HbA1c): *Hemoglobin* A1c measures the average blood glucose level average of 2-3 months period (Handelsman et al., 2015).

Normoglycemia: This is HbA1c of less than 6.0% or FPG of less than 100 mg/dl (Handelsman et al., 2015).

Glycemic control (GC): Is the ability of a patient to maintain normoglycemia as defined by FPG and HbA1c being within desired limits (Handelsman et al., 2015).

Inadequate glycemic control: Is HbA1c above 6.5% or FPG greater than 125 mg/dl (Handelsman et al., 2015).

Standard treatment protocol (STD): Standard treatment protocol is a stepwise treatment for T2DM that start with lifestyle modification as a first step and insulin as a last option.

Short-term intensive insulin therapy (SIIT): Short-term intensive insulin therapy is fasting prandial glucose (FPG) or HbA1c-guided insulin therapy that uses a combination of long and short-acting insulin with the daily adjustment until normoglycemia is achieved while maintaining intensified lifestyle modification therapy (Liu et al., 2018; Liehua Liu et al., 2018).

Non-insulin therapy: All therapies used to treat T2DM that is not insulin, including lifestyle modification therapy (Handelsman et al., 2015).

Life modification therapy: This includes adequate sleep, reduced calorie intake, weight loss, and active lifestyle (Handelsman et al., 2015).

Role of the DNP Investigator

The role of the DNP investigator in this QI project was to evaluate T2DM quality improvement measures data that was provided by the clinic manager at the beginning of the project and 6 months after. The T2DM quality measures data is part of quarterly collected quality performance measures that are distributed to all 12 clinics within the organization on various clinical quality measures. The clinic tracks its performance on

T2DM patients using HbA1c aggregate levels compared to other clinics in the organization and against the Center for Medicare and Medicaid Services (CMS) benchmark for T2DM quality measures, which is the percentage of T2DM patients with HbA1c less or equal to 8%. The data are reported as percentages of T2DM patients in 10th, 25th, 50th, 75th, and 90th percentile. Therefore, the DNP investigator's role was to coordinate with the clinic manager who provided the de-identified QI data for evaluation. The DNP investigator then evaluated the QI data, made the dissemination plan of the QI project findings, and identified appropriate recommendations for practice change.

The DNP investigator is a nurse practitioner volunteer at the clinical site where the QI project was conducted. During volunteer work at the clinic, the DNP investigator has taken care of T2DM patients presenting with persistently elevated blood sugar levels and has first-hand experience with the challenges of treating T2DM patients with established illness using a stepwise treatment protocol. SIIT therapy would be an appropriate treatment plan that would lower the cost of drugs for the clinic and improve patient treatment compliance for this population because it will reduce the need for long-term insulin use and help clients resume their non-insulin self-care activities. The DNP investigator's commitment to the wellbeing of clients at this clinic and a passion for caring for the underprivileged was an added advantage in the project completion.

Summary

According to Liu et al. (2018), the number of T2DM patients with HbA1c greater than 9% increased between 2006 and 2013 and is expected to rise with current stepwise

treatment guidelines even with the discovery of newer and costlier diabetic drugs. The theory of self-care of chronic illness and self-efficacy were used to guide the QI project. The success of any provider directed treatment of T2DM, such as SIIT, largely depends on the individual patient's ability to effectively carry out self-care activities (Amer et al., 2018). The SIIT treatment plan is not just insulin intensification but the intensification of the recommended self-care activities (Handelsman et al., 2015). The role of the DNP investigator in this QI project was to evaluate T2DM quality improvement data that was provided by the clinic manager at the beginning of the project and 6 months after. The T2DM quality measures data is part of quarterly-tracked quality performance measures data that is distributed to 12 clinics within the organization. The next section will focus on data collection methodology and evaluate evidence-based literature for the QI project clinical problem.

Section 3: Collection and Analysis of Evidence

Introduction

It is essential for providers taking care of T2DM patients to develop a treatment plan that is effective, patient-centered, and affordable. Diabetes is a chronic illness that affects millions of individuals in the United States and is the seventh leading cause of death with a direct and indirect estimated healthcare cost of $327 billion in 2017 alone (AD, 2019). Insulin increases the healthcare cost of T2DM management by about 30-38% for a 1% increase in HbA1c compared with a 3.4% total care cost increase with other modalities (Rodriguez-Sanchez, Feenstra, Bilo, Alessie, 2019). According to Sokol (2019), insulin price has increased 600 fold in the last 2 decades leading to many

Americans with diabetes to cut back on their dosage while some stopped taking insulin altogether because they could not afford it. There is extensive literature coverage on SIIT and its effect on glycemic control in the short and long-term on newly diagnosed T2DM patients (Wansbrough, 2015; Weng, 2017).

Despite documented effectiveness of SIIT therapy on newly diagnosed T2DM patients, there is a lack of studies that focusing on its effectiveness on patients with established T2DM and on non-insulin therapy with an episode of hyperglycemia. The purpose of this QI project was to evaluate pre/post-QI data and synthesize results to make a recommendation for possible practice change. My role in this QI project was to evaluate data on T2DM quality measures that were provided by the clinic manager at the beginning of the project and 6 months later. The data on T2DM quality measures is part of quarterly collected quality performance measures that are distributed to all 12 clinics within the organization.

The theory of self-care of chronic illness and the theory of self-efficacy were used to inform the QI project. These two theories support patient-centered care which demands that any treatment plan should be a decision made between a provider and a patient. In the SIIT treatment plan, the decision includes strategies on how to overcome self-care barriers that can lead to persistent elevated HbA1c and the goal for reverting to non-insulin therapy. Non-insulin therapy is more acceptable by patients and easy for a patient to self-manage and therefore increase compliance, reduce mortality, and disease complications (Shrivastava, Shrivastava, & Ramasamy, 2013).

I conducted this DNP QI project. at a primary care clinic. This clinic serves a large metropolitan area in the eastern part of the United States. The clinic is one of nine clinics operated by a non-profit organization, and is certified as a Federally Qualified Health Center (FQHC) dedicated to providing primary care services to low-income, uninsured, and Medicaid-enrolled patients.

This section will discuss the practice-focused question and how it aligned with the purpose of the QI project. This will be followed by a discussion about the sources of evidence for the project. I end with data collection methodologies and strategies that were used in this QI project.

Practice-focused Question

The guiding practice-focused question for the DNP QI project was: What is the effect of a short-term intensive insulin therapy intervention on non-insulin dependent T2DM patients with an episode of hyperglycemia in comparison to T2DM patients who used standard insulin therapy over a 6-month time span? It is imperative for nurse practitioners caring for T2DM patients to develop a patient-centered treatment plan that is effective and affordable. Current T2DM treatment guidelines recommend a stepwise approach with life modifications as the first step and insulin therapy acting as the last resort when all other non-insulin therapies fail to achieve normoglycemia (Handelsman et al., 2015). However, these therapies have failed to stop the progression of T2DM because they improve the performance of already failing beta-cells function (Wansbrough, 2015).

SIIT is recommended as a treatment of choice for newly diagnosed T2DM with severe hyperglycemia (Cheng et al., 2016). While SIIT is meant to be temporary, it is

recommended as a treatment of choice for an episode of inadequate glycemic control on patients previously on glycemic control with non-insulin therapy because it had been proven to reverse beta-cell dysfunction (Wansbrough, 2015). Therefore, the purpose of this QI project was to evaluate pre/post-QI data and synthesize results to make a recommendation for possible practice change.

Sources of Evidence

The sources of evidence for this DNP QI project was derived from peer-reviewed journals, evidence-based literature, reputable professional websites, clinical guidelines, and from the pre/post-QI data analysis of the QI data. I performed a systematic search to retrieve literature that addressed T2DM current treatment protocols and the effectiveness of SIIT therapy as compared with standard treatment protocols. I conducted a multi-database search that included CINAHL Plus, Embase, Medline, ProQuest Nursing and Allied Health Source, PubMed, Cochrane Database of Systemic Reviews, Science Direct, Joanna Briggs Institute Evidence-Based Practice Database, Guideline Central, Evidence-Based Nursing Database, and American Diabetes Association (ADA). The literature search terms for the project included *diabetes, type 2 diabetes mellitus, T2DM, short-term insulin therapy, characteristics of T2DM patients, the effectiveness of T2DM standard treatment, effects of SIIT treatment, insulin intensification, type 2 diabetes management, types of insulin regimen,* and *glycemic control*.

