A1C POINT OF CARE TESTING WITH TYPE II DIABETES PATIENTS TO INCREASE PATIENT ENGAGEMENT AND IMPROVE GLYCEMIC CONTROL

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Abstract

Background: Diabetes is at the forefront of chronic disease management. As the 7th leading cause of death in the United States, 34.2 million Americans are diagnosed with diabetes, and 95% have type 2 diabetes. Uncontrolled diabetes can result in long-term complications, increased hospitalizations, and premature deaths. Patient and provider partnerships are essential to increasing patient engagement to improve health care outcomes. Patient engagement, inclusive of collaboration with healthcare providers, promotes shared decision-making, enhancing patient self-care behaviors and effective disease self-management. Evidence supports that implementing point-of-care A1c testing (POCT HbA1c) in primary care settings promotes patient engagement with diabetes self-management resulting in improved patient glycemic control and attainment of organizational benchmarks for diabetic Value-Based Care quality metrics. **Purpose:** The purpose of this quality improvement project was for uncontrolled (HbA1c>8%) Type II diabetes patients to use POCT HbA1c to improve their glycemic control. **Methods:** Bandura's Self-Efficacy Theory provided the theoretical framework. The RE-AIM model with PDSA cycles guided the project implementation. Data analysis consisted of descriptive and inferential analyses to track the implementation effectiveness of POCT HbA1c to improve glycemic control. **Results:** Data tracking demonstrated that implementation of POCT HbA1c increased diabetes patient self-management and improved glycemic control as evidenced by decreased HbA1c and FBS results. SES scores did not demonstrate statistical significance but there was clinical significance with increased patient engagement. **Conclusions/Implications for Practice:** The project outcomes supported that uncontrolled Type II diabetes patients who engage in the use of POCT HbA1c increase self-management resulting in improved glycemic control. Health care providers managing uncontrolled Type II diabetes patients should strongly consider using POCT HbA1c

for diabetes patient self-management. Positive financial outcomes for both the patient and healthcare system can be a benefit with the use of POCT HbA1c. Project alignment with organizational initiatives is essential for obtaining support for implementation changes and long-term sustainability by conducting subsequent PDSA cycles.

Section I: Introduction of the Problem

Introduction/Background

Diabetes is at the forefront of chronic disease management. As the 7th leading cause of death in the United States, 34.2 million Americans are diagnosed with diabetes, and among those, 95% have Type II diabetes (Janapala, 2019). Uncontrolled diabetes can result in long-term complications, increased hospitalizations, and premature deaths (Berbudi et al., 2020). Those diagnosed with diabetes have an increased all-cause mortality rate by 1.8 times due to diabetes-associated complications such as a heart attack (Office of Disease Prevention and Health Promotion [ODPHP], 2021). Healthy People 2020, diabetes is the leading cause of kidney 0020failure, lower-limb amputations, and adult-onset blindness (ODPHP, 2021)

From an economic perspective, diabetes is the most expensive chronic condition in the nation (Center for Disease Control and Prevention, 2021). The financial burden of diabetes nationwide and in the State of Texas is enormous. In 2017, the national estimated cost of diagnosed diabetes was $327 billion with $237 billion in direct medical expenses and $90 billion in reduced productivity (American Diabetes Association [ADA], 2018). The cost of health care is 2.3 times higher among those with diabetes. In Texas, the total healthcare direct cost for diagnosed diabetes is approximately $18.9 billion, with an additional $6.7 billion of the indirect cost attributed to productivity loss (ADA, 2018). According to the ADA, Texas is one of four states with a total annual cost of $25.6 billion (ADA, 2018).

Self-Management

Diabetes self-management is the core foundation of comprehensive diabetes management (Beckerle & Lavin, 2013). Effective self-management support for diabetes consists of activities that assist the person with diabetes in implementing and sustaining essential behaviors needed to

successfully manage their condition on a continuous basis (Beck et al., 2017). Typically, support encompasses a combination of behavioral, educational, psychosocial, and clinical activities (Beckerle & Lavin, 2013). Fundamental to diabetes self-management support is ongoing education that develops and enriches the required knowledge, skills, and abilities necessary for diabetes self-care (Beck et al., 2017). Development of evidence-based patient competencies is centered around the individual needs of each patient with diabetes. Ultimately, the patient with diabetes can actively participate in informed problem-solving for effective diabetes self-management.

Self-Care

Diabetes self-care is an evolutionary process of developing knowledge or awareness through learning to survive with the complex nature of diabetes (Shirvastava et al., 2013 p.2). This entails a deliberate action to achieve an expected result preceded by examination, reflection, and judgment to appraise the situation and determine what should occur (Lambrinou et al., 2018). A vast majority of daily diabetes care is managed by patients and/or families (Shirvastava et al., 2013, p.2). “Self-care behaviors are “reliable and valid measures” needed for diabetes self-management and are helpful to providers in facilitating self-care activities” (Shirvastava et al., 2013, p2). These seven essential self-care behaviors in patients with diabetes, as defined by the Association of Diabetes Care and Education Specialists (ADCES) that are positively correlated with good glycemic control, reducing complications, and improving quality of life (Shrivastava et al., 2013 p.2). These seven self-care behaviors include healthy nutrition, exercise, monitoring blood sugar, medication compliance, good problem-solving skills, healthy coping skills, and risk-reduction behaviors (p.2). These measures are useful for providers managing individual patients. In addition, self-care encompasses performing such activities and includes

interdependence amongst them (Shrivastava et al., 2013). Diabetes self-care involves the patient making dietary and lifestyle modifications, supplemented with the supportive role of healthcare providers for sustaining a higher level of self-confidence, leading to a positive behavior change (Shrivastava et al., 2013, p. 2).

Patient Engagement

Patient engagement is the partnership between the patient and provider focused on actively working together to promote positive behavioral changes necessary for a healthy lifestyle and improved health (Sheikh et al., 2016). Essential to patient engagement is the concept of self-efficacy, which focuses on what an individual believes that one can achieve and ultimately accomplish specific to one or more targeted goals (D'Souza et al., 2017). Increasing patient engagement is essential to the enhancement of self-efficacy, self-management, and self-care behaviors. According to the ADA (2018), " a patient's perceptions about their ability, or self-efficacy, to perform self-management of diabetes is the most critical psychosocial factor related to improved diabetes self-management and treatment outcomes in diabetes"(p.S29). Thus, self-efficacy ought to be the objective of ongoing assessment, patient education, and treatment planning for every patient with diabetes (ADA, 2020, p.S38)

Point of Care

Advances in modern technology, such as point of care testing devices, have been increasingly utilized to provide innovative therapeutic solutions that effectively manage diseases like diabetes (Vamvini et al., 2019). According to the ADA (2021), POCT HbA1c devices, when coupled with education, can effectively promote self-management and improve patient health outcomes among diabetics. The utilization of POCT HbA1c provides an efficient and effective alternative to standard A1c laboratory testing within the clinic setting for overcoming therapeutic

inertia in diabetes self-management (Patzer et al., 2018). Point of care testing has proven to be valuable for improving HbA1c control and the achievement of organizational benchmarks for diabetes value-based care quality metrics (John et al., 2019). The use of POCT HbA1c strengthens patient education by allowing the provider to communicate needed treatment modification(s) during the patient-provider office visit in contrast to routine HbA1c lab draws associated with delayed communication of test results from a clinical staff (Schnell et al., 2017). This lack of timely patient-provider communication can significantly affect optimal glycemic control.

According to the ADA, "the goals of diabetes treatment are to prevent or delay complications, optimize quality of life, and establish a care plan with patients based on their individual preferences, principles, and goals" (2020). Hemoglobin A1c is the gold standard for diagnosing and managing diabetes (John et al., 2018). It represents the average blood glucose control over the past two or three months, accounting for pre-and post-prandial blood glucose (Crocker et al., 2020). Hemoglobin A1c parameters range from less than 5.7% within the normal range, 5.7 % to 6.4%, suggests prediabetes, and 6.5% or higher, is indicative of diabetes (Centers for Disease Control and Prevention, 2021). The ADA recommends "performing quarterly A1c testing in patients who have treatment changes and/or not meeting glycemic goals" (2020, p.S66).

Value-Based Care

Health care systems have shifted their payer model to value-based care to reduce the cost of healthcare and improve the quality of care provided to patients. The Value-Based Care (VBC) model centers around patient and provider accountability, shifting emphasis from fee-for-service

to patient outcomes (Office of National Coordinator for Health Information Technology [ONCHIT], 2019). The VBC goal star rating, used by the Centers for Medicare & Medicaid Services, measures the quality of health and drug services received by Medicare and Medicaid beneficiaries (Centers for Medicare & Medicaid Services, 2020). Incentives strengthen the adoption of patient engagement strategies, for instance patient-provider collaboration and self-management programs targeted to improve outcomes for the patients and reduce healthcare costs (Rodriguez et al. 2019; Weiner, 2019).

Healthcare Effective Data and Information Analysis (HEDIS) collects and analyzes data of providers and healthcare organizations to measure the quality of care (Center for Medicare and Medicaid, 2021). HEDIS, a component of VBC, is the tool used to capture data that establishes measurement standards necessary for improving the quality of healthcare and closing performance gaps (Gruessner, 2016). According to the Center for Medicare and Medicaid, HEDIS can identify the gaps in performance, track improvement(s), monitor QI initiatives' success, and establish realistic targets for improvement (2021).

Diabetes A1c control is a VBC quality metric used within healthcare organizations to evaluate the quality of diabetes care and aligns with HEDIS measures for Comprehensive Diabetes Care. Key data points represent patient outcomes and organizational benchmarks. Based on HEDIS criteria, Type II diabetes mellitus patients ages 18-75 in the electronic health record database, known as the Epic diabetes registry, must have a Hemoglobin A1c (HbA1c) test annually with results less than 8.0%. Failure to meet this criterion typically results from poor patient compliance to follow-up and lack of adherence to treatment recommendations.

Purpose/Aim(s)/ Objective

The ***purpose*** of this quality improvement project was aimed at clinic patients with uncontrolled (HbA1c>8%) Type II diabetes to improve glycemic control. The specific aims included:

1. Increase patient engagement in uncontrolled (A1c>8%) Type II diabetes mellitus patients as evidenced by increased self-efficacy scores.
2. Increase self-management in uncontrolled (A1c>8%) Type II diabetes mellitus patients as evidenced by using POCT HbA1c.
3. Improve glycemic control in uncontrolled (A1c>8%) Type II diabetes mellitus patients as evidenced by decreased HbA1c and fasting blood glucose numbers.

Objective: This quality improvement project aimed to increase patient engagement of clinic patients with uncontrolled (HbA1c>8%) Type II diabetes mellitus with their diabetes self-management by using POCT HbA1c to improve their glycemic control.

Practice Setting

The practice setting was an ambulatory outpatient primary care clinic managing patients across the lifespan for acute and chronic health conditions. The practice is part of a large health care organization in a southern state. The five providers at this location included (2) Medical Doctors (MD), (1) Doctor of Osteopathy (DO), and (2) Advanced Practice Nurse/Family Nurse Practitioners (APRN/NP-C). Patient demographics for race/ethnicity, gender, and age at this clinic were diverse.

Target Population

The target population for this project was Type II diabetic patients with an A1c greater than 8%, ages 18-75, in the QA/VBC metric. Approximately 390 patients in the quality alliance (QA) have diabetes, with nearly 150 with an A1c >8%, ages ranging between 18-75 years at the

clinic. Data extraction for racial demographics is problematic for this organization due to limitations in data retrieval, as race/ethnicity are not tracked. Per self-report, patients were approximately 50% Caucasian/White, 30% African Americans, 15% Hispanics, and 5% Asian or other.

Needs Assessment

During the 2020-2021 fiscal year, the clinic setting for this quality improvement project did not achieve the target benchmark for the QA initiative using the HEDIS core measures for diabetes control. The HEDIS diabetes metric is that commercial (CMCL) or Medicare (MCARE) insured patients, ages 18-75, have an A1c control <8% from a test performed annually.

The goal for the clinic was to achieve a VBC goal star rating of 5. The VBC star score for CMCL was 3.84, while the MCARE score was 3.92, with an overall VBC star score of less than 4.50 (BSWH, 2020). Approximately 28.9% of QA Medicare and 43.4% of commercially insured patients with diabetes had poor glycemic control. The VBC measure target rate for commercial insurers (CMCL) in the Quality Alliance (QA) was 60.2%, and the MCARE insured was 81.8%. Thus, the clinic was operating below the target for both CMCL and Medicare (MCARE) insured patients at 56.6% and 76.2%, respectively. See Appendix A. for a detailed Root Cause Analysis.

SWOT/GAP Analysis

A SWOT/Gap analysis was conducted for this project to identify performance gaps that need process improvement (Institute for Healthcare Improvement, 2016) (see Appendix B). This analysis evaluated the organizational healthcare system's strengths, weaknesses, opportunities, and threats (SWOT) and the availability of essential resources used within the clinical setting (Institute for Healthcare Improvement, 2021).

Strengths. This DNP project aligned with a large healthcare organization's mission, vision, and values "*to be a trusted leader, educator, an innovator in value-based care delivery customer experience and affordability*." It supports the promotion of self-management to empower patients to be more active in managing their health. Additional organizational strengths included advocating for community health, providing educational sponsored resources to promote health and wellness. It also highlighted the importance of early detection through health screening and disease prevention. There was alignment with Quality Alliance (QA) in meeting the healthcare needs to ensure high-quality care is delivered to patients at an affordable cost.

The clinic is part of one of the largest non-for-profit faith-based organizations in the State of Texas and one of the largest healthcare systems in the United States. The clinic aims to align with the organization's mission, vision, and value as financial stewards to improve quality and reduce healthcare costs. The staff is dedicated to delivering high-quality care for patients, emphasizing primary preventative care and improved health outcomes. The clinic staff comprises five providers consisting of three physicians and two nurse practitioners, with a support staff that consists of three administrative/clerical representatives, and three permanent medical assistance (MA). To promote access to care, the clinic provides telehealth as an alternative to onsite office visits to address ongoing patient care demands and close patient-provider care gaps. Monthly organized executive meetings with senior leadership target the clinic's VBC metrics compared to other clinics within the regional organization. Thus, there is organizational support from the top administrators to achieve organizational benchmarks and regional rankings.

Weaknesses. The recent shift in clinic leadership and organizational realignment impacted the clinic's structural process and ability to achieve quality improvement metrics.

The clinic has experienced missed opportunities in patients' scheduling follow-up appointments due to the current workflow process resulting in patients bypassing checkout. In addition, delays in laboratory test review by the providers resulted in treatment gaps and timely follow-up. Insufficient staffing to meet clinical demands created delays in patient callbacks with provider recommendations. Also, there was limited availability and access to supportive resources (diabetic educators, counselors, and/or nutritionists) to assist in managing patients with diabetes and/or weight management concerns. Both organizational and external competitors utilize POCT HbA1c testing as an alternative to guide diabetes management. Thus, supply availability associated with cost has been a challenge for obtaining a regular supply of the cartridges.

Opportunities. Increasingly, healthcare organizations are adopting POCT as a cost-effective tool to aid in care delivery and improve patient compliance. This expansive "buy-in" to use POCT HbA1c further increased the need for possible adoption. Furthermore, select clinics within the organization had conducted a POCT HbA1c drive-thru, known as the "sugar rush program" to improve the VBC diabetes quality metrics. As part of the "sugar rush program" patients are scheduled for follow-up virtual visits to promote patient compliance in testing and follow-up care. POCT HbA1c is currently an optional tool for clinics within the organization. However, among those clinics that opted to utilize the tool, it has been effective in improving diabetes self-management and achieving targeted quality metric goals (St. John & Price, 2014).

Additionally, other organizations have established curbside laboratory tests to meet the current shifts in healthcare delivery. Currently, the clinic has yet to establish criteria or protocols for patients who are sick or reluctant to be in an office environment needing tests performed. Curbside testing affords the opportunity to ensure ongoing access to care is provided to meet patient care demands. It also generates additional revenue for the clinic.

Remote monitoring such as the use of continuous glucose monitoring is increasingly used by providers to track the blood sugar trends of a diabetic patient. It provides real-time data for the provider to modify treatment plans if needed. This technology enhances patient-provider engagement and encourages positive patient self-care behaviors.

Threats.