In order to retrieve comprehensive literature from the multiple databases, the literature search was guided by the following questions:

- What is diabetes?

- What are the characteristics of T2DM patients?
- What are the current diabetes treatment guidelines?
- What is SIIT?
- What is the effectiveness of SIIT compared to diabetes standard treatment?
- What is considered adequate glycemic control?
- What is considered inadequate glycemic control?
- What are the measuring parameters for glycemic control in T2DM?

The inclusion criteria for the literature review were studies about (a) T2DM patients aged between 18 and 65 years of age, (b) SIIT treatment (c) T2DM standard treatment protocol, (d) comparisons of SIIT to standard therapy, and (e)various T2DM pharmacological interventions. Studies involving pregnant patients, T2DM patients below the age of 18, T2DM patients 65 years and older, T2DM patients with severe cardiovascular comorbidities, diabetic complications, and studies older than 5 years were excluded from the project consideration. QI sample data followed the same criteria of exclusion with the additional exclusion of patients taking medications that can affect glycemic levels such as corticosteroids and psychotic medications.

The initial search using Boolean string: "*type 2 diabetes* or *type 2 diabetes mellitus* or *T2DM*) AND *short-term insulin therapy* NOT (*pregnancy* or *pregnant* or *prenatal* or *antenatal* or *perinatal* or *maternal*) NOT (*pediatrics*) NOT (*elderly* or *aged* or *older* or *elder* or *geriatric*" returned 60 articles. Out of the 60 articles, 24 of them met the project criteria, 12 specifically addressed the superiority of SIIT over standard T2DM treatment, and the remaining 5 articles addressed the current nature of T2DM disease

profile, disease management, symptomology, and issues relevant to the topic of SIIT. The articles that were excluded from the 60 identified were either duplicates or addressed T2DM issues not related to SIIT treatment.

Wansbrough (2015), during a Q&A with Chicago Medical Post, identified the most significant challenge in treating T2DM as the worsening progressive chronicity that is driven by the worsening beta-cell ability to secrete insulin. What is more troubling is that current therapies have failed to curtail the natural progression of T2DM because all they do is improve the performance of the already failing beta-cell function (Wansbrough, 2015). SIIT, on the other hand, had shown promising results of the ability to reverse beta cell dysfunction after 2-5 weeks of therapy (Retnakaran, 2015). Retnakaran (2015) proposes a treatment plan that includes two phases: induction phase that utilizes SIIT and maintenance phase that would use life modification therapy or oral antidiabetic drugs to maintain euglycemic states achieved during SIIT.

McInnes et al. (2017) used a randomized controlled trial to show how T2DM patients treated with intensive lifestyle and SIIT resulted in on-treatment normoglycemia, sustained weight loss, and prolonged, drug-free diabetes remission. Another randomized control trial conducted by Liu et al. (2018) shows that patients with stricter overall glycemic control during SIIT have better remission compared to those who do not.

An open parallel randomized clinical trial conducted by Qingfeng et al. (2015) showed that newly diagnosed T2DM with severe hyperglycemia patients were able to achieve long-term glycemic control when they were switched to metformin similar to insulin glargine after 20-14 days of SIIT therapy. Although the literature focused on the

effects of SIIT therapy on newly diagnosed T2DM patients, there is a literature gap on the effects of SIIT therapy on non-insulin dependent T2DM patients with established disease. However, the literature reviewed suggests that SIIT has a clinical significance as an effective and safe practice that can be adopted by clinicians while caring for non-insulin dependent T2DM patients with an episode of hyperglycemia to achieve remission or reversal to non-insulin therapies.

Analysis and Synthesis

The DNP QI project utilized Donabedian's model for quality improvement. This model has been used in healthcare to analyze the quality of care in different contexts. Mahdavi et al. (2018) used Donabedian's model to investigate the quality of life, adequate coverage and service satisfaction, and their relationship with the structures, processes, and outcomes of T2DM services in 6 regions in Europe. In another study, Savjani, Haseeb, and Reay (2018) used the Donabedian's model to amplify the importance of outcomes, processes, and structures as a measure of quality improvement in acute care settings. For this DNP QI project, the structural measures are the ratio of providers to patients and the ability of patients to acquire insulin and resources needed during SIIT therapy. SIIT therapy requires collaboration between the provider and the patient with an increased frequency of encounters to be successful. Therefore, if the provider has to care for a large number of T2DM patients, this may determine if the SIIT would be initiated or providers would resort to a stepwise treatment protocol, thus affecting the T2DM patients' health outcomes. The process measure includes the provider's decision-making tools and having in place a standardized SIIT protocol. Lastly, the outcome measure is

the number of T2DM patients who successfully had their hyperglycemia controlled after SIIT therapy by having HbA1c of less or equal to 8%.

The DNP QI project involved evaluating pre/post-QI data and then providing recommendations for clinical practice based on the results of data analysis. The clinic manager provided the retrospective pre/post-QI, de-identified data for a 6-month period. A random sample of 50 patients was selected from the de-identified data provided by the clinic manager for analysis. The data was organized and placed into two comparative groups of patients with T2DM who had an episode of hyperglycemia and received SIIT treatment and those who had an episode of hyperglycemia but did not receive SIIT treatment. The independent variables for the project were SIIT and standard treatment protocols and dependent variable was HbA1c lab values. Statistical Package for Social Sciences (SPSS) software was utilized for the QI project to analyze data by use of descriptive statistics, which included frequency distribution, percentages, and *t*-test for comparing the two groups of patients. The analyzed data was presented in a narrative format and tables, comparing the pre- and post-QI data.

The role of Walden University is to ensure that any project conducted by its students comply with ethical standards as stipulated by Walden University and U.S federal regulations of human protections, privacy, and confidentiality. This was a QI DNP project guided by the Walden University quality improvement evaluation manual. Therefore, I did not collect project data or interact with patients but collaborated with an authorized site representative who provided the retrospective de-identified quality improvement data for analysis and reporting. The role of the DNP investigator was to

evaluate the pre/post-QI data provided by the authorized site representative. I obtained a signed site agreement form to release the data for the QI project from the clinic's authorized representative. The form was then submitted to the Walden University institutional review board (IRB) for approval. The IRB approval number is 02-11-20-1008334.

Summary

This DNP QI project addressed the existing gap in practice on SIIT therapy among T2DM patients with established disease experiencing an episode of hyperglycemia. There is overwhelming evidence-based literature that has shown SIIT as an effective intervention for newly diagnosed T2DM with an episode of hyperglycemia. SIIT therapy is multipronged and involves an intensification of other self-care activities. Provider initiated interventions such as SIIT, when initiated as a shared decision-making process, has been shown to improve self-care management and self-efficacy. Therefore, this DNP project was initiated to address the existing gap in practice involving SIIT therapy and to identify recommendations for clinical practice change, thereby contributing to improved T2DM management and self-care.

Section 4: Findings and Recommendations

Introduction

T2DM continues to be a major illness affecting approximately 30 million diabetic patients in the US, with direct and indirect estimated healthcare cost of $327 billion in 2017 alone (ADA, 2019; Skyler et al., 2017). According to the ADA (2019), almost half of diabetic patients do not meet at least one of the general targets of adequate glycemic control, blood pressure, and cholesterol levels, and only 14% meet all three measures. Failure to meet glycemic goals is associated with disease progression and complications, leading to increased morbidity, low quality of life, and mortality (ADA, 2019). Also, the risk of developing and worsening T2DM is associated with low socioeconomic status, with low income and low literacy levels having a high correlation (Skyler et al., 2017). Therefore, there is a need for healthcare professionals caring for patients with T2DM to develop evidence-based treatment strategies that take into account the patient's preferences and characteristics. The DNP QI project was conducted at a primary care clinic that is owned and operated by a nonprofit organization dedicated to providing primary care services to low-income, uninsured, and Medicaid-enrolled patients.