The coronavirus pandemic in the United States in 2020 and 2021 posed a significant impact on the delivery of care globally (CDC, 2021). The pandemic continues to impact how providers deliver services to the patient at the clinic, influencing patient outcomes and provider performance both clinically, and organizationally, compared to other organization systems in the region. Also, the pandemic created a nurse shortage affecting patient care delivery and straining the workload capacity. This has resulted in a limitation on the number of patients that can be seen daily by providers. There has also been a delay with distributions of medical supplies due to Covid-19 related to associated shipment and staffing issues. The nursing shortages and delays in supply chain distribution hinder the ability to effectively provide healthcare services needed for patients which creates more competition among healthcare systems.

Inquiry Question

The project question presents in the form of a PICOT question. PICOT questions have the subcomponents of the population (P), intervention (I), comparison (C), outcomes (O), and time (T) (Melynk & Fineout-Overholt, 2015). The PICOT question for this project was:

- For patients with Type II diabetes mellitus with an A1c>8% at a local health care clinic (P)
- does using POCT HbA1c (I)
- compared to standard venipuncture laboratory HbA1c testing (C)

- increase patient engagement and improve glycemic control (O)
- during a 3-month timeframe (T)?

Conceptual/ Theoretical Framework

Bandura's Self Efficacy Theory (1977) provided the theoretical framework to support this project. The Self-Efficacy Theory is a sub-theory of Bandura's Cognitive Behavioral Therapy, which emphasizes the interaction of cognitive, behavioral, personal, and environmental factors on influencing behaviors and motivation (McLeod, 2016). According to Bandura (1978), self-efficacy is the belief in one's capabilities to organize and execute the course of action. Self-efficacy is an essential aspect of human behavior and motivation and influences the activity that can impact one's life (p. 191). Specifically, the concept refers to individual judgment or belief in the likelihood of one's ability to perform and or complete a task. (Bijl & Shortridge-Baggett, 2001).

According to Bijil and Shortridge-Bagget (2001), "the self-efficacy theory's primary principle is that performance and motivation are determined by how individuals perceive their confidence and capability to be efficient"(p. 191). This theory postulates that people are more likely to engage in activities if they have high self-efficacy and less likely to engage with low self-efficacy (Bijl & Shortridge-Baggett, 2001). Sakar et al. (2006) purported that an individual's confidence in performing health behavior activities influences which behaviors they will engage.

From the perspective of Holman (2013), Bandura's Self-Efficacy Theory provides process insight and strategies to influence an individual's confidence in their abilities to promote healthy behaviors. Perceived self-efficacy (PSE) refers to a "individual's ability to implement situation-specific behaviors to attain established goals, expectations, or designated types of outcomes" (Holman, 2013, p. 4). PSE is achieved through changes in behavior (Holman, 2013).

It is a component of the cognitive process that defines the self-directed methods of employing changed behaviors that include recognizing, preventing, and decreasing the time and intensity of unpleasant symptoms to achieve optimal outcome performance (Holman, 2013). The PSE model frames around four significant elements: (a) mastery experiences (performance activities), (b) vicarious experiences (observation of other success or failures in activity performance), (c) social persuasion (belief in capabilities to achieve a goal), and (d) emotional status. See Appendix C for the definition of each model component (McLeod, 2016). Figure 1 depicts the main components of the Bandura self-efficacy model.

Figure 1

Bandura's Perceived Self-Efficacy Model Components

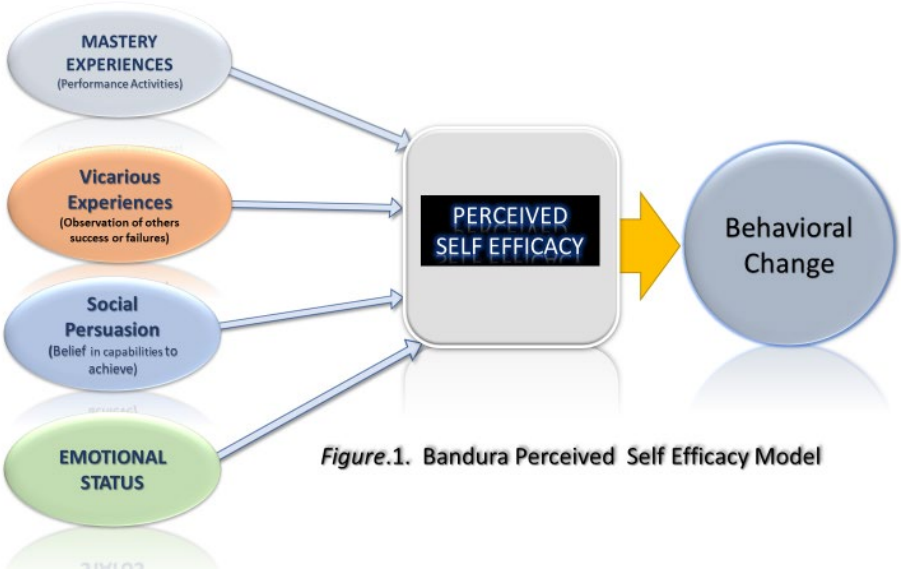


Figure.1. Bandura Perceived Self Efficacy Model

The application of Bandura's perceived self-efficacy model in this DNP quality improvement project assessed the interrelationship between self-efficacy and self-management by measuring the patient engagement and glycemic control of patients with uncontrolled Type II diabetes mellitus. The mastery experiences in the model are successful or achievable outcomes from gained experiences and new challenges (McLeod, 2016). For this project, mastery

experiences included monitoring blood glucose, interpreting the readings, counting carbs, and modifying the diet to maintain glycemic control. In addition, the patient is engaged in learning knowledge of diabetes, administration of medication, and adjusting insulin dosage per nutritional intake, physical activity, or illness (McLeod, 2016). Ongoing patient-provider engagement, diabetes education, dietitian support, and pharmacy involvement help facilitate the mastery experience.

Vicarious experience exposes patients to the success of others' experiences and can be encouraged with patient participation in diabetic support groups activities. Additionally, group education courses such as diabetes self-management education support (DSMES) encompass vicarious experience (McLeod, 2016).

Social persuasion and information sharing between patients can help them manage their diabetes and achieve successful outcomes (McLeod, 2016). Social influence encourages verbal feedback and empowers one to accomplish a goal or a given task (McLeod, 2016). Counseling patients about A1c using POCT HbA1c guides the conversation and encourages patient-provider collaboration and shared decision-making. The process of communicating with a patient about their diabetes is critical to their engagement, conceptualization of disease management, treatment outcomes, and psychosocial wellbeing (Dickinson et al., 2017).

Emotional status, or physiological feedback, focuses on emotional wellbeing that influences behavioral outcomes (McLeod, 2016). A person who lacks motivation is likely to experience low self-efficacy associated with poor self-management outcomes. Assessing a patient's mental health and wellbeing is necessary for increased self-efficacy and improved patient outcomes in self-management. (McLeod, 2016). The ADA recommends routine

monitoring of patients with diabetes for diabetes distress, particularly at the onset of diabetes complications or with unaccomplished treatment targets (Young-Hyman et al., 2017).

Evaluating PSE in uncontrolled type II diabetics is essential to increasing patient engagement. It provides an opportunity for patient-provider partnership, knowledge acquisition, and establishing individualized therapeutics that increase patient confidence in diabetes self-management. Recommendations from the ADA suggest that providers consider the burden of treatment and patients' level of confidence/self-efficacy for management behaviors (Young-Hyman et al., 2017). Interventions for managing diabetes should focus on increasing self-efficacy (SE) since it can be a significant predictor of self-management behaviors (SMB) as defined by the AADE and improved diabetes outcomes (Harrington et al., 2017). Behavioral and lifestyle changes are the most effective strategies for managing T2DM and sustaining glycemic control (Harrington et al., 2017).

Section II: Presentation of the Evidence

Search Strategy

A comprehensive literature review was conducted using several search engines from the Texas Woman's University library nursing database including Cochrane, CINAHL complete EBCOS host, Google, Google Scholar, PubMed, ProQuest, and Scopus to search for relevant articles with supporting evidence clinical application to this QI project. The article search conducted was between January 2021- February 2021. Publication dates ranged between 2011-2021 using the following criteria: adults ages 18 to 75, and English. Key Medical Subject Heading (MeSH) terms extracted from the PICOT question included "type II diabetes," "point of care HbA1c testing", "patient engagement," "self-efficacy," and "glycemic control" to narrow the article search. Additional MeSH terms included "patient-provider communication," "self-management," and "self-care behaviors." MeSH terms combined for a more focused search with "point of care" and "diabetes," yielding 431 articles; 67 were relevant to the topic searched, with 16 selected that met criteria. The search terms included with diabetes involved "self-efficacy" and "self-care behaviors," and "self-management," yielding 6,084 articles, and 409 were relevant to the search criteria, with 25 meeting criteria and six articles selected for the project. Abstraction and articles summary were examined for inclusion and exclusion research topics aligned with project criteria.

Review of Evidence

Articles selected from the literature review aligned with this project's objective and aimed to address the PICOT question. The following section discusses the processes used to establish levels of evidence, and synthesis of the evidence with identification of themes.

Levels of Evidence. The level of evidence of the articles ranged from Level III through IV, the strength of the evidence was moderate (2b). The review of evidence that aligned with the PICOT question was obtained from the following articles, includes one qualitative, two descriptive, one feasibility, four quality improvement studies, two cross-sectional, three cohort studies, two randomized control, one meta-analysis, and systematic reviews, see Appendix I for detail. John Hopkins Level of Evidence-based toolkit was used to analyze the quality and strength of literature reviewed for application in the project (John Hopkins University of Nursing, 2017).

Critical Appraisal. The articles reviewed were critically appraised using the Critical Appraisal Skills Programme (CASP) and the Centre for Evidence-Based Medicine (CEBM). These appraisal tools evaluated the article's quality, strength, and validity for use to answer the PICOT question (see Appendix I for detailed appraisal and level of evidence).

Evidence Synthesis

The evidentiary summary of the articles supporting POCT HbA1c implementation to increase patient engagement is detailed below. For a more thorough synthesis of evidence, refer to the Evidence Matrix table in Appendix I.

Articles by Crocker et al. (2020), Schnell et al. (2017), Egbunike & Gerard (2013), and Berbudi et al. (2020) critically analyzed the clinical and statistical benefit of POCT HbA1c in managing diabetes, motivating self-care management behaviors, improving patient compliance, satisfaction, and provider workflow. The studies found significant benefits with using POCT HbA1c to improve diabetes management and deemed POCT HbA1c an effective tool to implement in the primary care setting. Furthermore, POCT HbA1c application in diabetes management consistently increases patient engagement and promotes provider partnership

resulting in measurable changes, inclusive of improved hemoglobin A1c and overall health outcomes (Crocker et al., 2020, Schnell et al., 2017, Egbunike & Gerard 2013, and Berbudi et al., 2020).

Hoffman (2013), D'Souza et al. (2017), and Al-Khawaldeh et al. (2012) evaluated the influence of self-efficacy on self-care behaviors and impact on diabetes management and improved glycemic control. These studies support that self-efficacy is most predictive of diabetes SCB as it can induce motivation directly taking health-promoting behaviors through efficacy expectation (Mohebi et al., 2016). Beckerle and Lavin (2013) analyzed the correlation of self-efficacy to an individual's success in self-management and the impact of SCBs on influencing A1c levels by comparing the level of confidence using an SES survey to determine the intervention necessary to improve self-care behavior for optimal glycemic control. The study revealed no statistically significant correlation between the overall self-efficacy and self-care and A1c levels; however, self-efficacy was determined to be significantly related to A1c ($p<0.009$) for two questions in the questionnaire related to selecting appropriate food to eat and ability exercise (Beckerle & Lavin, 2013)

Themes

Four themes identified from the studies included (1) point of care A1c test (POCT HbA1c), (2) self-efficacy, (3) self-management, and (4) patient-provider communication. Details of these themes are discussed below.

Point of Care HbA1c

Guidelines on frequent hemoglobin A1c testing and treatment modifications aim to support the achievement of glycemic targets among patients with low adherence (Schnell et al., 2016, p. 611). The ADA recommends POCT HbA1c to offer the opportunity for more timely treatment changes (Schnell et al., 2016, p. 611). In contrast, the International Diabetes Federation (IDF) recommends the determination of HbA1c either at the POCT or in the laboratory before clinical consultation (Schnell et al., 2016, p. 612). The quick availability of HbA1c test results has facilitated diabetes management and allows for more prompt treatment changes (Schnell et al., 2016). Crocker et al. (2020) revealed that POCT HbA1c increased patient satisfaction, adherence to therapeutics prescribed, compliance with scheduled follow-ups, and improved workflow compared to traditional HbA1c laboratory testing.

Egbunike and Gerard (2013) conducted a quasi-experimental study asking three research questions evaluating the impact of POCT HbA1c. The study compared 6 -and 3-month pre and post-implementation on 164 patients with type II diabetes, ages 25-94. The research question of the study included: (1) evaluating the number of documented A1c levels at the time of a clinic visit in the past six months pre- versus post-implementation of A1c testing, (2) assessing the A1c levels pre- vs. post-implementation, and (3) focusing on the provider documentation of treatment changes (Ebgunike & Gerard, 2013).

> Statistical results concluded there was a more significant number of patients with documented A1c levels at the time of their office visit (n=39) in 6 months post-implementation compared to the (n=27) patient with documented A1c levels three months pre-implementation of A1c testing (x2=0.001; df=1; P=0.05) (Ebgunike & Gerard, 2013). Findings were also consistent, showing a more significant number of patients with documented A1c levels at six months post-improvement (n=39) when

> compared to the documentation at six months pre-implementation (x2=0.002; df=1; P=.05) (Ebgunike & Gerard, 2013). A decline was noted in the mean A1c value 6 months post-implementation (7.7%) compared to mean A1c 6-month pre-implementation (8.1% t=-2.809; P=0.008). The finding from the third research question evaluating documentation of treatment changes concluded that 13 patients had a treatment change in the past six months post-implementation compared to 6 months pre-implementation. Nine patients did not meet the criteria for treatment change (Ebgunike & Gerard, 2013). The study's findings showed significant improvement in A1c monitoring compared to pre-implementation and increased provider compliance with A1c 6- and 3-month post-implementation (Ebgunike & Gerard, 2013, p 70-71).

Hirst et al. (2019) conducted a qualitative research study in the UK evaluating the impact of HbA1c point of care testing in behavior changes for diabetic patients and clinicians. Fifteen participants from three GP practices in the Thames Valley region of the UK were individually interviewed, comparing (pre and post) point of care testing experiences to regular HbA1c testing (Hirst et al., 2020). Participants were interviewed twice with open-ended, semi-structured themed questions on patient expectation (interview 1) and experience using POCT (Hirst et al., 2020). Three clinicians were interviewed (2 nurses and one general practitioner) regarding "clinical decisions and intervention on test results within the point of care consultation" (Hirst et al., 2020). The study results found that receiving end of care testing on the same day as the scheduled appointment was more convenient, reduced anxiety from prolonged wait time for receiving test results, encouraged lifestyle modification, and motivated behavioral changes of diabetes (Hirst et al., 2020). The clinician feedback regarding point of care HbA1c was also positive but related that the immediate viewing of the test did not result in significant changes in

their act of decision making and expressed a considerable amount of concern regarding cost (Hirst et al., 2020). The study concluded that point-of-care testing showed favorability for encouraging behavior change and reinforcing lifestyle choices (Hirst et al., 2020).

Crocker et al. (2020) conducted a prospective quality improvement cohort study on three practices: 2 practices using interventions Hb A1c and one control group using standard central laboratory. The study evaluated the impact of POCT HbA1c an onsite synchronous HbA1c testing frequency for population health performance metric in the primary care setting, measured the utility of HbA1c POCT in identifying clinically meaningful changes in disease, and measured staff satisfaction with POCT compared to traditional A1c testing (Crocker et al., 2020). The study determined that practices with HbA1c were 3.7 times less likely to miss A1c testing at the time of the visit than practices where POCT HbA1c testing is not available ($P<0.01$). One in four patients from each group studied had worsening A1c (HbA1c >0.5% or 5. mmol/mol), suggesting that without POCT HbA1c, there can be missed opportunities for providers to make clinical decisions, counsel, and educate patients (Crocker et al., 2020).

Ansari et al. (2011) conducted a systematic review and meta-analysis (PRISMA) on seven trials to determine whether POCT HbA1c compared with conventional laboratory testing improved outcomes for Type 1 or 2 diabetes patients. The trial results showed a nonsignificant reduction of 0.09% (95% CI -0.21 to 0.02) to those tested with POCT HbA1c compared to the standard group. However, due to insufficient evidence on the effectiveness of POCT for HbA1c testing, further research study is warranted (Ansary et al., 2011).