In this QI project, I address the elusive and ongoing T2DM treatment decision making challenges faced by both the providers and patients in managing T2DM due to its chronicity and natural progression. The guiding practice-focused question for this DNP QI project was: What is the effect of a short-term intensive insulin therapy intervention on non-insulin dependent T2DM patients with an episode of hyperglycemia in comparison to T2DM patients who used standard insulin therapy over a 6-month time

span? The purpose of this QI project was to evaluate pre/post-QI data and synthesize results to make a recommendation for a possible practice change. The DNP QI project evaluated the effectiveness of SIIT treatment in T2DM management by comparing two sets of data for the de-identified pre- and post-QI data of HbA1c lab values within a 6-month period. One set of data included patients treated with SIIT, and the other set, patients treated with the standard stepwise protocol. The HbA1c value was used because the field site tracks the T2DM quality measure using patient HbA1c levels with a benchmark goal of HbA1c less than 9.0%. The project used a retrospective approach to collect and analyze the QI data. The de-identified QI data was provided by the clinic manager, who was the authorized representative of the organization. The medications prescribed to the patients were used to identify the use of SIIT protocol and the standard protocol after an episode of hyperglycemia. For SIIT, the use of a combination of basal and bolus insulin combined with close follow-up such as weekly or biweekly appointments were considered SIIT for this QI project. The use of pre-mixed and long-acting or intermediate insulin with follow-up appointments scheduled at more than 2 weeks interval or use of oral medications was considered standard protocol.

A sample of 50 T2DM cases was randomly selected from the total population of T2DM patients cared for by the clinic for pre- and post-QI data analysis. The sample was further organized into two groups: Group 1 consisted of those who were treated with standard protocol and Group 2 consisted of those who were treated with SIIT. There were 33 cases in Group 1 and 17 cases in Group 2 (Table 1). The pre-QI data set was further for those with HbA1c greater than 8% and those with HbA1c below 8%. The HbA1c of

pre-QI data group with HbA1c greater than 8% was compared with post-HbA1c values after treatment with standard and SIIT therapies. The data were analyzed using Statistical Package for Social Sciences (SPSS). The randomization was done using a random number generator from Random.org. Finally, the DNP QI project used descriptive statistics for frequency distribution analysis and a one-sample *t*-test to analyze the HbA1c mean score of pre-QI data and post-QI data for both therapy groups.

Findings and Implications

The QI project first looked at how many cases out of the sample of 50 were treated with standard protocol as compared with SIIT irrespective of their data point. Table 1 shows that 33 cases were treated with standard therapy representing 66% and 17 cases were treated with SIIT, representing 34% at any time within the 6-month period.

Table 1

Pre-and Post-QI Data by Therapy Type

	N	Freq	Percentage
SIIT*	50	17	34
STD**	50	33	66

Note. Short-term intensive insulin therapy*; Standard protocol**

In order to reflect the field site quality performance measure indicators, the QI project used HbA1c lab values as a measure of T2DM therapy success. The project used descriptive statistics to compare the HbA1c mean values 6 months before (pre-QI data)

and 6 months after (post-QI data). As shown in Table 2 the HbA1c mean score on pre-QI data was 7.98 (*SD* 2.02), and the HbA1c mean score for post-QI data was 7.76 (*SD* 1.53).

Table 2

Pre-and Post-QI Data of HbA1c Lab Values

	N	Mean	*SD*
Pre-QI Data	50	7.9760	2.01854
Post-QI Data	50	7.7580	1.53411

There was a statistically significant difference between the pre-QI data and the post-QI data mean score ($p<0.001$). This difference might account for the variation in treatment protocols within the 6 month period. Notably, the mean HbA1c score for post-QI data was slightly lower than that of pre-QI-data (Table 3).

Table 3

Pre-and Post-QI HbA1c t-test Analysis

					95% *CI*	
	T	*df*	*sig(2-tailed)*	Mean *dif*	Lower	Upper
Pre-HbA1c	27.94	49	.000	7.976	7.402	8.550
Post-HbA1c	35.76	49	.000	7.758	7.322	8.194

The project also analyzed the HbA1c range to evaluate the percentage of clients who were able to meet the HbA1c goal set by the field site (HbA1c less than 9%) and Center for Medicare and Medicaid Services (CMS) recommended benchmark of HbA1c

less than 8%. Noticeably, the field site HbA1c goal is one point higher than the CMS benchmark. As depicted in Table 4, there were 33 cases in pre-QI data that met the CMS benchmark of HbA1c less than 8% compared to 29 cases who had an HbA1c less than 8% in post-QI data. Five cases had HbA1c greater than 8% but less than 9% in the pre-QI data set as compared with 13 cases in post-QI data. For cases with HbA1c greater than 9%, there were 12 cases in pre-QI data as compared to only 8 cases in the post-QI data set. Overall, more cases had met the field site benchmark of HbA1c less than 9% in post-QI data (84%) compared to pre-QI data (76%; see Table 4).

Table 4

Pre-and Post-QI Data of HbA1c Lab Values Range

	Pre-QI data		Post-QI data	
HbA1c Range	Freq	Percentage	Freq	Percentage
Less than 8%	33	66	29	58
Greater than 8% but Less than 9%	5	10	13	26
Greater than 9%	12	24	8	16
N	50	100	50	100

In order to evaluate the effect of the two therapies, cases with greater than 8% HbA1c were analyzed by comparing the HbA1c range for pre- and post-QI data when subjected to either SIIT therapy or standard therapy. There were 17 cases selected from the pre-QI data that met this criterion for further analysis, with 8 cases being on SIIT therapy and 9 cases on standard therapy at one point during the 6 month period (Table 5).

Table 5

Pre-QI HbA1c Greater Than 8%

Therapy	Freq	Percentage
SIIT*	8	47
STD**	9	53
N	17	100

Note. Short-term intensive insulin therapy *; Standard protocol **

As shown on Table 6, for those pre-QI data cases with HbA1c greater than 8% and treated with SIIT therapy, the HbA1c mean score was 6.87% (*SD*=0.49) post-QI data, compared with HbA1c mean score of 10.41% (*SD=2.22*) six months before. For those cases treated with standard protocol, the HbA1c mean score was 8.43% (*SD*=2.09) as compared with 10.1% (*SD*=1.44) six months before. Both these mean scores were statistically significant ($p<.001$).

Table 6

Pre-and Post-QI Therapy Type for Pre-QI HbA1c Greater than 8%

	N	Minimum	Maximum	Mean	*SD*
Pre-SIIT*	8	8.1	14.4	10.41	2.22
Post-SIIT*	8	6.3	7.9	6.86	0.49
Pre-STD**	9	8.5	12.9	10.10	1.44
Post-STD**	9	5.6	12.1	8.43	2.09

Note. Short-term intensive insulin therapy *; Standard protocol **

Table 7 shows a further breakdown of the HbA1c score by therapy type. Out of 8 cases treated with SIIT, seven cases had HbA1c of between 6.5% and 8%, and one case below 6% with no case a HbA1c greater than 8%. For standard protocol, there were 6 cases with HbA1c greater than 8% and 3 cases with HbA1c of less than 8%. Therefore, for those cases with a HbA1c greater than 8% in pre-QI data, all of them recorded an improved post-QI data HbA1c and both CMS and Field site HbA1c benchmark of 8% and 9%, respectively. Standard protocol, on the other hand, although there was an improvement, only three cases met CMS benchmark and a total of 6 cases that met the field site HbA1c benchmark of less than 9%.