Self-efficacy

Seven studies identified a significant correlation between self-efficacy and self-care behavior that influences the glycemic control outcome in diabetic patients (Hoffman, 2013;

D'Souza et al., (2017). One study demonstrated the use of self-efficacy survey questionnaires to guide clinical decision-making to specifically self-management interventions (Berkele et al., 2013). The study found two questions from the Stanford Diabetes Self -Efficacy scale to significantly correlate with A1c ($P<0.009$) but had no statistical significance among global measures of self-efficacy and self-care and A1c levels (Berkele et al., 2013).

In a study on diabetes self-management, comparing pre-and post-intervention responses to the Stanford diabetes self-efficacy scale (SED) showed an increase in the pre and post-test scores (Harrington et al., 2017). The Stanford DSES was statistically significant with the mean scores in the two measurements $t(14)=8.67$, $p<0.001$, further concluding that diabetes education and self-management is essential to managing diabetes and improving diabetes outcomes (Harrington et al., 2017). With a collaborative partnership between the patient and provider, individuals may ultimately experience increased self-efficacy leading to improved diabetes self-management (Harrington et al., 2017). Another study found a significant link between self-efficacy and self-care and its effect on positive health behaviors (Mohebi et al., 2013). Several articles reviewed with the study determined that self-efficacy in diabetes patients is unacceptable, and self-care behaviors are also unsatisfactory (Mohebi et al., 2013). Self-care plays a significant role in controlling diabetes, but self-efficacy is vital in changing self-care behavior (Mohebi et al., 2013).

Self-Management

A similar study on the correlation between diabetes self-efficacy, diabetes self-management behaviors, and glycemic control using face-to-face interviews showed that low levels of self-management behavior among the Jordanian participants contributed to higher levels of HbA1c (Al-Khawaldeh et al., 2012). Low DSM attributed to social, cultural, and

financial barriers that resulted in low or nonadherence to self-care recommendations contributing to poor glycemic control (Al-Khawaldeh et al., 2012). Karimy et al. (2018) concluded that higher self-care scoring correlated with improved self-efficacy, social support, and attitudes towards self-care. The patient's education level revealed a significant relationship with self-care behaviors and a powerful influencer for healthy behaviors and efficient disease management (Karimy et al., 2018).

Patient-Provider Communication

Power et al. (2016) revealed that a patient-centered approach, collaboration, and effective communication are considered the route to patient engagement(p. 73). When patients and physicians partner together to create diabetes self-care plans, patients are likely to make the lifestyle modifications needed to manage their diabetes (Peek et al., 2014). A randomized control study by Peek et al. (2014) evaluated patient-provider communication and patient adherence. This study analyzed patient-provider self-management behaviors using the Perception Involvement in Care (PIC) scale that focused on three themes: doctor facilitation, patient information exchange, and patient decision making (Peek et al., 2014). Findings in the study concluded that patients with more significant chronic disease burdens and disease requiring self-management reported sharing more information and participating in shared decision making with their physician more. In contrast, no correlations were identified among those who did not require disease management (Peek et al., 2014).

Schnell et al. (2017), in a prospective cohort study evaluating the impact of POCT HbA1c across three primary care clinics, found that the pre-post intervention findings corresponded with an increase in treatment intensification in patients with HbA1c values >8%. The results demonstrated positive outcomes because of the opportunity for direct face-to-face

counseling using POCT HbA1c. Furthermore, "POC testing was able to enhance the patient-provider relationship" (Schnell et al., 2017, p. 614).

Summary

In summary, the four themes identified from the comprehensive literature search provide a moderate to a high level of evidence that using POCT HbA1c results in significant improvement in glycemic control. POCT HbA1c encouraged patient participation in self-management of diabetes that is associated with positive behavior and lifestyle changes. Furthermore, patient/provider collaboration promoted effective clinical decision-making, counseling, and education.

Utility/Feasibility

The utility/feasibility of POCT HbA1c implementation at the local clinic was considered and determined by the efficiency of the clinic's workflow and HbA1c controls <8%. Most of the diabetes treatment-related costs were associated with complications and fragmented disease management processes. The utilization of POCT HbA1c streamlined the workflow process increasing efficiency (Hirst et al., 2017). The implementation of POCT HbA1c provided real-time glycemic control data and provided opportunities for patient-provider engagement (Patzer et al., 2018).

Successfully implementing a new intervention in an environment with competing demands is contingent on health professionals adopting the intervention and abandoning old practices (Hirst et al., 2017, p. 118). The adoption of this QI project was developed and promoted through discussion with the providers. There was open dialogue regarding opportunities to improve clinic performance using POCT HbA1c as an effective tool to address gaps in care in the diabetic population at the clinic.

Section III: Methodological Framework

The *purpose* of this quality improvement project was for clinic patients with uncontrolled Type II diabetes to use POCT HbA1c to improve glycemic control. The methodological framework of the quality improvement project was outlined using the RE-AIM model (Glasgow, 2003). The application of RE-AIM guided the improvement process using the PDSA cycle framework (Institute for Healthcare Improvement, 2021).

Inquiry Question [PICOT] (Restated)

The PICOT statement for this project guided the methodological approach. As noted, the PICOT statement is: For patients ages 18-75 years with Type II diabetes mellitus with an A1c >8% at a local health care clinic (P), does use of POCT HbA1c (I), compared to standard care with venipuncture laboratory blood test (C), increase patient engagement and improve glycemic control (O), during a 3-month timeframe (T)?

Project Type and Description (Quality Improvement)

Quality improvement (QI) projects "involve a combined effort among health care staff and stakeholders to diagnose and treat problems in the health care system" (Silver et al., 2016, p. 893). This project is deemed a quality improvement project because the focus was on using evidence-based literature to make changes with patterns of diabetes patient care, track the changes over time, and evaluate the implementation's effectiveness on outcomes.

This quality improvement project was guided and framed by the strategic organizational performance platform. The project aimed to develop and implement effective quality improvement initiatives that improve patient health outcomes, patient satisfaction, and overall clinical experience at an affordable cost (large academic teaching health organization in the southern US). Part of the key identifiers within the organization's mission statement is "to be a

trusted leader, educator, an innovator in value-based care delivery customer experience and affordability" (large academic teaching health organization in the southern US). Advocating and influencing positive lifestyle changes is essential to improving health outcomes in patients with uncontrolled diabetes with an A1c>8%.

This project identified gaps in current diabetes care practices, assessed proposed practice changes by tracking data and evaluated the data for effectiveness for the potential adoption of evidence-based processes into practice. According to DNP Essential II, "the DNP graduate can organize care to address emerging practice challenges, and ethical dilemmas as new diagnostic and therapeutic technologies evolve" (AACN, 2006, p. 10). This quality improvement project focuses on improving current practices in care management that impact health outcomes among people with diabetes with poor glycemic control, as evidenced by an A1c >8%. The population is focused on type II diabetic patients ages 18-75 with an A1c of 8% and higher receiving care at the clinic.

RE-AIM Model with PDSA

The methodological framework for this quality improvement project was the RE-AIM model (Glasgow, 2003). The application of RE-AIM guided the improvement process using PDSA cycles (Glasgow, 2003; IHI, 2021). RE-AIM evaluates health behaviors, changes in research and translates scientific advancements into practice (Glasgow et al., 2019). This framework can direct the planning of new ongoing interventions and provide systematic evaluations of complex interactions between individuals and organizational outcomes (Harden et al., 2018, p. 2).

RE-AIM identifies "what is needed" and stands for *Reach, Effectiveness, Adoption, Implementation, and Maintenance* (Glasgow, 2003). **R**each identifies the population of focus

needing intervention within the practice; **E**ffectiveness is how the success of the intervention is determined; **A**doption addresses the organizational and clinical support or buy-in; **I**mplementation is the delivery or application into practice, and **M**aintenance assesses the sustainability over time (Glasgow, 2003). The RE-AIM framework is widely used in diabetes care management. "It focuses on the issues, dimensions, and steps in the design, dissemination, and implementation processes that can either facilitate or impede success in achieving a broad and equitable impact on the population base" (Glasgow et al., 2019, p. 1). Furthermore, it impacts intervention effectiveness and suitability in population and public health. Its application in health promotion best aligns in addressing the PICOT question for this DNP quality improvement project (Glasgow, 2003).

Reach*:** Uncontrolled Type II diabetic patients with A1c >8% between the ages of 18-75. The Effectiveness*** and success of the project were determined by improved HbA1c and glycemic control. ***Adoption*** was achieved with "buy-in" from key stakeholders within the clinic and organization (Medical Director, Physicians, Nurse Practitioner, and Office of CMO/Director of Strategic Initiative). The results of ***implementation*** included increased patient engagement (SES), diabetes self-management (POCT HbA1c), and glycemic control (A1c, fasting blood sugar). ***Maintenance:*** sustainability to extend beyond the six-month timeframe conducted in this project.

IRB Review Process

The organization's Quality vs. Research determination forms with project abstract were submitted for IRB review. IRB oversight for this QI project was deemed not a requirement by

the organization's Office of Research Regulatory Affairs as the project was determined to be a quality improvement project. See Appendix F for the letter of approval for this QI project. An online Cayuse IRB form for this project was also submitted for review by the Texas Woman's University research department. The review concluded that the project was a QI project and not research. See Appendix G for the letter of approval for this QI project.

Interprofessional Collaboration

Interprofessional collaboration is the partnership between a team of healthcare providers working together to solve clinical problems and active collaboration in shared decision-making to improve patient care quality (Moran et al., 2020). Collaborative partnerships allow health professionals to share ideas, knowledge, and shared decision-making, enhancing cost-effectiveness and quality of care (Moran et al., 2019).

The charter team for this project included (2) Medical Doctors (MD), (1) Doctor of Osteopathy (DO), and (2) Advanced Practice Registered Nurse (APRN-NP). Each is represented by their initials and roles with the project.

1. T.H. (MD)
2. N.H. (MD)
3. S.G.B. (DO)
4. C.K. (APRN-NP)
5. K.M. (APRN-NP)

Monthly executive committee meetings helped close the gaps in the evaluation of clinic productivity and VBC measures/metrics. The providers analyzed data trends with organizational targeted benchmarks goals to identify gaps for improvement. Brainstorming helped to identify specific gaps in the targeted patient population. This interprofessional collaboration enhanced

this project by identifying areas for improvement in our current practices. It also promoted the opportunity to address areas with the greatest need for improvement and ensure the clinic aligns with organizational initiatives, meets quality measure goals, and improves the quality of care.

The role of the DNP graduate as team lead was to ensure accountability for the quality of health care and patient safety for populations with whom they work (AACN, 2006). According to DNP Essential II, organizational and systems leadership are critical for the DNP graduate to improve health outcomes (2006, p.10). The DNP graduate directed care and focused on the need of a panel of patients, a set or target population, or community (AACN, 2006, p. 10).

As the lead, the framework for the proposed project plan of implementing POCT HbA1c in the clinic was disseminated to the staff through verbal and written documentation. Weekly active engagement with the team was conducted to ensure project goals aligned with clinic needs and the organization's mission and vision. The team collectively reviewed reports and trends from the healthy planet database in Epic of those diabetic patients who are not in compliance or did not have an HbA1c goal of <8%. Coordination with the scheduler to contact identified patients to schedule face-to-face follow-up visits was reinforced. Staff members were reminded daily of patients needing POCT HbA1c and SES completed for data collection. The team collected the data and scanned survey data into the EHR to track required trends for statistical analysis.

Implementation Framework

The implementation framework to guide this project was the Plan, Study, Do, Act (PDSA) framework (IHI, 2021), along with the RE-AIM framework (Glasgow, 2003). The PSDA was applied to the operational components of the project, while the RE-AIM framework guided the sustainability component. This project's sustainability was extended beyond the

projected timeline of 3 months and was determined by improved glycemic control, reduced cost, and continuous stakeholder buy-in.

Defining responsibilities for the providers and supporting staff included:

- Providers:
  - Training on the SES tool and scoring.
  - Initiate conversation with the patient using POCT HbA1c and SES survey tool.
    - Notate any SMART goals with the patient, intervention (if established), and follow-up.
    - Follow-up and A1c tests per the ADA and organizational recommendations.
    - Consider frequent DM-focused follow-up visits (6 weeks), if > 10% or higher with low self-efficacy and compliance concerns with self-care behavior to address barriers and knowledge deficits that influence poor health outcomes.
- To identify those patients in the QA that are not in compliance with the VBC metric of A1c<8%, coordination with the office manager was necessary.
- Front office scheduler: schedules face-to-face appointments, labs, and follow-up visits.
- Medical Assistance (MA):
  - POCT HbA1c training was conducted via the onsite website for DCA, and the organization's laboratory department presented Clinitek Clinical Laboratory Improvement Amendment (CLIA) training.

- Conduct POCT HbA1c testing and give identified patients (SES) questionnaire
  - Ensure that the patient's MRN, date of birth (DOB), and visit date are on the forms, then scan into the patient EHR and place in the designated provider's folder at the end of each visit for data collection.

Plan- Do-Study-Act

PDSA is a problem-solving measure used to improve processes and change outcomes using four cycles: Plan, Do, Study, Act, and frequently repeated an indefinite number of times (IHI, 2021).

PLAN: The plan included the addition of the Siemen DCA POCT HbA1c for treatment with uncontrolled diabetes A1c>8% to improve A1c in the clinic. The DCA Vantage is a point of care analyzer that monitors glycemic control, providing HbA1 results within 6 minutes via fingerstick for capillary blood sampling (Siemen Medical Solution, 2021). The data resulting from the analyzer can interface with the electronic medical record (EHR) system for data integration as a test qualifier for the HbA1c test value-based metric (Siemen Medical Solution, 2021).

STEP 1: MA's will room patients

(Obtain vital signs, fasting labs, and POCT HbA1c – only patients QA/ VBC with uncontrolled T2DM with an A1c >8%)

STEP 2: Self-Efficacy for Diabetes given to those identified patients at their initial and 3-month follow-up visits. Providers will review the scoring during the visit to guide decision-making and course of intervention. Scan completed SES survey on patient chart.

STEP 3: Engage in shared decision-making (patient-provider engagement).

STEP 4: Set SMART goals and AADE7 activities

(Recommended follow-up as per ADA recommendations)

- ❑ Monitor blood sugar logs
- ❑ Consider referral to diabetes educator/nutritionist and or Endocrinology- if recurrent A1c 9% or greater

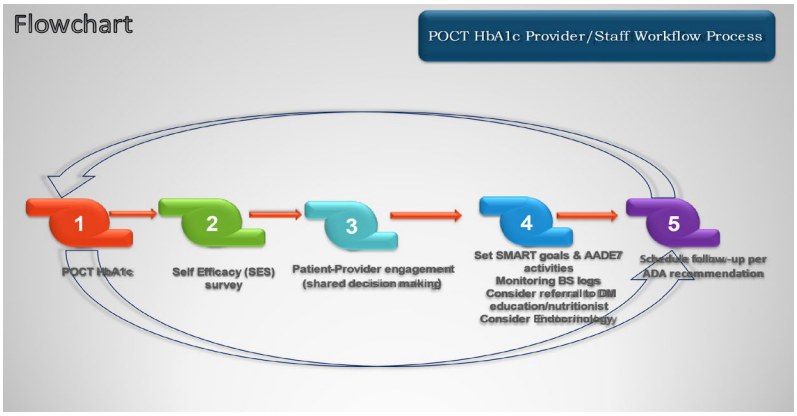
STEP 5: Document follow-up in the wrap-up section

(Recommended follow-up as per ADA recommendations)

- ❑ A1c>8% follow up every three months (face-to-face)
- ❑ Consider more frequent follow-ups if A1c >10% (virtually as an option). See Figure 2 for the POCT HbA1c flowchart.

Figure 2

POC A1c Implementation Flowchart



DO: Conduct chart review

- ❑ Input standing order for POCT HbA1c testing
- ❑ An SES survey will be given to each participant during their office visit to answer the aim questions (see Appendix B)

STUDY: Complete an analysis of A1c before intervention to post-intervention A1c

- Use SPSS (psychdata.com)
- Conduct descriptive and inferential statistics
- Monitor Quantitative measure (SES) inclusive of pre-and post-level of confidence trends (psychdata.com)
- Conduct independent t-test and paired sample t-test: assess pre-and post-intervention outcome measures for improved glycemic control (psychdata.com)
- Analyze standard venipuncture A1c laboratory collection to POCT HbA1c capillary sampling to determine if POCT HbA1c increases patient engagement.
- Conduct Outcome analysis to evaluate the trends across race/ethnic groups and gender.
- Analysis of the pre and post data trend of VBC metric

ACT: repeat PDSA cycle to evaluate improvement in the implementation process

RE-AIM: Evaluate the sustainability over time, assessing the provider satisfaction and feasibility of POCT HbA1c testing for patient engagement.