Table 7

Post-QI Therapy Type for Pre-QI HbA1c Greater than 8%

HbA1c range score	SIIT	STD
Less than 6.5%	1	2
>6.5%<8%	7	1
>8%<9%	0	3
Greater than 9%	0	3
N=17	8	9

Note, Short-term intensive insulin therapy *; Standard protocol **

Although the analyzed QI data is too small (17 data set), the findings for this QI project indicate that there was a definite improvement for HbA1c for cases treated with SIIT therapy. Despite the field site HbA1c benchmark being higher than CMS

recommended benchmark, providers who used some form of SIIT to treat T2DM patients with an elevated blood sugar were able to achieve not only the field site benchmark but also the CMS benchmark of HbA1c less than 8%. This is in comparison to only 3 cases out of 9 cases that achieved CMS benchmark of HbA1c of less than 8% when treated with standard protocol. This outcome amplifies the effectiveness of SIIT over standard stepwise therapy in treating an episode of hyperglycemia in the management of T2DM (Cheng et al., 2019; Liu et al., 2018; Liehua et al., 2018; Nunes et al., 2019).

The fact that the field site care for low income, uninsured, Medicaid recipient's population who are known to have a higher rate of non-compliant due to their unique socio-economic characteristics might explain the clinic decision to set a higher HbA1c benchmark of less than 9% instead of CMS benchmark of HbA1c of less than 8%. (Mogre, Johnson, Tzelepis, Shaw, & Paul, 2017). Also, the clinic depends on donations and funding from well-wishers to provide services to their clientele. Sometimes the funding is not enough to procure medications needed to cover the treatment needs of their clients. Insulin is expensive, and the cost might be restrictive for this field site when funding is not available as needed. Therefore, although the CMS goal was to have a client achieve a HbA1c less than 8%, the site has settled for HbA1c less than 9% as their benchmark goal. According to Qingfeng et al. (2015), SIIT treatment for 10 to 14 days has been shown to help clients with T2DM achieve normoglycemia and, when switched to metformin, have been able to achieve long-term glycemic control same as those patients using long-acting insulin. Metformin is an oral antidiabetic medication that is

affordable, convenient to take, and also helps with weight loss and would be an ideal option for this population segment cared for by this site (Qingfeng et al., 2015).

The ideal HbA1c level is below 6.5%. However, as noted above, it has been a common practice for providers not to treat their T2DM patients to completely control their blood glucose levels (Skyler et al., 2017). Intensification of treatment therapy is often delayed, exposing clients to hyperglycemia for years, as evidenced by the above set benchmarks (Skyler et al., 2017). The outcome of this project may be a wake-up call for this site and healthcare organizations in general that it is possible to treat T2DM patients with SIIT to achieve lower blood sugar levels to meet the CMS HbA1c goal of less than 8% and even lower HbA1c values.

Providers' use of insulin intensification helped the clients with HbA1c level above 8% achieve both the site goal, and the CMS benchmark. The outcomes show that the improvement in HbA1c was not a coincidence. Providers made the evidence-based clinical decision to initiate an aggressive treatment plan that involve insulin intensification for clients with HbA1c greater than 8% in order to achieve the field site HbA1c goal and as a result performed better by achieving the CMS HbA1c benchmark. The mean score for the SIIT treatment group was statistically significant using the one-sample *t*-test, indicating that the result was representative of the larger population of T2DM patients in this field site. Therefore, insulin intensification can be recommended for clients with elevated HbA1c with close follow-up to mitigate the risk of hypoglycemia.

T2DM treatment is challenging as it depends on providers working closely with their clients to identify patient's strengths, preferences, and socio-economic barriers that may hinder treatment adherence (Ivers et al., 2019). SIIT treatment is an aggressive treatment protocol that demands the provider's time and commitment to frequent follow-ups with the client to ensure compliance and treatment adjustments. On the other hand, patients must be willing to commit to the provider's directed self-care behaviors and be able to perform T2DM self-care tasks with competency and efficacy required. These results are even more significant as they show that the achievement of the CMS benchmark is possible even to the vulnerable and at-risk population, such as the patients cared for by this field site. Therefore, the project has the potential to bridge the knowledge gap in the management of T2DM patients leading to reduced disease complications, improved quality of life and thereby contributing to positive change.

Recommendations

Most of the studies on SIIT therapy have been conducted on newly diagnosed T2DM with an episode of hyperglycemia. The outcome of this QI project is evidence that insulin intensification can be a useful treatment option in the management of T2DM patients with stable disease during an episode of hyperglycemia. Many providers avoid insulin intensification due to concern of hypoglycemia (Huang, 2018). However, according to Huang (2018), patients who were given 80% of the recommended total daily dose of insulin as the initial dosage, were found to experience a shorter time to glycemic goal, lesser insulin variability, and low incidence of hypoglycemia. According to Kobayashi, Takemura, and Kanda (2011), patient experiences during care delivery may

represent the quality of care given under the structure-process-outcome approach that practitioners, managers, and policymakers may use to effect quality improvement. The success of SIIT therapy requires a combination of factors that address the structure, process, and the desired outcomes as advanced by Donabedian's model for quality improvement (Berwick & Fox, 2016).

The healthcare organization that includes SIIT as part of its T2DM treatment protocol must have an established structure that guarantees enough providers to meet the demand of SIIT therapy, close follow-up, and frequent provider-patient contact. When the ratio of patients-to-provider is high, the SIIT protocol might be unfeasible to implement. The patient must also be able to acquire insulin and other resources needed for intensive self-care management. The field site has a robust medication assistant program called beta medications, where they connect patients who need help filling their prescriptions with non-profit organizations and pharmaceutical companies' free medication programs.

To address the issue of process, there must be established standardized SIIT protocol for all providers to follow while treating T2DM patients with an episode of hyperglycemia (Liu et al., 2018). The protocol must address. patient safety, and unique patient characteristics in order to avoid pitfalls that may arise due to variation in provider treatment regimens while using insulin intensification. The providers should exercise shared decision-making and team approach while initiating SIIT to ensure its success (Ivers et al., 2019; ADA, 2019)

Lastly, there must be standardized outcome measurements in place to ascertain treatment success and when to intervene. For example, the use of FPG, PPG, and HbA1c are very effective for monitoring the treatment outcome of SIIT (Liu et al., 2018; Liehua et al., 2018; Liu et al., 2015). FPG and PPG are ideal during the induction phase of SIIT treatment because daily blood glucose monitoring is required. Using HbA1c as lab value of measurement is ideal during the initiation of the SIIT and also to monitor average blood sugar during the maintenance disease phase. Also, healthcare organizations should set their HbA1c benchmark to align with the recommended CMS benchmark.

Strengths and Limitations of the Project

The main strength of this QI project is its design and methodology. The use of quality improvement data provided by the clinic authorized representative was useful in maintain objectivity and eliminated bias in carrying out the project. The data analyzed was the same data the organization used to track their clinical performance and therefore provided an ideal lens to evaluate how the organization was doing in T2DM disease management. The use of a randomized sample also added the authenticity of the results of this project as it ensured that the sample is a true representation of the T2DM population cared for by this field site. Another strength of this QI project was the long duration of the study. Evaluating QI data that span 6 months allowed at least two instances of HbA1c testing that is done every 3 months for pre-/post-QI data analysis. This duration is also ideal for patients with an episode of hyperglycemia and under treatment protocol to show the sustained effect of the treatment. Finally, the use of theory of self-care of chronic illness and theory of self-efficacy was another strong attribute of

this QI project. T2DM is a chronic illness that require the patients to adjust their lifestyle to adapt to the illness. SIIT treatment plan is anchored in these two theoretical frameworks because any treatment success depends on the established strong link between the provider-initiated treatment recommendations and the self-care competency of the T2DM patients.

One of the project's limitations was that the study design did not allow for the interaction with providers to understand treatment decision-making processes. Secondly, T2DM is a chronic illness, and 6 months is not enough time to evaluate the disease variations even after achieving normoglycemia. More time is needed to be able to understand the effect of SIIT treatment over the years or during the lifetime progression of T2DM disease. Therefore, there is a need for future projects that will track the effect of SIIT over a more extended period. Also, future projects should focus on evaluating the perception of providers on SIIT protocol and the factors that influence their clinical decision-making process and the level of patients' involvement in the treatment decision-making process.

Section 5: Dissemination Plan

Introduction

The objective and driving force to conduct a quality improvement project in a healthcare organization or institution is to discover new insights into a problem and use these insights to propose a needed practice change. The outcomes of a project such as this DNP QI project are not useful unless it is disseminated to the relevant stakeholders for implementation and evaluation (Edwards, 2015). The purpose of this QI project was to evaluate pre-/post-QI data and synthesize results to make a recommendation for possible practice change. Dissemination of the project outcomes facilitates sharing of the results to relevant stakeholders for implementation of the proposed change in practice. Therefore, it is imperative to employ the most effective methods of disseminating the knowledge gained in order to reach as many intended audiences as possible. Publication of the project outcomes through reputable journals and health professional organizations would guarantee to reach healthcare policymakers, nursing scholars, decision makers, practitioners, healthcare students, and the general public (Edwards, 2015). Moreover, social media platforms, membership panels, and webinars are all crucial avenues to disseminate the findings of a DNP project (Edwards, 2015).

Results of this DNP QI project indicated that SIIT is an effective treatment protocol in helping T2DM patients with an episode of hyperglycemia achieve normoglycemia. Therefore, results will be useful to both T2DM patients struggling with blood sugar control and their healthcare providers. It is also useful information to the organization’s leadership, who formulate organizational policies and resource allocation.

Sharing these findings with these stakeholders would change the T2DM disease trajectory for better by helping T2DM patient control their HbA1c to desired levels. Improved blood sugar control among T2DM patients means fewer disease complications, fewer emergency room visits, and hospital admissions (Skyler et al., 2017). This, in turn, will lead to low T2DM morbidity and mortality rates and an overall reduction in healthcare costs associated with T2DM (ADA,2019).

The result of this QI project will be disseminated through a PowerPoint presentation during providers' quarterly meeting when all 12 clinic primary care providers meet for new guidelines and clinical practice updates. Another method of dissemination will involve preparing a large poster presentation of the summary of the QI project to promote the evidence-based process that led to the findings. The poster will be divided into three sections. Section 1 will include the background of the problem, the project purpose, and project design. Section 2 will include project findings, implications, and recommendations. The poster will also include a third section for the project implementation plan and change model for the proposed practice change.

Analysis of Self

Practitioner

This QI project has made me a better practitioner. The project provided an opportunity for me as a provider to view the impact of the care I give to my clients at the aggregate level and how it is part of organizational performance. Also, findings generated from this QI project will be a great addition to my evidence-based practice decision-making tool kit when managing T2DM patients. I have come to appreciate the challenges

of clinical decision-making and the need for standardized clinical protocols to guide providers during patient care in order to improve patient health outcomes. Throughout this QI project, I grew as a provider and as a practitioner, and I became empowered to continue applying my clinical knowledge and skills in providing safe, effective, and affordable, patient-centered care. Therefore, this QI project results on the effectiveness of SIIT treatment is an essential evidence-based finding that I can add to my clinical decision-making tool kit in order to continue to provide effective quality care to my T2DM clients.

Scholar

According to the American Association of Colleges of Nursing (AACN; 2006), the DNP program should prepare the DNP investigator for system-level thinking that focuses on solving complex health issues through clinical research and ensuring effective, safe, and high-quality patient-centered care. This project was an opportunity for me as a scholar to engage in clinical scholarship to analyze complex health issues in the management of T2DM. DNP graduates can contribute to nursing science by evaluating and translating research into practice (AACN, 2006). The project focused on the effective treatment plan in managing T2DM patients. It also addressed the safety of patient care that is a concern for many providers while deciding between intensification of insulin and the risk of hypoglycemia (Huang, 2018). The QI project was an opportunity to gain skills necessary for this unique ability as a DNP scholar that includes designing evidence-based interventions and evaluating practice outcomes through the analysis and synthesis of QI data.

An effective healthcare professional stays informed through scholarly inquiry into their specialty area in order to provide the best care to their clients using current guidelines and latest evidence-based practices. The QI project helped me as a scholar to sharpen my scholarly skills by being able to translate evidence-based findings from this QI project into recommendations for practice change. The QI project findings of this project indicated that SIIT treatment is superior to the standard protocol in the treatment of T2DM patients with an episode of hyperglycemia. The project findings were validated with overwhelming evidence from the literature reviewed.

Project Manager

This was a project that relied on the QI data provided by the authorized organization representative for evaluation. The success of this QI project depended entirely on my organizational skills, time management, and priority-setting. The project also presented an opportunity for the development of advanced nursing skills in the area of interprofessional collaboration and effective communication. The project could not have been successful if it were not for the close collaboration between me and the clinic leadership. This collaboration ensured that the data required was available for analysis and dissemination of the project findings to the relevant stakeholders. This was in line with the AACN and IOM position that team-based care is crucial for the safety and well-being of all patients (AACN; 2006).

I have learned a lot and improved in the leadership and management skills. I have grown as a leader and a manager who can set goals and make crucial decision in light of competing priorities. These skills will continue to be useful in my career as a healthcare

professional and a DNP-prepared nurse. The health healthcare system is growing at an alarming rate, and the new leaders in healthcare require skills to engage other stakeholders and be part of the healthcare policymaking process (AACN; 2006). As I come to the end of this QI project, I feel empowered and better equipped to be part of the new generation of nurse leaders ready to tackle challenges facing our healthcare system at the national and global levels.

Challenges, Solutions, and Insights Gained

The idea that was transformed into this DNP QI project was a product of my passion and commitment as a family nurse practitioner to provide the best care to my clients. The development of this project was not without challenges, but at the same time, new insights were gained that could be of potential benefit for the management of T2DM disease in a primary care setting.

Diabetes is a chronic illness that affects millions of individuals in the United States and is the seventh leading cause of death (National Diabetes Statistics Report, 2017) There are nearly 30 million people in the US with diabetes, and 95% of those have T2DM, while an additional 86 million have prediabetes (Skyler et al., 2017). The progression of the disease despite the use of stepwise treatment protocol has continued to be a significant challenge for providers and patients alike. SIIT treatment has been successful in inducing T2DM remission on newly diagnosed T2DM patients and thus helps reverse the disease progression (Liehua et al., 2018; Liu et al., 2018). This fact has been validated by the findings of this QI project, where all the T2DM patients with a

HbA1c level of greater than 8% treated with SII able to achieve the HbA1c goal set by CMS of HbA1c less than 8%.

The use of SIIT to optimize T2DM treatment when patients are experiencing persistent hyperglycemia is recognizing the chronicity of T2DM that require adaptation over time by both the patient and the provider (Ivers et al., 2019). Standard treatment guidelines would suggest the use of insulin as a last resort for persistent hyperglycemia, which will increase the T2DM cost of care tremendously (Rodriguez-Sanchez, Feenstra, Bilo, Alessie, 2019). SIIT as a temporary treatment offers an affordable and effective alternative, thereby contributing to less disease burden by reducing the risk of disease complications, hospital admission, and emergency room visits (Skyler et al., 2017).

Many providers are concerned about insulin intensification therapy, such as SIIT, due to the risk of hypoglycemia. A study conducted by Huang (2018) showed that SIIT, when properly administered, has lower hypoglycemia incidences compared to standard insulin therapy. Another challenge of SIIT is that it demands close monitoring by the provider and frequent clinic visits. This can become a challenge if a patient with a busy lifestyle or is employed fails to get time off to come to the clinic when needed. It can also present a challenge to primary care clinics without enough providers or with high patient-to-provider ratios. The issue of patients being able to keep up with frequent clinic appointments can be resolved by telehealth and phone follow-up appointments (Kanadli, Ovayolu, &Ovayolu, 2016).