Data Analysis Plan

The analysis plan for the study included A1c monitoring, self-efficacy scale, and diabetes self-management participation with the new POCT approach to diabetes management. In addition, demographic variables to describe the sample of project participants were collected and analyzed.

A1c Monitoring

According to the ADA (2019), glucose monitoring is critical to achieving blood sugar targets for most people with diabetes. Glucose monitoring allows patients to evaluate their response to therapy and assess whether their target blood sugar levels are safely achieved (ADA,

2019). The ADA (2021) recommends setting glycemic status at least quarterly and as needed in patients whose therapy has recently changed and who are not meeting glycemic goals (p. S73).

A1c pre-and post-intervention were tracked using SPSS for descriptive statistics (Pallant, 2020). Descriptive statistics, independent t-test, and paired-sample t-test (Pallant, 2020) were also used to analyze the tracked POCT HbA1c and SES survey data.

Self-Efficacy Scale

The instrumentation used in this project was the Stanford Self Efficacy scale for Diabetes (see Appendix D) (Ritter et al., 2016). The tool is an 8 question Likert-type scale with 10-point items ranging from (0 no confidence) to (10 total confidence) (Ritter et al., 2016). The questions are divided into two subscales: (1) self-efficacy for behaviors to manage diabetes and (2) self-efficacy to control blood sugar and medical aspects of diabetes (Ritter et al., 2016). Items 1-4 focus on behavior, exercise, and behavior, while items 5-8 target diabetes-specific blood sugar and health (Ritter et al., 2016).

A pre- post-survey using SES was given to each participant to assess their level of confidence in self-management. This instrumentation's validity, reliability, and history are strong, with similar results from studies related to chronic diseases (Ritter et al., 2016). The internal consistency reliability for the SES is strong for both subscales and consistently high across different samples. The item scale correlation was also significantly high, suggesting convergence validity for the DSES items. According to Ritter et al. (2016), there was a strong association with DSES scores and medical outcomes/behavior test at baseline; however, except for A1c, there was a significant association between improved self-efficacy and improvement in exercise, hypoglycemic symptom, and communication with the doctor (Ritter et al., 2016).

Descriptive statistics and an independent t-test (Pallant, 2020) were conducted to track data changes.

Sample Size

The sample size for this QI project was n=46 participants who seek routine medical care at the local clinic. Patients selected to participate were uncontrolled type II diabetic A1c > 8% in the QA/VBC metric, ages 18-75 years, and not managed by an endocrinologist. The exclusion criterion included gestational diabetes and type I diabetes.

Data Collection Approach

Data collection was obtained from the EHR and uploaded into SPSS 25 after collecting on an Excel worksheet. Patient demographics included case number, race, age, and sex. The clinical demographics consist of the patient's last visit date, the pre-and-post fasting blood sugar (FBS), the HbA1c (standard care via laboratory venipuncture) before the initiation of POCT, HbA1c, at the initiation of POCT HbA1, and the repeat POCT HbA1c result at the 3-month follow-up visit.

Data Evaluation Plan

A critical aspect of this quality improvement project is the evaluation. Before implementing practice changes, project-specific process and outcome indicators must be evaluated (Cullen et al., 2018). An analysis was conducted to track data to evaluate the effectiveness of evidence-based practice implementation and make modifications with implementation to achieve outcomes (Cullen et al., 2018). All data collection was conducted solely by the project lead and analyzed with a statistician's assistance.

Quantitative Analysis

Descriptive analysis using the IBM SPSS statistical program was conducted on the patient demographic variables (age, race, sex), patient (SES) scores, and patient clinical variables (A1c and FBS). Display of the results in graphics as well as comparisons was conducted.

A paired t-test using the IBM SPSS statistical program tracked changes for initial and repeat POCT HbA1c implementation outcome variables. The paired t-test determined the pre-and-post-POCT HbA1c implementation variable (Pallant, 2020). Cohen's *d* was calculated to determine the effect size of the same two variables (Pre/Post A1c and SES score). Displays of the results in graphics as well as comparisons were conducted.

An independent-samples t-test using the IBM SPSS statistical program tracked the mean changes of pre- and post-SES implementation outcome variables (A1c and FBS), including gender and race. The independent-sample t-test determined the changes in SES implementation mean (Pallant, 2020). Displays of the results in graphics in Appendix F, as well as comparisons, were conducted.

Operational Definitions

The operational definitions of the variables for the QI project are defined in Table 1.

Table 1

Variable and Definitions

Variable	**Operational Definitions**	**Comments**
Self-Management:	Active engagement in AADE self-care behaviors: routine DM follow-up, medication adherence, monitoring BS, and DM diet/carb counting. Participating in DM education/ nutrition classes	
Value-Based Care *(VBC*):	Improved VBC metrics for A1c controls <8% at 3-month evaluation among identified QA/VBC patients not in compliance	
Patient Engagement:	SES measurement of engagement = (SES), improved A1c and FBS	

Variable	Operational Definitions	Comments
Self-Efficacy *(*SES*):*	Measurement of patient engagement - pre- and post-intervention using POCT HbA1c testing. (Likert/ordinal scale: 1-10)	
Point of Care:	POCT HbA1c= in office fingerstick capillary blood test from glycolate hemoglobin A1c 3 - month BS measurement	
Glycemic control:	HbA1c <8%. (FBS) 80-120 pre- and post-intervention at three months DM follow-up.	

Budget.

A budget for this project was developed, demonstrating actual clinic cost for the 46 participants to the budgeted cost if all 157 non-compliant diabetic patients participated in the project. The budget analysis demonstrates a breakdown of the actual vs. budgeted total project expenses and the revenue generated. The implementation of the POCT HbA1c in the clinic setting showed an overall net increase in generated revenue, indicating a financial benefit to the clinic. See Appendix E for the detailed budget plan spreadsheet.

Section IV: Finding/ Results

The findings were analyzed utilizing IBM SPSS version 25 for descriptive, paired-samples t-tests, and repeated measures ANOVAs. Patient demographic information (age, race, sex) and SES scores are continuous variables defined for descriptive analysis, assessing each variable's mean, mode, and standard deviation (Pallant, 2016). The clinical variables (initial and repeat HbA1c) were analyzed using a paired t-test to track changes in the HbA1c, and the mean outcome of each variable to determine the overall clinical significance ($p < 0.001$) of POCT HbA1c for implementation at the local health clinic (Pallant, 2020). Repeated measures ANOVA was also conducted to track the SES to the outcome variables (A1c and FBS) and analyze the clinical significance for both gender and race (Pallant, 2020). The Cohen's *d* was examined to determine the effect size between each of two variables (Initial/Repeat HbA1c, FBS, and SES score) in the intervention (Pallant, 2020). Result findings and graphs are further detailed below.

Characteristics of Sample

Basic Demographic

The demographics of the patients for this project included race/ethnicity, gender, and age. The sample size is 46. Races/ethnic groups consisted of twenty-one identified as African American/black (n=1); twenty-one identified as Caucasian/ white *(*n=2*),* two identified as Hispanic/Mexican (n=3), and two identified as Asian (n=4); See Figures 3, 4, and 5). The distribution is equal amongst African American/black and Caucasian/white at 45.7%, and 8.6% are Hispanic and Asian.

The gender of the patients analyzed in the project included twenty-seven males and nineteen females. The gender distribution for the sample size is 58.7% male and 41.3% female. The age of the patients ranged between 33-75, with a mean average age of 55 years with a

standard deviation (SD)=11.5). See Appendix F to view graphs on demographics for each clinical variable.

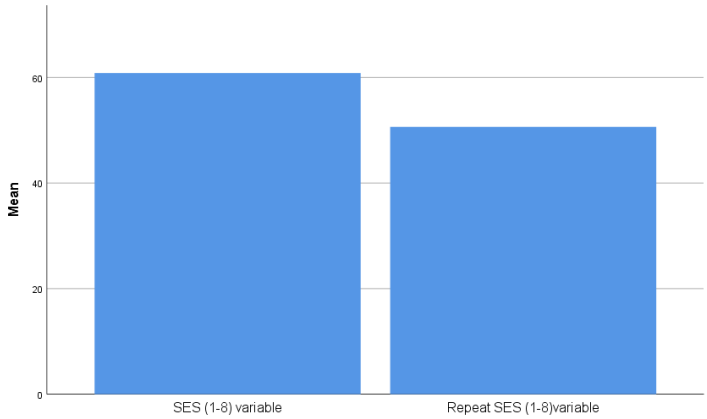
Clinical Demographics

SES and Repeat SES. The instrumentation used to measure patient engagement was the Stanford Self Efficacy (SES) Survey for Diabetes due to its strong validity and reliability in evaluating the correlation of self-efficacy to patient health outcomes (Ritter, 2016). This 8-item questionnaire, which was on a Likert type scale (1-10), assessed the uncontrolled T2DM with A1c>8% perceived level of confidence in managing their diabetes and paired with two clinical variables (initial and repeat POCT HbA1c) during face-to-face office visits every three months for detailed analysis (Ritter et al., 2016).

The data collected was documented in Excel, and then the SES survey scored for each patient was computed for the overall SES (8-80). The excel data were imported into SPSS to analyze the patients' perceived level of confidence and engagement and tracked variable changes with POCT HbA1c implementation at the local clinic (see Figures 3 below for details).

Figure 3

Initial-and Repeat Self Efficacy Survey (SES) score



A descriptive analysis and paired sample t-test were used to analyze SES's mean and standard deviation (SD) and the track trend of the two variables. The finding of the analysis

demonstrates a mean score of 60.84 for the SES with *n*=31 and (SD) =11. 181, with a tracked change, mean score 50.65 with n=31 and (SD)=26.898. A decline by 10 was tracked for the SES variable indicating minimal statistical significance on patients' perceived level of confidence using POCT HbA1c to increase patient engagement. However, the p-value between the two variables, p= 0.075 (p>0.01), concluded that the result was not statistically significant on the perceived level of confidence and increased patient engagement with the change. The Cohen's *d* =0.33, indicating a small to medium effect size, further concluding that the relationship is practically significant and usable at the local clinic to increase patient engagement.

Initial and Repeat POCT HbA1c. The initial and repeat POCT HbA1c were retrieved during the patients' face-to-face office visit and at their 3-month follow-up. The data collected was uploaded manually into Excel and imported into IBM SPSS version 25 for statistical analysis. Descriptive analyses were conducted to track data trends POCT HbA1c intervention and analyzed the mean and standard deviation (SD) of the two variables (see Figure 4).

Figure 4

Initial and Repeat POCT HbA1c

Paired Samples Test

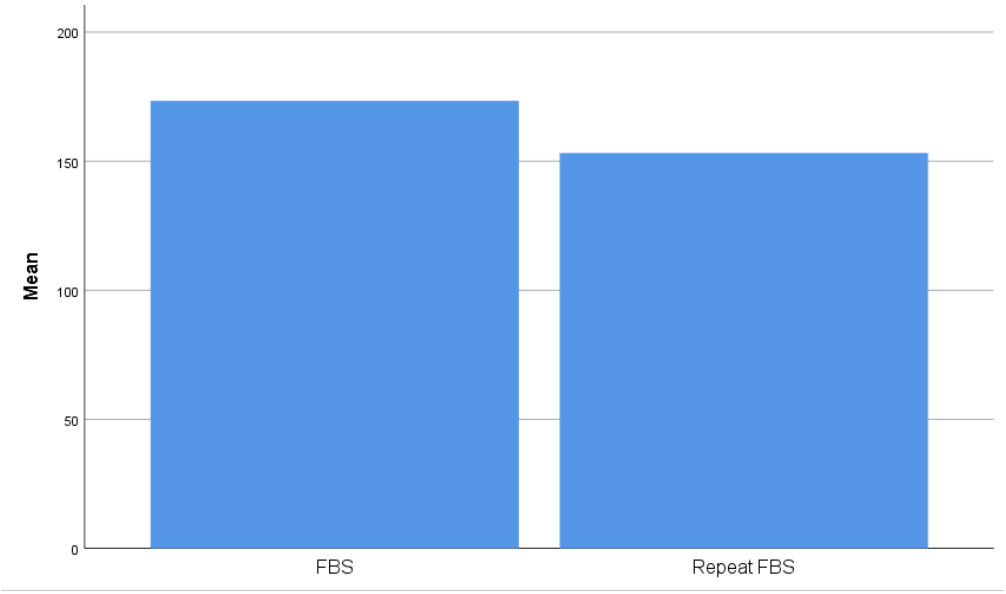
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Pre- A1c - Initial POCT A1c	.8710818182	1.968852140	.2968156280	.2724960565	1.469667580	2.935	43	.005
Pair 2	Initial POCT A1c - Repeat POCT A1c	1.464285714	2.095712428	.3960524218	.6516532692	2.276918159	3.697	27	.001

A paired sample t-test compared the two-variable means (initial and repeat POCT HbA1) to analyze and interpret tracked changes (Pallant, 2016). The analysis determined a mean score of 9.25 for initial POCT HbA1c (n=28) with (SD) 2.07, and the repeat POCT HbA1c mean score was 7.78, (SD)=1.96. Findings demonstrated a decrease in the mean score of 1.46, indicating an improved HbA1c tracked change from the pre-to post-intervention mean variable. The p-value ($p<0.01$) further indicates statistical significance for the implementation of POCT HbA1c at the local primary care clinic. The Cohen's d demonstrated an effect size, d=0.72, concluding the effectiveness of the intervention is medium to large, further supporting its usability for implementation into the clinic setting.

Fasting Blood Sugar (FBS). The data collected for the FBS was retrieved from the patient's EHR and manually uploaded in an Excel file. The data was then imported into SPSS for analysis of glycemic trends. Descriptive analysis, paired sample, and independent t-test were used to determine the statistical significance of POCT HbA1c on FBS and improved glycemic control (See Figure 5).

Figure 5

Fasting Blood Sugar and Repeat Fasting Blood sugar



Paired sampled t-test compared FBS to repeat FBS and determined the tracked variables' mean score (Pallant, 2016). The mean score for FBS was 173.3 for *n*=22 with (SD)=59.21, and the repeat FBS mean score was 153.18 for (*n*=22) patients with (SD)- 61.96. The p-value, 0.181, indicated no clinical significance; however, there was a decrease in the mean score by 20 points, demonstrating improved FBS. The Cohen's *d* effect size for the two variables (FBS and repeat FBS) was (*d* =0.33). The results indicate a small to medium effect that could be statistically significant for using POCT HbA1c to improve glycemic control if the results remained consistent with a larger sample size. The findings indicate that the study was potentially underpowered to detect a significant difference in the tracked changes between FBS and repeat FBS.

Discussion/Conclusion

This evidence-based QI project demonstrates the effectiveness of using POCT HbA1c to increase patient engagement in uncontrolled T2DM A1c >8% and improve glycemic control for implementation in the local clinical practice setting. The application of this project also aligns with organizational initiatives that focus on patient-provider performance, improved outcomes—

using HEDIS diabetes core measures for Comprehensive Diabetes Care (CDC) and VBC metrics to enhance patient quality of care.

The project data collection extended from May 2021 to October 2021 (see Appendix G for a detailed project timeline). Data tracking was conducted for HbA1c, FBS, and SES on T2DM patients with A1c>8% in addition to the VBC metric and QA of the organization. The statistical analysis was conducted to answer the PICOT question and address the specific aims and objectives of using POCT HbA1c at the local clinic. Increased patient engagement was not demonstrated, and there was no statistical significance when using POCT HbA1c, as evidenced by decreased SES scores. However, further analysis of tracked SES scores in figure 3 could suggest clinical significance. The decreased tracked change in the pre-and post-SES questionnaire responses on their perceived level of confidence in diabetes self-management was suggestive for increased engagement.

Increased self-management was demonstrated in figure 4 when using POCT HbA1c as evidenced by decreased HbA1c results and statistical significance, $p<0.001$. The correlation between FBS and HbA1c proved significant for using POCT HbA1 to improve glycemic control, as seen in figure 5 when analyzing the change trends when using POCT HbA1c. However, the p-value of 0.181 demonstrated no clinical significance because of the sample size analyzed. On the other hand, the Cohen *d* effect size ($d=0.33$) indicated that using POCT HbA1c to improve glycemic control could be statistically significant. This finding demonstrates the potential benefit of using POCT HbA1c for clinical implementation as an opportunity to promote patient-provider engagement that encourages positive self-care behavior and improves diabetes self-management.