According to Zhang, Lin, Pforsich, and Kin (2020), there is a huge shortage of primary care providers in the US, and this shortage is going to get worse each passing year. The ongoing granting of full authority to nurse practitioners across the nation is easing this shortage, but the demand for providers is growing faster than the supply of nurse practitioners and other general practitioners (Zhang et al., 2020). The shortage leaves the current primary care providers with heavy patient loads, making it difficult and unsafe to manage patients under SIIT treatment effectively. Therefore, the lack of enough primary care providers will continue to be a barrier for the full implementation of SIIT by primary care clinics until the shortage is mitigated. In a nutshell, SIIT has proven to be an effective treatment for T2DM patients with an episode of hyperglycemia. Therefore, healthcare organizations and practitioners should consider using the SIIT within the constraints of the limited workforce to improve health outcomes of T2DM patients.

Summary

This DNP QI project evaluated the effectiveness of SIIT treatment in the management of T2DM. There was overwhelming evidence from the literature that SIIT is effective in treating T2DM patients with elevated blood glucose levels. However, the majority of literature evidence was for newly diagnosed T2DM patients. Therefore, this QI project was set to evaluate QI data for the effect of insulin intensification for patients with the established illness. The findings of this QI project showed that SIIT is effective in treating T2DM patients with an episode of hyperglycemia compared to standard stepwise therapy. SIIT, when implemented in primary care settings, has the potential to improve health outcomes for T2DM patients struggling with uncontrolled blood sugar. It

also provides healthcare providers taking care of T2DM patients with evidence-based clinical tools to provide effective and quality care to their clients. Therefore, SIIT can be crucial in reducing disease complications, improve quality of life, and reduce overall healthcare costs. The project recommended healthcare organizations, policymakers, and clinical experts to develops standardized SIIT protocol for use in primary care settings for management of T2DM patients struggling with blood sugar control.

References

Amer, F. A., Mohamed, M. S., Elbur, A. I., Abdelaziz, S. I., & Elrayah, Z. A. (2018). Influence of self-efficacy management on adherence to self-care activities and treatment outcome among diabetes mellitus type 2 Sudanese patients. *Pharmacy Practice, 16*(4), 1–7. doi: 10.18549/PharmPract.2018.04.1274

American Association of Colleges of Nursing (AACN). (2006). The essentials of doctoral education for advance practice nursing. Retrieved March 19, 2020 from https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf

American Diabetes Association (2019). Position Statements-2019. *Diabetes Care*. *42*(1).

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist, 37*(2), 122–147. doi: 10.1037/0003-066X.37.2.122

Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review, 84*(2), 191–215. doi: 10.1037/0033-295X.84.2.191

Berwick, D., & Fox, D. M. (2016). "Evaluating the quality of medical care": Donabedian's classic article 50 years later. *The Milbank Quarterly*, *94*(2), 237–241. doi: 10.1111/1468-0009.12189

Boström, E., Isaksson, U., Lundman, B., Lehuluante, A., & Hörnsten, Å. (2014). Patient-centered care in type 2 diabetes - An altered professional role for diabetes specialist nurses. *Scandinavian Journal of Caring Sciences, 28*(4), 675–682. doi: 10.1111/scs.12092

Cheng, L., Xu, M., Lin, X., Tang, J., Qi, Y., Wan, Y., … Yan, L. (2016). The intriguing effects of time to glycemic goal in newly diagnosed type 2 diabetes after short-term intensive insulin therapy. *Endocrine Journal*, *63*(8), 739–746. doi: 10.1507/endocrj.EJ16-0154

Choi, H., Kramer, C. K., Zinman, B., W Connelly, P., & Retnakaran, R. (2019). Effect of short-term intensive insulin therapy on the incretin response in early type 2 diabetes. *Diabetes & Metabolism*, *45*(2), 197. doi:10.1016/j.diabet.2018.01.003

Dao, J., Spooner, C., Lo, W., & Harris, M. F. (2019). Factors influencing self-management in patients with type 2 diabetes in general practice: A qualitative study. *Australian Journal of Primary Health*, *25*(2), 176. doi:10.1071/PY18095

Edwards D. J. (2015). Dissemination of research results: On the path to practice change. *The Canadian Journal of Hospital Pharmacy*, *68*(6), 465–469. doi.org/10.4212/cjhp.v68i6.1503

Fritz, H. A. (2017). Challenges to developing diabetes self-management skills in a low-income sample in North Carolina, USA. *Health & Social Care in The Community*, *25*(1), 26–34. doi:10.1111/hsc.12172

Hallberg, S. J., Gershuni, V. M., Hazbun, T. L., & Athinarayanan, S. J. (2019). Reversing type 2 diabetes: A narrative review of the evidence. *Nutrients*, *11*(4). *766*. doi:10.3390/nu11040766

Handelsman, Y., Bloomgarden, Z. T., Grunberger, G., Umpierrez, G., Zimmerman, R. S., Bailey, T. S., … Zangeneh, F. (2015). American Association of Clinical Endocrinologists and the American College of Endocrinology clinical Practice

guidelines for developing a diabetes mellitus comprehensive care plan--2015--executive summary. *Endocrine Practice*, *21*(4), 413–437. doi: 10.4158/EP15672.GL

Huang Xinwei. (2018). The impact of different initial insulin dose regimens in short-term intensive insulin therapy. *Diabetes*, *67*(1). doi:10.2337/db18-1054-P

Ivers, N. M., Jiang, M., Alloo, J., Singer, A., Ngui, D., Casey, C. G., & Yu, C. H. (2019). Diabetes Canada 2018 clinical practice guidelines: Key messages for family physicians caring for patients living with type 2 diabetes. *Canadian Family Physician*, *65*(1), 14–24. PMID: 30674509; PMCID: PMC6347316

Kanadli, K. A., Ovayolu, N., & Ovayolu, Ö. (2016). Does telephone follow-up and education affect self-care and metabolic control in diabetic patients? *Holistic Nursing Practice*, *30*(2), 70–77. doi: 10.1097/HNP.0000000000000137

Kayar, Y., Kayar, N. B., Erden, S. C., Onem, R., Ekinci, I., Emegil, S., … Danalioglu, A. (2017). The relationship between depression and demographic risk factors, individual lifestyle factors, and health complications in patients with type 2 diabetes mellitus. *Biomedical Research*, *28*(4), 1560–1565.

Kobayashi, H., Takemura, Y., & Kanda, K. (2011). Patient perception of nursing service quality: An applied model of Donabedian's structure-process-outcome approach theory. *Scandinavian Journal of Caring Sciences*, *25*(3), 419–425. doi:10.1111/j.1471-6712.2010.00836.x.

Li, H., Ji, M., Scott, P., & Dunbar-Jacob, J. M. (2019). The effect of symptom clusters on quality of life among patients with type 2 diabetes. *Diabetes Educator*, *45*(3), 287–294. doi:10.1177/0145721719837902

Liehua Liu, Siyue Yang, Jianbin Liu, Hai Li, Juan Liu, Xiaopei Cao, … Yanbing Li. (2018). Fasting plasma glucose indicates reversibility of the acute insulin response after short-term intensive insulin therapy in patients with various duration of type 2 diabetes. *Journal of Diabetes Research*, *9423965*, 1-9. doi:10.1155/2018/9423965.