Providers are key catalysts in promoting positive self-care behaviors, increasing patients' ability to achieve mastery experience in self-management. With the implementation of POCT,

HbA1c increased self-efficacy is achieved through vicarious experiences, social persuasion, and evaluation of the patient's mental/emotional health related to the disease process and ability to attain self-management (McLeod, 2016). The project was well supported by the interprofessional team in the clinic, and the results supported sustainability with subsequent PDSA cycles to further reinforce system changes. The implementation of POCT HbA1c with SES for instrumentation provides more immediate feedback and increases patient awareness of their diabetes self-care behaviors. It also aided the providers in clinical decision-making that is more individualized and tailored to the patient's diabetes self-management needs.

Limitations

The limitations of the project are detailed below.

- Covid-19 protocols in place at the clinic and the ongoing organizational Covid-19 office restrictions.
- Staffing shortages resulted in project delays and missed opportunities by providers and medical staff to perform the POCT HbA1c and capture the follow-up data. Delegation of project tasks and responsibilities was limited due to the ongoing staffing issues.
- The clinic recently joined an outsource call center for scheduling patients, which resulted in challenges in coordinating with offsite schedulers in ensuring appropriate follow-up visits for those diabetic patients not in compliance.
- There was a minor issue with the reordering of test cartridges that limited the number of tests performed. There was a discrepancy in the ordering system that required the office manager to contact the supply chain directly.
- Lack of a structured process to obtain provider and patient feedback.

Section V: Recommendation/ Implications for Practice

Diabetes is an ongoing public health crisis and imposes a significant impact on the healthcare infrastructure and cost. Approximately 8 million people are hospitalized annually due to diabetes-related illnesses and complications (Fingar & Reid, 2021). The DNP graduate coordinates care to address an evolving practice problem. This DNP project addressed the current clinic needs to enhance the quality measure for people with diabetes and reduce the risk of long-term complications (AACN, 2021).

The shift in the healthcare model from fee for service to performance (VBC) in evaluating the quality of care delivered to patients revealed the current gaps in the management of diabetic patients at the local clinic that pose a risk for adverse clinical outcomes. These gaps attribute to the delays in more frequent patient-provider engagement, follow-up, and referrals to the interdisciplinary teams for collaboration in management. The ADA (2021) suggests that point of care A1c is an effective tool for providing more timely treatment during the patient/provider encounter and optimization of diabetes management. POCT HbA1c should be used in diabetes patient self-management to support improved glycemic control. It can contribute to positive financial outcomes for both the patient and the healthcare system when used in diabetes self-management.

The project integrated DNP Essential III, Clinical Scholar, and Analytical Methods for Evidence providing the DNP students ability to translate evidence base into practice for integration and dissemination of new knowledge. In addressing the current care gap, the application of translation science using RE-AIM for implementation demonstrates the effectiveness of using POCT HbA1c as an evidence-based practice tool to increase patient engagement and improve glycemic control. As a DNP graduate, applying knowledge translated

from science and evidence-based research that can quickly and effectively benefit the patient is essential to the DNP's ability to influence care delivery and practice (AACN, 2006). This quality improvement project is supported by strong evidence-based practice implications that can be successfully implemented in a practice setting.

Implications

The project using POCT HbA1c at the local clinic to increase patient engagement was deemed beneficial to the organizational quality improvement initiatives to improve HbA1c and glycemic control among diabetic patients. POCT HbA1c is a cost-effective tool to increase patient compliance among those at the highest risk for long-term complications and improve quality metrics.

Patients and providers were receptive to the current practices changes and appreciated the real-time data necessary for education and clinical decision-making about managing their diabetes during office visits. The application of the SES survey in conjunction with POCT HbA1c was also seen as an effective tool by the providers in identifying barriers hindering self-management and providing more immediate intervention with the interdisciplinary team. Since implementing POCT HbA1c, utilization and referrals have increased for diabetic education and nutrition support to address patient barriers and knowledge gaps that impact positive self-care behaviors.

From an organizational perspective, the standardization of POCT HbA1c can be critical to achieving quality core measures that impact healthcare outcomes, decrease risk reduction, and promote long-term sustainability. Its application also poses a financial benefit of increased revenue income for the clinic and reduces overall healthcare costs. When considering the project's effectiveness and the organization's quality improvement initiative, the project should

continue and expand beyond the uncontrolled type II diabetic with an A1c>8% diabetic patients in VBC/QA metric to all diabetic patients. The project demonstrated strong evidence that supports its application into the practice setting. To ensure long-term sustainability, ongoing evaluation of process improvement using PDSA model to implement process change as deemed necessary.

DNP Essentials

The DNP Essentials of Doctoral Education for Advanced Nurse Practice was applied, and several applications were integrated to fulfill this quality improvement project initiative. The following DNP Essentials were integrated within the project: Essentials II, Organizational and Systems Leadership for Quality Improvement and System Thinking; Essentials III, Clinical Scholarship, and Analytical Methods for Evidence-Based Practice; Essentials IV, Information Systems/Technology and Patient Care Technology for Improvement and Transformation of Healthcare; Essentials VI, Interprofessional Collaboration for Improving Patient and Population Health Outcomes; and Essential VII, Clinical Prevention and Population Health for Improving the Nation.

DNP Essential II, Organizational and Systems Leadership for Quality Improvement and System Thinking, afforded the opportunity to build leadership competencies for spearheading practice and process improvements at the local clinic site (AACN, 2006). Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice, are vital to the DNP graduate in translating new knowledge to the clinical practice to support the clinical project implementation and dissemination for POCT HbA1c for improvement of clinical variables (AACN, 2006). Knowledge translation is critical for the DNP to attain buy-in and organizational support from key stakeholders. Essential IV, Information Systems/Technology and Patient Care

Technology for Improvement and Transformation of Healthcare were applied through information/ technology systems to track the patients' progress in relation to health care system outcomes (AACN, 2006). The DNP project lead tracked patients' self-efficacy using the SES questionnaire to determine the effectiveness of POCT HbA1c technology in improving patient outcomes.

Essential VI, Interprofessional Collaboration for Improving Patient and Population Health Outcomes, was essential for the project's success. The DNP student successfully established a collaborative interprofessional partnership through the use of formal and informal meetings. Open dialogue and feedback with the team were integral to team building. As project lead, an outlined explanation of the goal and objectives was provided to the staff, along with daily reminders via chat message or verbal communication. Clarity and redirection were also given if missed steps were identified in the project's process (AACN, 2006)

Essential VII, Clinical Prevention and Population Health for Improving the Nation, align with the EBP project objective in using POCT HbA1c to increase patient engagement and improve glycemic control in uncontrolled T2DM. Quality improvement initiatives that are geared toward health promotion and disease prevention are essential to the role of the DNP in improving health outcomes and care delivery. For the DNP graduate, the implementation of clinical prevention and population health is central to achieving the national goal of improving the health status of the population of the United States (AACN, 2006). Essential VIII, Advanced Nursing Practice, was foundational to the project providing standards for practice (AACN, 2006).

Risk/Benefits/Ethical Consideration

The ethical consideration for the project can be a benefit to some and pose a risk to others when focusing on the uncontrolled diabetic with an A1c>8% in the VBC/QA metric. The exclusion may be considered an ethical risk for justice and nonmaleficence of unintended health inequity that can contribute to poor health outcomes (Melnyk & Fineout-Overholt, 2019). It can be seen as unethical because it limits the ability of others at achieving similar desired outcomes.

The IRB process was not required for the project, given that it was deemed a quality improvement for EBP implementation. In QI, project application focuses on implementation and sustainability of the desired outcomes, whereas research focuses on the generalizability of variable findings in the research studied (Melnyk & Fineout-Overholt, 2019). A potential ethical dilemma for the project is mixing the application of research science into a QI project when analyzing data to determine the effectiveness of the intervention being implemented. Research evaluates the statistical significance between variables, whereas QI tracks changes in data trends that determine the impact of the project. QI improvement projects use implementation science to translate evidence into policy or clinical practice to improve health outcomes (Melnyk & Fineout-Overholt, 2019).

Self-Reflection

As I reflect over these last few years as a DNP student, I have gained a greater understanding of the DNP role in leadership and the application of implementation science to improve practice processes, procedures, policy changes, and improve care delivery outcomes. Key stakeholders are vital to the progress and achievement of the project's success and outcomes. Also, the presentation of the evidence is instrumental to attaining the necessary support for implementation and sustainability. Additionally, I've learned the importance of doing

a project that is impactful for the patients and their families and communities in which they live and benefits the clinic and organization's goals and objectives.

I've gained perspective that my project's progress and outcomes may not proceed as smoothly as anticipated. Unanticipated challenges may delay the project's progress necessitating the inclusion of additional evidence-based changes. I'm reflective on the importance of having that interprofessional collaboration with the team as they are an essential component to the project's success. The importance of open dialogue and constructive feedback on what is working and not working is critical to achieving the desired outcomes. Great leaders are only great because of the team of support that backs them in ensuring the purpose and objectives of the project are accomplished.

I appreciate the support throughout this journey from both the DNP leadership and supporting staff at TWU as well as within the organization. My Ah'Ha moment, I am reflective of the statement by my mentor of the importance of having a seat at the table, that my ideas matter, and that I can be the change agent in how care is delivered.

Next Step for Dissemination

Dissemination of the project results includes an executive summary and oral presentation during the diabetic council committee meeting for standardization and utilization at other clinics. Also, submission of the project manuscript to the TWU DNP repository will be completed pending final approval of all DNP degree plan requirements. Submission of my project for potential publication in a refereed journal such as the Doctor of Nursing Practice or Journal of Nurse Practitioners will be another avenue for dissemination of my project.

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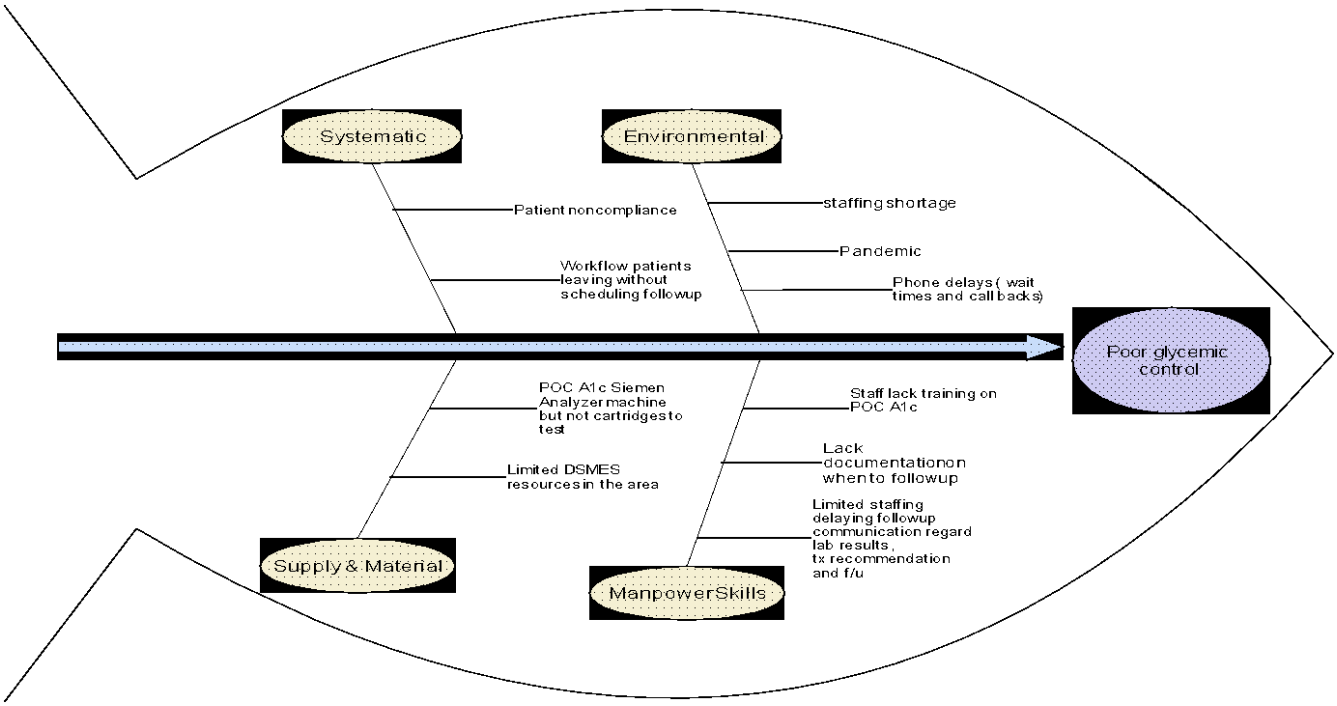
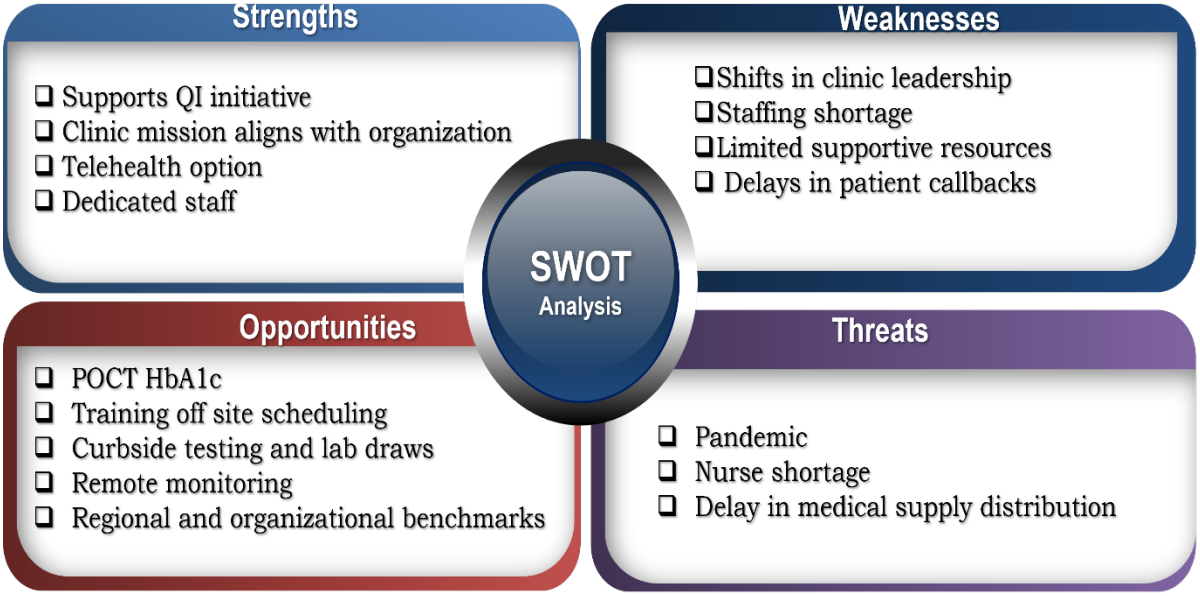
Appendix A: Fishbone Process Analysis



Appendix B: SWOT Analysis



Appendix C: Bandura's Perceived Self-Efficacy Key Elements

Definitions of Bandura's Perceived Self Efficacy Key Elements

a). ***Mastery experiences*** **(performance outcome)** is the most influential source and postulates the notation that success builds robust belief in one's personal beliefs and failures undermine it if occurs prior to self-efficacy is firmly established (Bandura, 1978). According to Bandura (1978) once strong efficacy expectations are developed through repeated success, the negative impact of occasional failures are likely to be reduced.

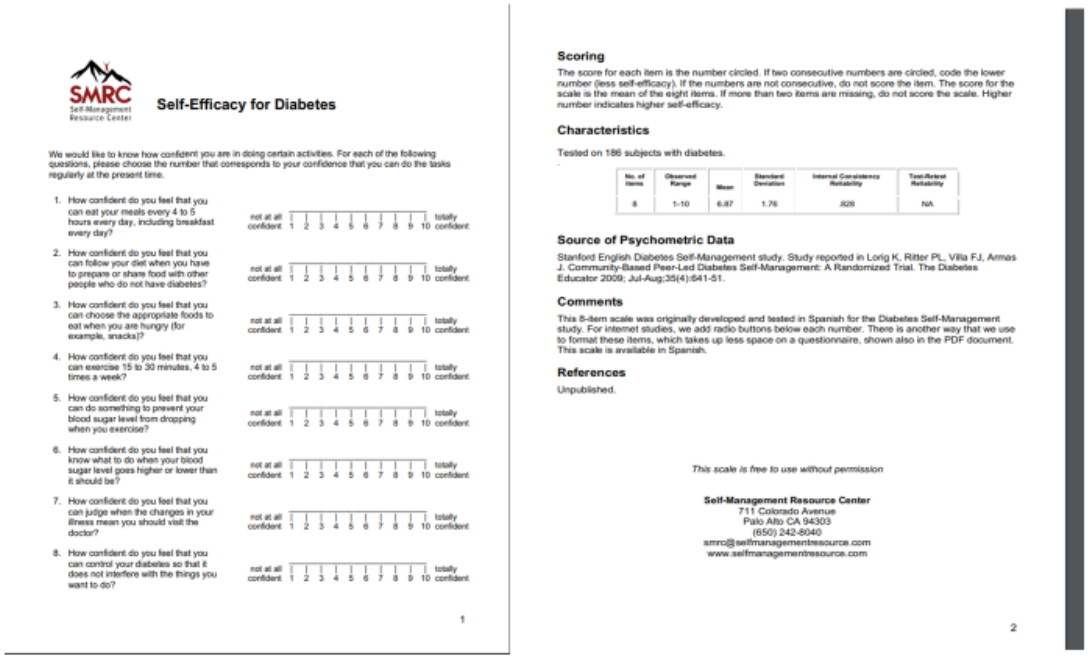
b) **Vicarious experiences** draw from the experience of others to influence behavioral outcomes. It is the ability to see others' performance to influence success or failures. Vicarious experiences have the ability to increase and or decrease self-efficacy of individuals. It is further defined as the observation of the success or failures in comparison to own competences and abilities.

c) **Social persuasion** also known as verbal persuasion is influenced by encouragement and discouragement pertaining to an individual's performance and ability to perform. Credibility influences verbal persuasion, the greater the credibility the greater the chance for success. Counseling patients about Al1c using POCT A1c testing guides conversation and encourages shared decision-making among patients and providers.

d) **physiological feedback (emotional status)** is considered the least influential of the four elements. Self-efficacy is achieved by perceived emotional arousal that influences beliefs and explores how belief about capabilities affect motivation (Bandura 1978).

(Mcleod, 2016)

Appendix D: Self Efficacy for Diabetes Assessment Instrument



SMRC
Self-Management Resource Center

Self-Efficacy for Diabetes

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident
8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

1

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the eight items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 186 subjects with diabetes.

No. of Items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1-10	6.87	1.76	.828	NA

Source of Psychometric Data

Stanford English Diabetes Self-Management study. Study reported in Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-Management: A Randomized Trial. The Diabetes Educator 2009; Jul-Aug;35(4):641-51.

Comments

This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. For internet studies, we add radio buttons below each number. There is another way that we use to format these items, which takes up less space on a questionnaire, shown also in the PDF document. This scale is available in Spanish.

References

Unpublished.

This scale is free to use without permission

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www.selfmanagementresource.com

2

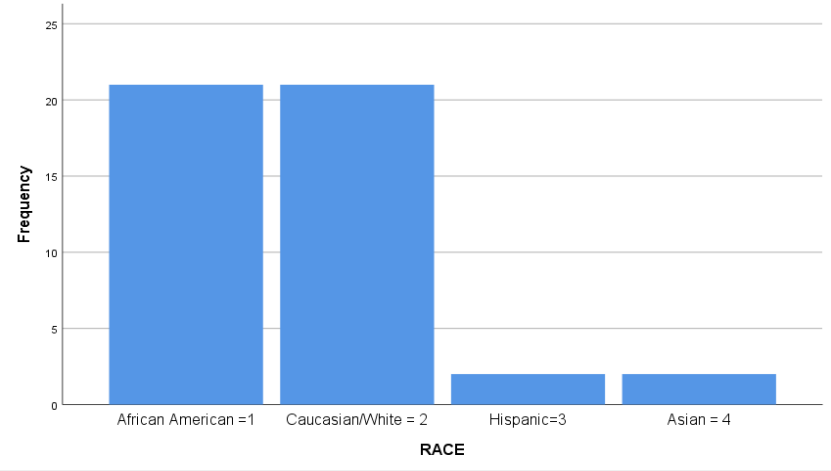
Appendix E: Project Budget

Project Fees/ Expenses:	ACTUAL	BUDGETED	
Particpants Tested	46	157	*
POCT HbA1C cost per participant	$7.50	$7.50	
Average Patient out of pocket (Co-pay)	$35.00	$35.00	
Siemen Test Cartidge ($300-40 per box)	$600.00	$1,200.00	
Lancet Finger Test ($35-200 per box)	$35.00	$70.00	
Estimated Cost of additional equipment (Refrigerator)		$1,000.00	**

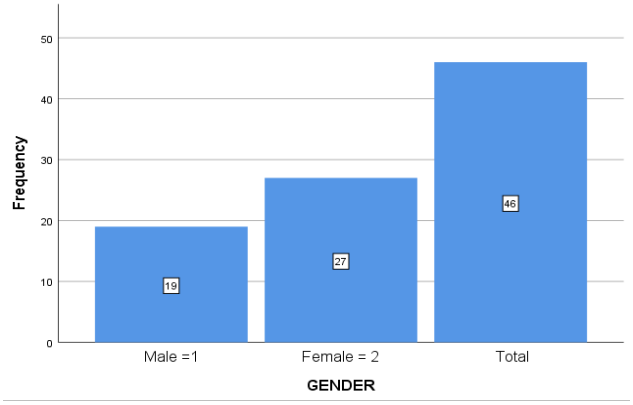
Income/Expense Statement	ACTUAL	BUDGETED	
Generated Revenue:			
POCT HbA1C Fees	$345.00	$1,177.50	
Out of Pocket Fees/Copays	$1,610.00	$5,495.00	
Total Revenue	$1,955.00	$6,672.50	
Project Expenses (Actual vs Est)			
Siemen Test Cartidge Cost	$600.00	$1,200.00	
Lancet Finger Test Cost	$35.00	$70.00	
Equipment Cost		$1,000.00	**
Total Expenses	$635.00	$2,270.00	
Net Project Impact	**$1,320.00**	**$4,402.50**	

Appendix F: Finding/Results Graphs

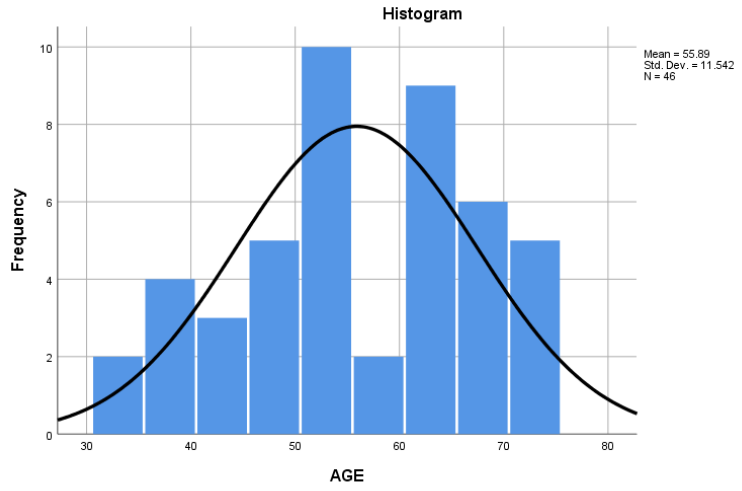
Race Distribution



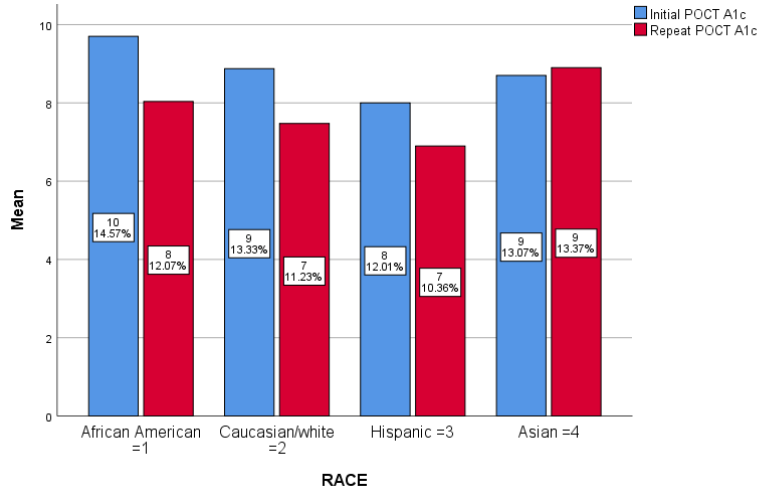
Gender Distribution

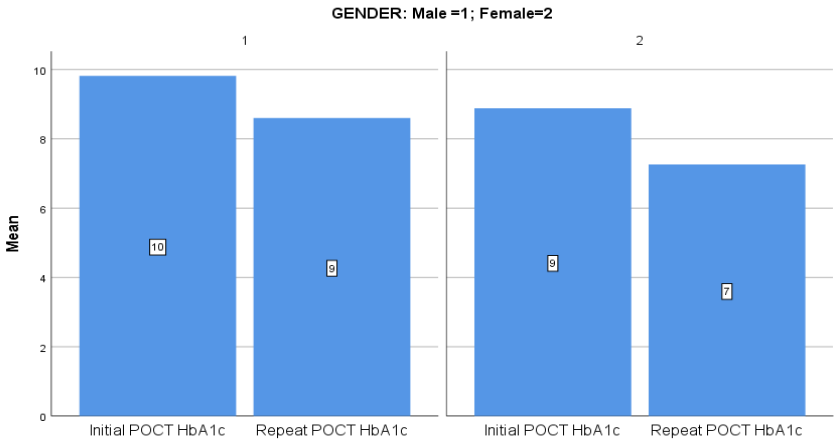


Age Distribution

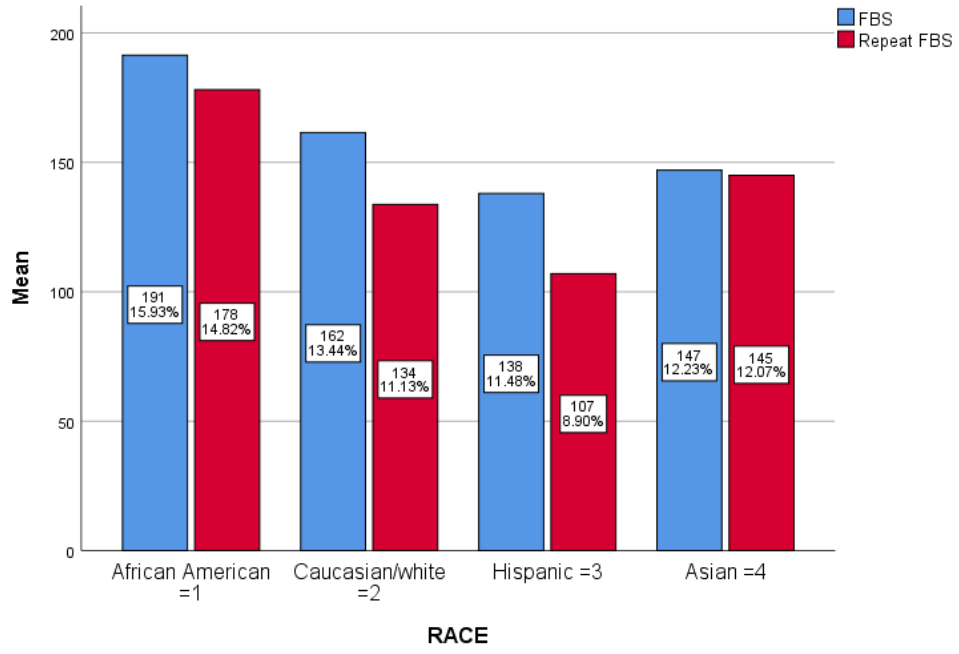


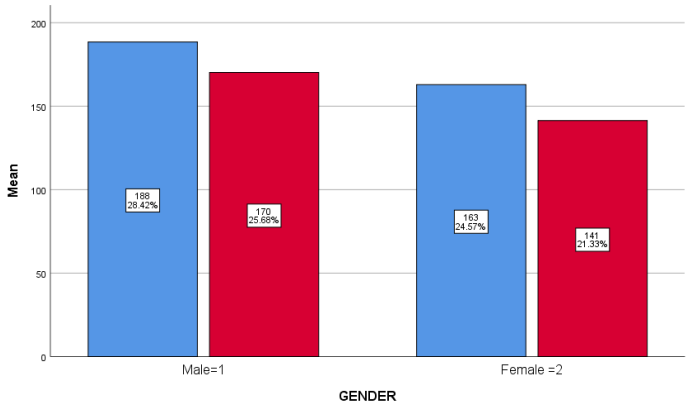
Initial and Repeat POCT HbA1c by Race/Ethnicity



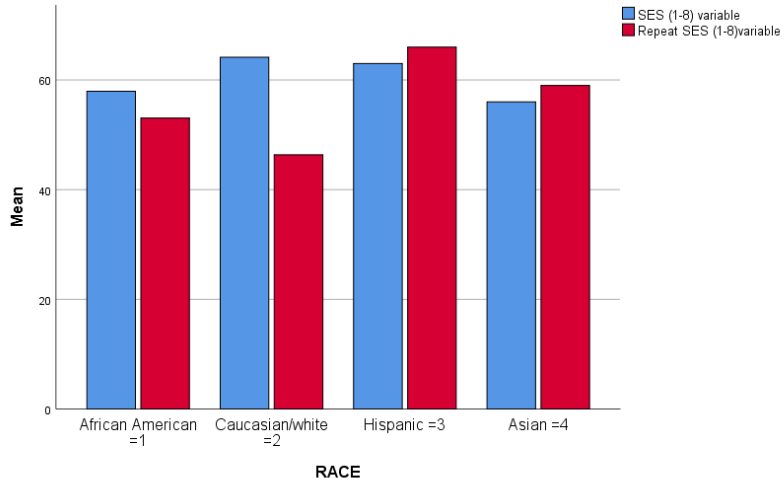


Fasting blood sugar and Repeat Fasting blood sugar by Race

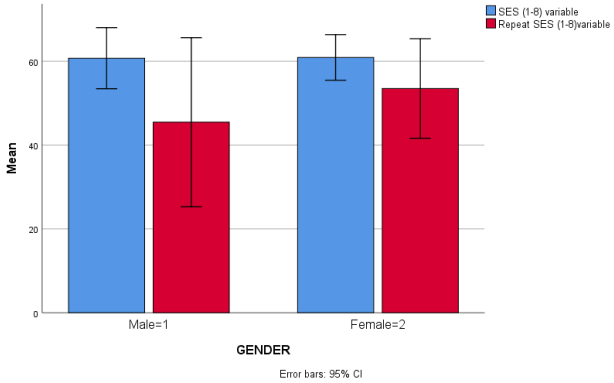




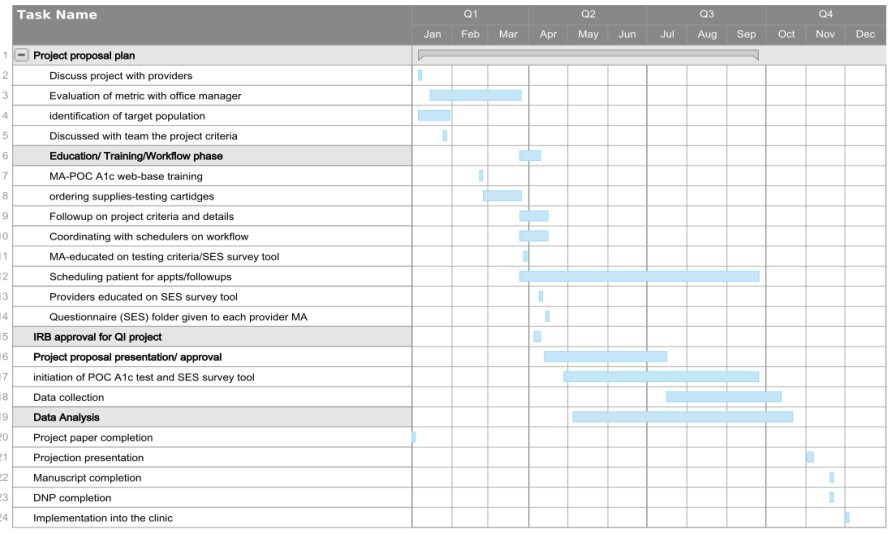
Pre- and Post-SES score by Race/Ethnicity



Pre- and Post-SES score by Gender



Appendix G. Project Timeline



Phase 1 Title				
Task 1	Project Planning	50%	1/6/21	4/1/21
Task 2	Coordinating MA- DCA/ CLIA training for POC A1c	100%	1/28/21	2/8/21
Task 3	MA- POC A1c Web-base training	100%	2/22/21	2/23/20
Task 4	Ordering of supplies- Testing cartidges	100%	2/25/21	3/25/21
Task 5	Discussed with Team regarding testing criteria	100%	3/25/21	4/15/21
Phase 2 Title				
Task 1	Evaluation of metrics with Office Manager	25%	3/25/21	8/1/21
Task 2	Identified target population	100%	1/28/21	3/25/21
Task 3	Contacting patient to schedule follow-up appointments	25%	3/25/21	5/15/21
Task 4	MA-educated on testing criteria/ SES survey	100%	3/28/21	4/15/21
Task 5	Coordinate w/schedule on workflow	50%	3/25/21	4/15/21
Phase 3 Title				
Task 1	Project IRB approval	100%	4/5/21	4/9/21
Task 2	Provider educated on SES survey tool	100%	4/9/21	5/5/21
Task 3	Questionaires given to each provider's MA	100%	4/14/21	5/6/21
Task 4	Implementation of POC A1c/SES tool	25%	4/28/21	8/1/21
Task 5	Project Planning	25%	3/25/21	7/23/21
Phase 4 Title				
Task 1	Data collection		5/5/21	10/15/21
Task 2	Project completion		10/15/21	10/15/21

Appendix H: Project Letter of Approval

to the IRB Office (IRBOFFICE@BSWHealth.org) and keep a dated copy of this checklist in your files. If the answer to ANY of these questions is NO, the project must be submitted to the IRB for review.