Liu, L., Liu, J., Xu, L., Ke, W., Wan, X., Li, H., … Li, Y. (2018). Lower mean blood glucose during short-term intensive insulin therapy is associated with long-term glycemic remission in patients with newly diagnosed type 2 diabetes: Evidence-based recommendations for standardization. *Journal of Diabetes Investigation*, *9*(4), 908–916. doi:10.1111/jdi.12782

Mahdavi, M., Vissers, J., Elkhuizen, S., van Dijk, M., Vanhala, A., Karampli, E., … van de Klundert, J. (2018). The relationship between context, structure, and processes with outcomes of 6 regional diabetes networks in Europe, *PLoS ONE*, *13*(2), 1–17. doi:10.1371/journal.pone.0225619

McInnes, N., Smith, A., Otto, R., Vandermey, J., Punthakee, Z., Sherifali, D., … Gerstein, H. C. (2017). Piloting a remission strategy in type 2 diabetes: Results of a randomized controlled trial. *The Journal of Clinical Endocrinology and Metabolism*, *102*(5), 1596–1605. doi:10.1210/jc.2016-3373

Mogre, V., Johnson, N. A., Tzelepis, F., Shaw, J., & Paul, C. (2017). Adherence to self-care behaviours and associated barriers in type 2 diabetes patients of low-and middle-income countries: A systematic review protocol. *Systematic Reviews*, *6*(1), 39. doi:10.1186/s13643-017-0436-4

National Diabetes Statistics Report (2017). *Estimates of diabetes and its burden in the United States*. Retrieved 1 August 2019 from http://www.diabetes.org/assets/pdfs/basics/cdc-statistics-report-2017.pdf

Pon, E. du, Azzati, S. E., Dooren, A. van, Kleefstra, N., Heerdink, E., & Dulmen, S. van. (2019). Effects of a Proactive Interdisciplinary Self-Management (PRISMA) program on medication adherence in patients with type 2 diabetes in primary care: A randomized controlled trial. *Patient Preference & Adherence*, *13*, 749–759. doi:10.2147/PPA.S188703

Qingfeng, C., Shumin, Y., Changhong, Z., Zhihong, W., Zhengping, F., Rong, L., … Qifu, L. (2015). Efficacy of metformin-based oral antidiabetic drugs is not inferior to insulin glargine in newly diagnosed type 2 diabetic patients with severe hyperglycemia after short-term intensive insulin therapy. *Journal of Diabetes*, *7*(2), 182. doi: 10.1111/1753-0407.12167

Retnakaran, R. (2015). Novel strategies for inducing glycemic remission during the honeymoon phase of type 2 diabetes. *Canadian Journal of Diabetes*, *39*(5), S142–S147. doi:10.1016/j.jcjd.2015.08.007

Riegel, B., Jaarsma, T., & Stromberg, A. (2012). A middle-range theory of self-care of chronic illness. *Advances in Nursing Science*, *35*(3), 194. doi:10.1097/ANS.0b013e318261b1ba

Rodriguez-Sanchez, B., Feenstra, T., Bilo, H., Alessie, R. (2019). Cost of people with diabetes in relation to average glucose control: An empirical approach controlling for years of onset cohorts. *European Journal of health Economics*, *20*(7), 989-1000. doi: 10.1007/s10198-019-01072-z

Saad, A. M. J., Younes, Z. M. H., Ahmed, H., Brown, J. A., Al Owesie, R. M., & Hassoun, A. A. K. (2018). Self-efficacy, self-care and glycemic control in Saudi Arabian patients with type 2 diabetes mellitus: A cross-sectional survey. *Diabetes Research and Clinical Practice*, *137*, 28–36. doi:10.1016/j.diabres.2017.12.014

Sanghani, N.B., Parchwani, D.N., Palandurkar, K.M., Shah, & Dhanani, J.V., (2013). Impact of lifestyle modification on glycemic control in patients with type 2 diabetes mellitus. *Indian Journal of Endocrinology and Metabolism*, *17*(6), 1030-1039. doi:10.4103/2230-8210.122618

Savjani, K., Haseeb, F., & Reay, M. (2018). Measuring quality and outcomes in intensive care. *Surgery, 36*(4), 196–200. doi:10.1016/j.mpsur.2018.01.008

Shrivastava, S. R., Shrivastava, P. S., & Ramasamy, J. (2013). Role of self-care in management of diabetes mellitus. *Journal of Diabetes and Metabolic Disorders*, *12*(1), 14. doi: 10.1186/2251-6581-12-14

Skyler, J., Bakris, G., Bonifacio, E., Darsow, T., Eckel, R.,… Groop, L. (2017). Differentiation of diabetes by pathophysiology, natural history, and prognosis. *Diabetes*, *66*(2), 241-255. doi:10.2337/db16-0806

Sokol, R. (2019). Understanding the high cost of insulin: What family physicians can do to help our patients with type 2 diabetes mellitus. *American Family Physician*, *99*(7), 416–417.

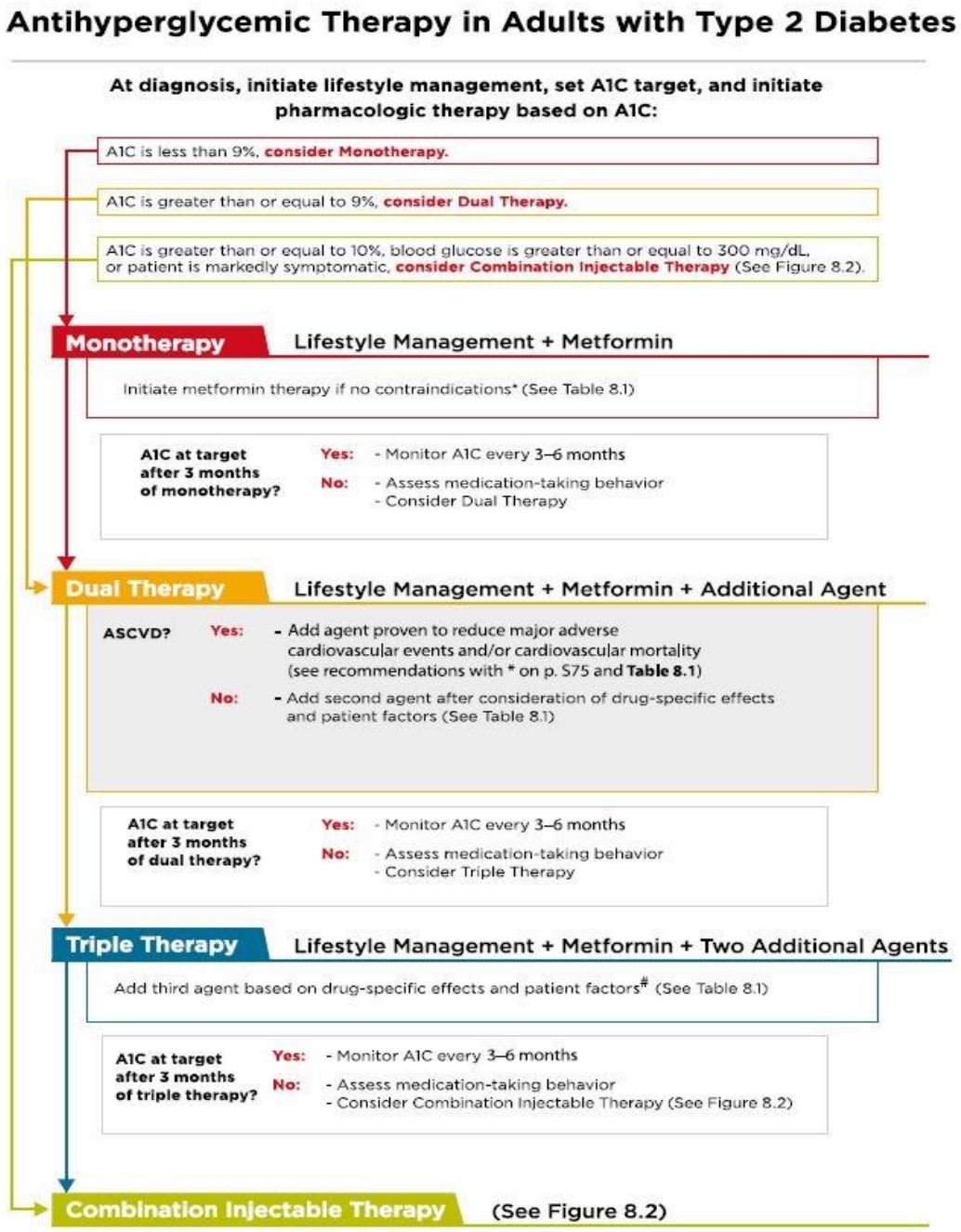
Wansbrough, G (2015). Clinical Q&A:" Changing the course of type 2 diabetes. *Medical Post;* Chicago. *51*(3), 19.