Please submit a complete copy of your proposed project with this completed form. Upon completion of review, you will receive a signed copy of the document and this will be your authorization to begin the project.

Project Title: "Point of Care Testing for Type II Diabetes Patients to Increase Patience Engagement and Improve Glycemic Control".

Form completed by: Kimberly N Mills FNP-C 4/5/2021 Kimberly N Mills FNP-C

Type or Print Name Signature
Date

In addition to completion of this checklist, you must ALSO obtain approval from the appropriate individuals in leadership, for your area, prior to beginning your project. This would be another individual in a leadership role who is knowledgeable in research and quality improvement/assurance activities, such as **Medical Education (medical students, residents, fellows), Nursing Education (nurses), Chief of Service (members of medical staff) or Hospital/Clinical Leadership (non-physician staff members).** If your project falls within one of these areas, please obtain review from the listed individual *or his/her designee.* If your project falls outside of these areas, you may obtain review from **another knowledgeable senior leader within your area** or you may contact the Office of Research Regulatory Affairs at Baylor Scott & White Research Institute for further guidance.

Form reviewed by: ____

Type or Print Name Signature
Date

Acknowledgement by Office of Research Regulatory Affairs:

Form reviewed by: Tracy Troxell 4/9/2021 Tracy Troxell

Type or Print Name Signature
Date

Appendix I: TWU Project Letter of Approval

Texas Woman's University
Institutional Review Board (IRB)
irb@twu.edu
https://www.twu.edu/institutional-review-board-irb/

October 6, 2021

Kimberly Mills
Nursing - Dallas

Re: IRB Not Required for IRB-FY2022-29 A1C Point of Care Testing with Type II Diabetes Patients to Increase Patient Engagement and Improve Glycemic Control

Dear Kimberly Mills,

The above-referenced project has been received by the TWU IRB - Dallas and it has been determined that this project does not require IRB review.

The project described is a quality improvement study that is not designed to contribute to generalizable knowledge and does not meet the definition of human subjects' research.
If you have any questions or need additional information, please contact the IRB at irb@twu.edu or refer to the IRB website.

Sincerely,
=
TWU IRB - Dallas

Appendix J: Evidence Matrix

Table X: Article Depicting Levels of Evidence

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
Crocker, J. B., Lynch, S. H., Guarino, A. J., & Lewandrowski, K. (2020). The impact of point-of-care hemoglobin A1c testing on population health-based onsite testing adherence: A primary-care quality improvement study. *Journal of Diabetes Science and Technology., 15*(3), 193229682097275. https://10.1177/1932296820972751	None	The assessment of POCT on synchronous Hg A1c testing to determine population health performance metrics in the primary care setting and measure the utility of POCT in identifying a clinically meaningful change in disease; measures staff satisfaction with POCT compared with the use of traditional A1c testing.	● Onsite HbA1c test (Siemens DCA Vantage analyzer ● IRB approved. A 6-month study conducted in 3 academic primary care practices for implementation of POCT testing ● Staff training (MA's) -Sample acquisition -Quality Control testing ● Use of EHR to identify patients with known DM q6mos HbA1c monitoring.	POCT HgA1c transmitted data in real-time into the EHR. Six hundred twenty-two consecutively scheduled visits and 472 among interventions group arrived. Four hundred sixty-two consecutively scheduled visits in the control group, 350 arrived. Eight hundred twenty-two testing prospects without POCT Hba1c were 3.69 times less adherent to every six monthHbA1c testings (20.3% vs. 5.5%, P<0.01). Pts of each study group with worsening DM (> 0.5% or 5.5mmol/mol rise in HbA1c POCT identified 49% of all clinically worsened glycemic control in the	**Level IV: Cohort Study** Prospective quality improvement **Quality: Good (B)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			● 3mos to incorporate into the workflow from 1/14-7/14. ● 530 patients in (intervention group with POCT HbA1c) and 377 (control group) with HbA1c POCT) ● Online survey (Survey Monkey) anonymous survey to participating staff. ● IBM SPSS for Windows was used for statistical	intervention group. 75% of respondents for HbA1c more favorable to administer compared to another POCT test currently used.	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			analyses (version 25) with an alpha set of P<0.05. ● A Fisher two-tailed test analyzed the difference between the intervention and control categorical outcomes. ● An independent sample t-test was performed to determine group differences in continuous outcomes.		
Hirst, J. A., McLellan, J. H., Price, C. P., English, E., Feakins,	None	A systematic review and meta-	Medline, Embase, and Web of Science	Searches identified	**Level I**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
B. G., Stevens, R. J., & Farmer, A. J. (2017). Performance of point-of-care HbA1c test devices: Implications for use in clinical practice – a systematic review and meta-analysis. *Clinical Chemistry and Laboratory Medicine (CCLM), 55*(2), 167-180. https://10.1515/cclm-2016-0303		analysis were conducted using a novel approach to compare the accuracy and precision of POC HbA1c devices.	databases were searched in June 2015 for published reports comparing POC HbA1c devices with laboratory methods. Two reviewers screened articles and extracted data on (capillary or venous blood), operator (clinical or laboratory operator), precision, and diagnostic accuracy. Mean bias and variability among the POC and laboratory tests were combined in a meta-analysis. Study quality was assessed using the QUADAS2 tool.	reviewed 1739 records for eligibility. Sixty-one studies were included in the meta-analysis of mean bias. Devices evaluated were A1cgear, A1cNow, Afinion, B-analyst, Clover, Cobas b101, DCA 2000/Vantage, HemoCue, Innovastar, Nycocard, Quo-Lab, Quo-Test, and SDA1cCare. Mean bias and 2SD range of difference in HbA1c between each POC device and comparator method \ showed considerable variability in bias for most devices. Nine devices had a negative mean bias which was significant for three devices. There was substantial variability in preference within devices. There was no difference in discrimination between clinical or laboratory operators in the two devices.	**Systematic review and meta-analysis** **Quality: High (B)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
Hirst, J. A., Stevens, R. J., Smith, I., James, T., Gudgin, B. C., & Farmer, A. J. (2017). How can point-of-care HbA1c testing be integrated into UK primary care consultations? – a feasibility study. *Diabetes Research and Clinical Practice, 130*, 113-120. DOI: 10.1016/j.diabres.2017.05.014	None	How can point of care HbA1c testing be integrated into UK primary care consultations?	Cohort Feasibility study Recruited 30 patients with type2DM for the past 3 months and HbA1c > 7.5%; Participants had 3 study visits over 6 months and two interviews. Eligible patients were identified by clinic staff in a recent laboratory. HbA1c results indicated that their glycemic control was sub-optimal. Letter of invitation and participant information sheet Given anonymous identifying #'s- as patient identifiers. All participants received POC HbA1c in three primary care clinics. Alere Afinon AS100 POC device was used in each clinic bar code scanner, printer, and HbA1c test cartridge. The first visit is the baseline, patient eligibility assessed and written informed consent, the venous blood sample was taken for laboratory A1c measurement, patient Ht/Wt. Measured & patients completed four questionnaires 15 patients were interviewed before their 1st appointment. 2nd study visit took place around 12 weeks after the baseline visit. 3rd and final study visit- around 24weeks after the baseline visits	Nurses and one by a GP run two clinics. Changes between baseline and visit three were compared; statistical significance was set at p-value<0.05 for all shifts. Equal # if men and women were recruited to the study. Mean age 57.8 years, 28 were white, 2 were Asian, mean diabetes duration was 6.7 years, and mean +/SD BMI was 32.2+/3.5kg/m2. Mean +/ SD HbA1c at baseline was 8.21 +/0.98% (66.3+/10.7mmol/mol).	**Level V: Cohort Study** <u>Quality:</u> High (A)

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			All four-questionnaire completed by patients. The survey consists of multiple-choice or tick box questions on ease of use and perceived barrier. Mean +/ standard deviation SD for the study visits. The questionnaires used: Diabetes Treatment Satisfaction Questionnaire (DTSQ+), appended with questions related to an understanding of HbA1c and satisfaction with the clinic, Revised Illness Perception Questionnaire (IPQ-R), Patient Activation Measure (PAM), Morisky Medication Adherence (MMAS)		
Hirst, J. A., Farmer, A. J., & Williams, V. (2020). How point-of-care HbA 1c testing changes the behavior of people with diabetes and clinicians – a qualitative study. *Diabetic Medicine, 37*(6), 1008-1015. https://10.1111/dme.14219	The thematic framework used for coding and analysis of clinician interviews based on prior framework Themes included: advantage and convenience, behavior and motivation, the immediacy of results, and visibility and concerns with the point of care.	How point-of-care HbA 1c testing changes the behavior of people with diabetes and clinicians – a qualitative study The aim is to explore adults with diabetes and clinician views of a point of care HbA1c testing.	Fifteen participants were selected from three GP practices in the Thames Valley region in the UK. 13 European 2 Asian; eight women, seven women with type II diabetes and HgA1c 7.5% who received HbA1c point of care testing were interviewed. The specified sample size was selected based upon social demographic criteria (age, sex, ethnicity, level of education, and duration of diabetes-from one year ten months to 20 years) Two nurses in one GP participated. The	Data saturation was not the aim as the study was exploratory. Respondent validation was not used. The data was analyzed around themes among participants. Clinician interviews were analyzed around the advantages of point of care testing and convenience, clinical decision making, patient flow, and	**Level IV Qualitative study** <u>Quality</u> Good (B)

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			clinician who cared out the point of care testing consultation was interviewed on their perspective on the point of care testing and its effect on clinical consultations and decision making. **Patient interviewed:** (experience pre and post point of care testing) Semi-structured interviews: Open-ended (verbatim quotation to illustrate differences or similarities in their views before and after receiving point of care testing Using QSR International NVivo, Inductive and deductive coding was conducted. Data charting using Microsoft Excel w/ each theme labeled separate tab in Excel spreadsheet. The collection was based on pre-specified sample sizes but did not continue until saturation was reached.	disadvantages and barriers of end of care testing. Overall clinician had a positive view on the use of POC HbA1c testing Rigor in the coding process was ensured by random sampling of coded transcripts double-checked by a senior qualitative researcher. Both the patient and clinicians demonstrated positive responses. Obtaining results at the time of their appt helps some pts understand how lifestyle behaviors affect diabetes control. It also reduces anxiety in waiting for results.	
Patzer, K., Ardjomand, P., Göhring, K., Klempt, G., Patzelt, A., Redzich, M., Zebrowski, M., Emmerich, S., & Schnell, O. (2018). Implementation of HbA1c point of care testing in 3 german medical practices: Impact on workflow and physician, staff, and patient satisfaction. *Journal of Diabetes Science and Technology., 12*(3), 687-694.	None	The study's objective was to evaluate the effects of introducing HbA1c POCT in practices specialized in DM. Switching from conventional laboratory testing to POCT can	Pre-post comparison quantity/quality regarding HbA1c POCT implementation. Evaluate the impact on practices processes and physician, staff-patient satisfaction. Three offices German city w/ 7 physicians,23.5	A total 578 evaluated documentation forms from all practices were analyzed: n = 300 before POCT implementation; n = 278 after implementation	**Level V pretest and posttest design.** Not clearly stated, but this is a descriptive study **Quality** Grade (B) Good

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
https://10.1177/1932296818759690		shorten the time to decision making and lessen treatment delay. Impact of POCT compared to standard laboratory testing.	staff members PA participated in the 8-month study b/w April-Dec 2015. Practice sizes 400,550, 950 DM. Quarterly HbA1c per guidelines Six questions (yes or no/same day or follow-up). 1. "Was venous blood sample collected?" 2. "Was an immediate follow-up appointment scheduled?" 3. "Was the patient contacted by phone?" 4. "Was the HbA1c value discussed with the patient the same day as an initial visit?" 5. "Was therapy changed due to the HbA1c value?" 6. "At initial patient presentation: when was therapy initiated due to the HbA1c value? Physicians, staff members, and patients completed written questionnaires with both open and closed questions: Physicians were asked: 1."Did the immediate availability of HbA1c results lead to an improved practice workflow? 2. "Did you experience a relief of burden?" 3. "Did the immediate availability of HbA1c values result in treatment improvement?" 4. "How do you rate the implementation of HbA1c measurement using POCT overall?"	After POCT implementation the # of required visits scheduled was reduced by 80% (88% vs 17.6%, P < .0001), the # of venous blood collections by 75% (91% vs 23%, P < .0001). Of patients, 82% (vs. 13% before POCT implementation) were able to discuss their HbA1c values with treating physicians immediately during their first visit (P < .0001). In two practices, the POCT process resulted in significant time savings of approximately 20 and 22 working days per 1000 patients per year (95% CI 2-46; 95% CI 10-44). All physicians indicated that POCT HbA1c implementation improved the practice workflow, and all experienced relief of burden for the office and the patients.	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			Staff members asked the following six multiple-choice questions about the HbA1c measurement process and impact of POCT: 1. "How did you experience testing with the Alere Afinion AS100 Analyzer?" 2. "How do you assess the finger-stick capillary blood collection?" 3. "Is there any difference between capillary and venous blood collection in terms of the time needed?" 4. "Did you avoid telephone conversations?" 5. "Has the process for scheduling appointments become easier?" 6. "Did you experience a relief of burden for yourself?" Patients were given written questionnaires to evaluate their opinions of the process	All staff members indicated that they found the POCT measurement easy to perform and experienced relief of burden. The majority (61.3%) of patients found the capillary blood collection more pleasant, and 83% saw an advantage in the immediate availability of HbA1c results.	
Egbunike, V., & Gerard, S. (2013). The impact of point-of-care A1C testing on provider compliance and A1C levels in a primary setting. *The Diabetes Educator, 39*(1), 66-73. https://10.1177/0145721712465340	Chronic Care Model	The purpose is to investigate the impact of Point of Care A1c testing on Provider Compliance and Alc levels in a Primary care setting 1The significant difference in the number of patients with documented A1C levels at the time of a clinic visit in the past six months pre- versus post-	IRB approved quasi-experimental, pretest and posttest design. Charts reviewed T2DM patients and data matching demographics (age, sex, race, BMI, insurance status, and the # of comorbidities). Sampling: Chart audit from the principal investigator a random scientific selection at 6 and 3 months before the	Data analysis was conducted using SPSS, version 19, T-a test used to answer research questions 1,2,3 $P<0.05$ = statistically significant The statistical test was performed on demographic data, dependent variables of provider	**Level III quasi-experimental, pretest and posttest design.** **Quality grade (B):** Good