Weng, J. (2017). Short-term intensive insulin therapy could be the preferred option for new onset Type 2 diabetes mellitus patients with HbA1c > 9. *Journal of Diabetes, 9*(10), 890–893. doi:10.1111/1753-0407.12581

World Health Organization. (2016). *Global Report on Diabetes*. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/204871/9789241565257_eng.pdf;jsessionid=5623D07E1BE16234FFD292D66364884E?sequence=1

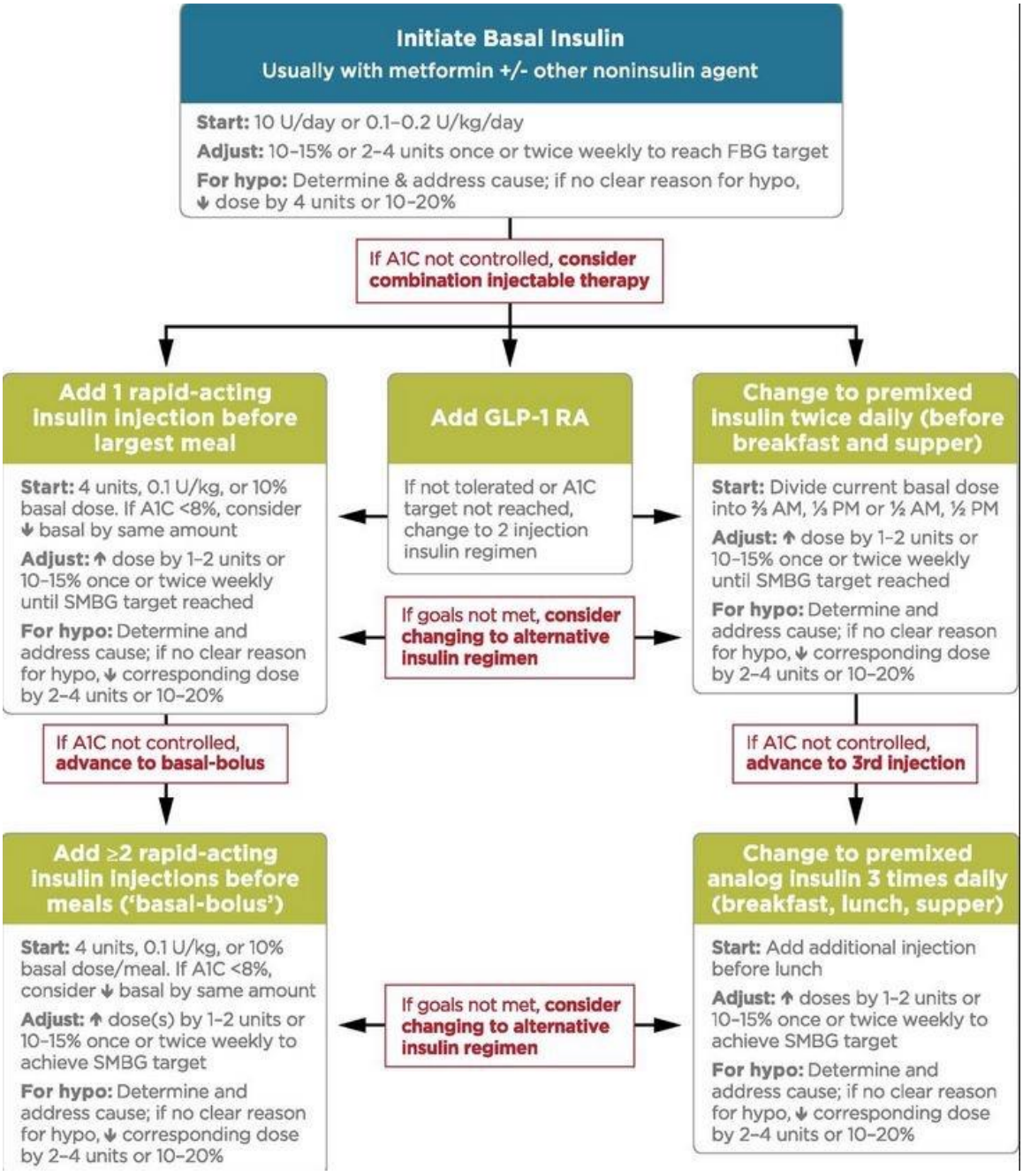
Zhang, X., Lin, D., Pforsich, H., & Lin, V. W. (2020). Physician workforce in the United States of America: Forecasting nationwide shortages. *Human Resources for Health*, *18*(1), 1–9. doi:10.1186/s12960-020-0448-3

Appendix A: 2018 ADA Meds Algorithm for Treatment of T2DM



Source: American Diabetes Association [ADA]. (2018). 2018 ADA Meds management updates. Retrieved 22 March 2020 from https://diabetesed.net/2018-ada-meds-management-update/

Appendix B: 2018 ADA Insulin Algorithm for Treatment of T2DM.



Source: American Diabetes Association [ADA]. (2018). 2018 ADA Meds management updates. Retrieved 22 March 2020 from https://diabetesed.net/2018-ada-meds-management-update/

Appendix C: 2018 ADA Medication Comparison Chart for T2DM

	Efficacy*	Hypoglycemia	Weight Change	CV Effects		Cost	Oral/SQ	Renal Effects		Additional Considerations
				ASCVD	CHF			Progression of DKD	Dosing/Use considerations	
Metformin	High	No	Neutral (Potential for Modest Loss)	Potential Benefit	Neutral	Low	Oral	Neutral	• Contraindicated with eGFR <30	• Gastrointestinal side effects common (diarrhea, nausea) • Potential for B12 deficiency
SGLT-2 Inhibitors	Intermediate	No	Loss	Benefit: canagliflozin, empagliflozin†	Benefit: canagliflozin, empagliflozin	High	Oral	Benefit: canagliflozin, empagliflozin	• Canagliflozin: not recommended with eGFR <45 • Dapagliflozin: not recommended with eGFR <60; contraindicated with eGFR <30 • Empagliflozin: contraindicated with eGFR <30	• **FDA Black Box:** Risk of amputation (**canagliflozin**) • Risk of bone fractures (canagliflozin) • DKA risk (all agents, rare in T2DM) • Genitourinary infections • Risk of volume depletion, hypotension • ↑LDL cholesterol
GLP-1 RAs	High	No	Loss	Neutral: lixisenatide, exenatide extended release Benefit: liraglutide†	Neutral	High	SQ	Benefit: liraglutide	• Exenatide: not indicated with eGFR <30 • Lixisenatide: caution with eGFR <30 • Increased risk of side effects in patients with renal impairment	• **FDA Black Box:** Risk of thyroid C-cell tumors (**liraglutide, albiglutide, dulaglutide, exenatide extended release**) • Gastrointestinal side effects common (nausea, vomiting, diarrhea) • Injection site reactions • ?Acute pancreatitis risk
DPP-4 Inhibitors	Intermediate	No	Neutral	Neutral	Potential Risk: saxagliptin, alogliptin	High	Oral	Neutral	• Renal dose adjustment required; can be used in renal impairment	• Potential risk of acute pancreatitis • Joint pain
Thiazolidinediones	High	No	Gain	Potential Benefit: pioglitazone	Increased Risk	Low	Oral	Neutral	• No dose adjustment required • Generally not recommended in renal impairment due to potential for fluid retention	• **FDA Black Box:** Congestive heart failure (**pioglitazone, rosiglitazone**) • Fluid retention (edema; heart failure) • Benefit in NASH • Risk of bone fractures • Bladder cancer (pioglitazone) • ↑LDL cholesterol (rosiglitazone)
Sulfonylureas (2nd Generation)	High	Yes	Gain	Neutral	Neutral	Low	Oral	Neutral	• Glyburide: not recommended • Glipizide & glimepiride: initiate conservatively to avoid hypoglycemia	• FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)
Insulin **Human Insulin**	Highest	Yes	Gain	Neutral	Neutral	Low	SQ	Neutral	• Lower insulin doses required with a decrease in eGFR; titrate per clinical response	• Injection site reactions • Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs
Analogs						High	SQ			

Source: American Diabetes Association [ADA]. (2018). 2018 ADA Meds management updates. Retrieved 22 March 2020 from https://diabetesed.net/2018-ada-meds-management-update/