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
		implementation of POC A1C testing? 2. Is there a significant difference in patients' actual A1C levels pre- versus post-implementation of POC A1C testing based on intensified treatment interventions? 3. Is there a significant difference between documented treatment changes made by providers pre- versus post-implementation of POC A1C testing?	implementation of POC A1c Patients were assigned numbers who met the study criteria and were seen a designated times pre-post implementation.	adherence using ADA guidelines, A1c value, and documented changes in treatment. Chart review conducted	
Berbudi, A., Rahmadika, N., Tjahjadi, A. I., & Ruslami, R. (2020). Performance of point-of-care testing compared with the standard laboratory diagnostic test in measuring HbA1c in Indonesian diabetic and nondiabetic subjects. *Journal of Diabetes Research, 2020*(Jul), 1-6. https://10.1155/2020/2037565	None	We aimed to investigate the use of POCT- HbA1c HemoCue A1c 501 as an alternative method for diabetes screening and monitoring to replace the HbA1c measurement in a standard diagnostic laboratory test.	Comparing HbA1c level of diabetic and non-diabetic subjected obtaining POCT A1c with that of the standard diagnostic laboratory 108 participants 61 diabetics ,47 nondiabetic; 37 females and 24 males w/ DM dx 15 females and 32 males were in the non-DM group Diabetic group= 61 individuals dx with type 2 DM and were undergoing diabetes treatment at several community health care centers in Bandung. HbA1c methods were analyzed and compared	The sensitivity and Specificity of POCT HbA1c data were compared with those of the standard diagnostic results Mean value HbA1c 6.96% for the standard laboratory versus 7.15% for POCT HbA1c with a mean difference of 0. 187. indicating POCT HbA1c measurement aligns with the HbA1c standard diagnostic test	**Level IV Cross-sectional study** **Quality Grade** High(A)

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			using the Bland-Altman agreement plot.	Bland-Altman plot analysis, HbA1c of 100 out of 108 subjects analyzed with POCT and standard diagnostic (95% confidence intervals: -1.675 to 1.301)w/ 3 upper outliers/5 lower outliers outside the agreement limit range indicating that 92.59% of HbA1c measurement in line with a standard laboratory test. POCT HbA1c method is less costly compared to standard laboratory analysis. POCT HbA1c has a sensitivity of 97.83% while the specificity of this tool was 77.42%; The probability of DM in subjects with HbA1c >6.5% tested by POCT-HBa1c (positive predictive value) was 76.27%; the likelihood of not having diabetes with HbA1c <6.5 test by	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
				POCT-HbA1c (negative predictive value) was 97.96%.	
Juneja, M., Mejia de Grubb, Maria C, Wang, H., Spooner, K., & Zoorob, R. J. (2015). Exploring point-of-care transformation in diabetic care: A quality improvement approach. *Family Medicine and Community Health, 3*(2), 20-26. doi:10.15212/FMCH.2015.0116	Patient-Centered Medical Home (PCMH) and integrated care in DM	The objective was to evaluate the impact of (POC) HbA1c stat lab intervention and nurse lead expanded visits in uncontrolled T2DM HbA1c >9%patient in Houston TX Q1. In a primary care setting, will a POC-expanded visit program show a reduction in the % of patients with uncontrolled diabetes? Q2. Will implementing this program reduce the need for ED visits and hospitalizations caused by complications among participants? Q3. Will the use of the screening algorithm affect cycle time and enhance the role of nurses in chronic disease management?	IRB approved. Primary measures: document HbA1c at the initial visit and -post-intervention HbA1c at follow-up after POC services provided. Pop: >18 years of age seen at the clinic Pt that lacked HbA1c results in the last 1 to 2 years were screened with a 3-point questionnaire Participants included provider (n=14), nurses (n=240 received an in-service education on the importance of glycemic control, EB guidelines on optimal HbA1c values HbA1c >9% had updated lab @ check-in, followed by a nurse intervention, assessment education goal setting, and referrals pending Descriptive statistics were performed and paired was T-test used to compare the mean between HbA1c, pre-and post-intervention periods. Pearson chi-square test was used to assess if their relationship b/w independent variables. The null hypothesis was rejected for p< for all comparisons.	Three hundred eighty-seven adults met the inclusion criteria. Pts had a baseline visit three months visit during the post-intervention. The absolute reduction in the level of HbA1c was 1.4% (t=12.89, p<0.000), a decrease of 13% during the post-intervention. Statistically significant differences were noted by race, ethnicity, and gender. Hispanic had the highest decrease in the avg HbA1c level (-1.66%) blacks (-1.38%), Asian (0.66%) and whites (-0.68%) No significant difference in age. Nineteen patients with no ER visits at the time of	**Pre and Post-intervention** Level III **Quality Grade** (B) Good

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			SPSS (version 22) for statistical analysis. At the end of the study, a nurse satisfaction survey on POC was conducted to assess the nurse's perception.	intervention and >1 post-intervention ER visit exhibited a change from 0 to an avg of 1.3 times. HbA1c drops of 14% (pre-ER =10.76 vs. post ER=9.26)	
D'Souza, M. S., Karkada, S. N., Parahoo, K., Venkatesaperumal, R., Achora, S., & Cayaban, A. R. R. (2017). Self-efficacy and self-care behaviors among adults with type 2 diabetes. *Applied Nursing Research, 36*(Aug), 25-32. https://10.1016/j.apnr.2017.05.004	Conceptual	The study aimed to examine the relationship between demographics, clinical factors, and glycemic control on self-efficacy and self-behaviors among adults with T2DM	T2DM registered @ the DM clinic at a public hospital b/w April – July 2016 Sample framework obtained from the electronic patient record maintained within the hospital Volunteer screened for inclusion: Age 18-80 years. Diagnosis of T2DM >2 years, Communicate in Arabic or English. Exclusion criteria were also noted. A power analysis was conducted using Cohen's power. A total of 160 adults were required to achieve 80% power to detect a medium effect size (f=0.25), at the 5% level of significance with an SD of 1% 160 participants random sampling Random #1-2000 in Microsoft Excel Diabetes Management of Self Efficacy (DSMSES) 20 item rating scale using a 5-point Likert fore perception SE to control DM.	SPSS version 22 analyzed double data entry, data cleaning, coding, and auditing for accuracy. The level of probability of < 0.05 was considered statistically significant. Adult with moderate self-efficacy and self-care behaviors is reflected in the outcome and reduced risk of diabetes-related complication. Freedom and responsibility are achieved satisfaction of adults perceived high self-efficacy. The highest total mean (x) and standard deviation (sd) for the self-care behaviors among the adults	**Descriptive Cross-sectional design** **Level V** **Quality grade:** good (B**)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
			Participants rate their confidence using a scale ranging from 0 (can't do at all) to 10 (certain to achieve); Total score 0-200 with a higher score and subscale scores reflecting high efficacy. The internal consistency ($\alpha = 0.81$) and test-retest reliability ($r = 0.79$) of the DMSES English version were acceptable. IRB approved General linear model, Anova, and Multivariate General Linear Model used	with T2DM was for real foot care mean ($x = 4.14$, $sd = 1.51$) and total diet mean ($x = 3.85$, $sd = 0.82$) There is no significant difference in the level of self-care behaviors (SCB), demographic and clinical, and differences in self-efficacy characteristics. Fasting blood glucose, HbA1c, understanding diabetes and its treatment, prevention of normal daily activities, ability to fit diabetes life positively, and patient-physician communication were highly significant ($p = 0.000$) with diet, exercise, blood glucose testing, foot care as well as medications self-efficacy	
John, Mary Nicole, Kreider, Kathryn E, Thompson, Julie A, & Pereira, Katherine. (2019). Implementation of A1C Point-of-Care Testing: Serving Under-Resourced Adults with Type 2	NONE	**Objective 1:** This study determined whether A1c POCT and face-to-face education	Quality Improvement (QI) Retrospective chart review of 74 adult patients w/T2DM	The sample size was calculated using G Power software, ANOVA	**Quality improvement Level V Quality grade: Good (B)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
Diabetes in a Public Health Department. *Clinical Diabetes, 37*(3), 242-249.		improved glycemic control for under-resourced patients with type 2 DM compared to standardized laboratory testing and telephone /letter communication, as evidenced by A1c trending downward to a goal of <7%. **Objective 2:** Determine whether clinical inertia decrease with A1c POCT compared to the standardized laboratory in under-resourced patients with T2DM and an A1c>7%, as evidenced by the clinician intensifying medication at face-to-face visits.	>18 years of age. Exclusion criteria anemia, hypoglycemia, limited life expectancy, advanced microvascular and macrovascular complications, extensive comorbid conditions, ESRD, pregnancy, and new patients Implementation began March 2017 through July 2017 Pre and Post design Data were collected at baseline (clinic visits held 3-6 months before project implementation and two additional time points: initial A1c and follow-up three months later.	Using an effect size of 0.25, a set of 0.05, and power set to 0.80, suggesting a sample size of 28 SPSS used for statistical analysis Descriptive statistics analyzed baseline characteristics and demographics Anova compared the changes in patient A1c using standard laboratory analysis versus POCT over the three months x2 test was used to compare the baseline regarding medication intensification after A1c POCT The ANOVA revealed an overall significant effect of time, F(2,62-5.87, p0.004. Post hoc pairwise comparison showed A1c increased significantly from baseline (	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
				M=8.98%, SD1.81%) to P1I (m9.93% SD= 2.21%), p-0.008. A1c decreased significantly from PI1 to PI2. There was no baseline difference between baseline and PI2. significant increase in the number of medication intensification for baseline (n=10, 23.8% to PI1 (n=37, 88.1# and a non-significant decrease from PI1 to PI2, there was a significant increase from baseline to PI2. , x2 (2, n-1190=3.680, p<0.001	
Beckerle, C. M, & Lavin, M. A. (2013). Association of Self-Efficacy and Self-Care with Glycemic Control in Diabetes. *Diabetes Spectrum, 26*(3), 172-178.	Bandura Self Efficacy Theory	1) What is the association between self-efficacy and self-care? Does the	IRB approved Comprises 31 private primary care offices in a large, Midwestern suburb The quality improvement committee oversees and the design and implementation Stanford Self Efficacy for Diabetes scale (SES) and Self-Care Inventory (SCI) Esse health dietitians were responsible for documentation of the two surveys – type 1 or type 2 diabetes.	Stanford Diabetes Self Efficacy for Diabetes Scale was significantly related to A1c (P<0.009). Q1 results showed that self-efficacy and self-care vary (x2=7.86 degree of freedom (df)1, P<0.009 Spearman's correlation coefficient	**Level III** **Retrospective cohort design** **quality grade: High (B)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
		risk of poor self-care increase as self-efficacy decreases ? 2) What is the association between self-efficacy and A1c? Does the risk of poor glycemic control increase as self-efficacy decreases ?	Specific questions were asked to analyze self-efficacy, self-care, and self-management data and their relationship to glycemic control. Archived data retrieved from all cognitively unimpaired people >18 years of age type 1 or type 2DM b/w Feb 10-March 10,2012 Data reviewed included SES and SCI scores and all A1c results conducted w/in the 12 months months months. Charts missing requiring data were excluded Sixty records are needed to detect a 33% improvement in the proportion of people with well-controlled glycemic levels of a=0.05. Data collected uploaded into SPSS window version 17 The study focused on two independent variables and one dependent or outcome. Variables were SES and SCI. Pearson X2 and Fishers exact in determining the association/w high and low self-care and self-efficacy score and A1c>7.0%and <7.0% (uncontrolled and controlled glycemia)	[p]=0.537. p<0.000, meaning high SES is associated with high SCI and vice versa there was also no difference in the mean A1c value between patients with high and low self-efficacy and self-care scores	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
		3) What is the association between self-care and A1c? Does the risk of poor glycemic control increase as self-care decreases? 4) Given that the above associations are positive, what			

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
		percentage of the variance in A1c values is accounted for by self-care or self-efficacy measures?			
Kimerling, Rachel, Lewis, Eleanor T, Javier, Sarah J, & Zulman, Donna M. (2020). Opportunity or Burden? A Behavioral Framework for Patient Engagement. *Medical Care, 58*(2), 161-168.	Engagement behavior Framework and Self-efficacy theory	Opportunity or Burden? Objective: Refine the framework's domains of behavior that comprise the construct of patient engagement; identify key behaviors within each part that describes meeting with providers and health systems or settings; illustrate examples for each behavior where higher self-efficacy describes an opportunity to enhance engagement and lower self-efficacy	Formative qualitative study using semi-structured individual interviews Behavior domains-derived from literature review and refined via an online Delphi panel completed by eight subject experts Purposive sampling target used heterogeneity in illness severity, comorbidity burden, and representation of both mental health and chronic conditions Recruitment: outpatient mental health clinic and care coordination program for high cost and high-need patients	Data collection continued until saturation was reached using an a priori criterion of 3 consecutive interviews that revealed no new behavior or themes. 25 completed interviews 88% male (64% white and 16% black) b/w age 25-92; mean age 60. Education level: 1-3 years beyond high school 76% received treatment for one chronic	**Level IV qualitative study**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
		describes difficulties that decrease concentration and risk burden	Providers referred participants or study contact. Interviews lasted 1hr and were conducted in a VA setting or by telephone by a trained research associate. Participants signed Informed consent and patient compensation with a $20 gift card. Interviews were audio-recorded and transcribed verbatim. Data were analyzed using the Framework Method using ATLAS. First, three transcripts – group coded The remaining transcript was double-coded independently by the study interviewer and one other team member and reviewed at team meetings. Coded data: charted, reviewed for interpretation, and recharted Methodologically organized by consolidated criteria for reporting qualitative research (COREQ)	medical or mental health condition; 60% had mental health and chronic conditions. Themes included Self-management, health information use, collaborative communication, and health care navigations	

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
Peek, M. E., Drum, M., & Cooper, L. A. (2014). The association of patient chronic disease burden and self-management requirements with shared decision making in primary care visits. *Health Services Research and Managerial Epidemiology, 1*, 233339281453877. https://10.1177/2333392814538775	None	Objective: (1) Evaluate patients with chronic diseases, particularly those requiring self-management, are more likely to engage in SDM behaviors than patients without chronic diseases (2) patients with chronic disease are more likely to have their physicians engage them in SDM.	A Cross-sectional study visits between patients and physicians evaluating adherence. Eligible patients included primary care physician African American adult patients with HTN 18 yrs of age and older at a community health clinic in Baltimore The multivariable regression model was used to determine the association between predictor variables (1)chronic disease burden and (2) disease requiring self-management outcomes with the outcome variables: patient information sharing, (2) patient decision making (3) physician SDM facilitation.	Patients with more significant chronic disease burden/disease requiring self-management reported more information sharing (B=07, P=.03, and B.12, P=.046, respectively) and decision making (B=.06, P=.02 and B=.21, P<0.001, as did patients who reported poor general health. Physician facilitation of SDM is associated with higher patient outcomes but not associated with disease burden.	**Randomized Controlled trial Level II Good quality**
Schnell, O., Crocker, J. B., & Weng, J. (2017). Impact of HbA1c testing at the point of care on diabetes management. *Journal of Diabetes Science and Technology., 11*(3), 611-617. https://10.1177/1932296816678263	none	Evaluation of evidence supporting the use of POCT HbA1c	Metanalysis was conducted Analyzing data on the improved diabetes management/treatment adaptation with the use of POCT HbA1c, improved glycemic control, and; high patient satisfaction	Literature review determined POCT HbA1c to have benefit for the improvement in diabetes self-management and glycemic control Also demonstrated a correlation with A1c results and	**Systematic review and Metanalysis Good**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
				improved glycemic control And provider and patient perception of the US of POCT HbA1c, agreeing that it improved opportunity for treatment	
Al-Ansary, L., Farmer, A., Hirst, J., Roberts, N., Glasziou, P., Perera, R., & Price, C. P. (2011). Point-of-care testing for HbA1c in the management of diabetes: A systematic review and meta-analysis. *Clinical Chemistry (Baltimore, Md.), 57*(4), 568-576. https://10.1373/clinchem.2010.157586	None	To perform a systematic review of current trials to determine whether POCT for HbA1c compared with conventional laboratory tests improves outcomes for patients with diabetes.	PRSMA Randomized control trial Evaluating outcomes of primary variables for HbA1c Inclusion criteria: type 1 or type 2 DM comparing the effects of POCT with an independent laboratory test. Analysis was conducted on the mean HbA1c using inverse variance with a weighted average of the outcome measure and a fixed-effect model.	Seven trials were found. No significant reduction of 0.009% (95% CI-.021 to0.02) in the HbA1c in the POCT compared to the stand. No efficient evidence for the effectiveness of POCT of HbA1c for management of HbA1c in eh management	**Systematic review and metanalysis Quality level Low (c)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
Al-Khawaldeh, O. A., Al-Hassan, M. A., & Froelicher, E. S. (2012). Self-efficacy, self-management, and glycemic control in adults with type 2 diabetes mellitus. *Journal of Diabetes and its Complications, 26*(1), 10-16. https://10.1016/j.jdiacomp.2011.11.002	Bandura Self - Efficacy theory	The study proposed four research questions: 1. What are the levels of diabetes management self-efficacy? 2. What are the levels of DSM behaviors? 3. Does diabetes management self-efficacy predict DSM behaviors? 4. Do socioeconomic and clinical characteristics, self-efficacy beliefs for diabetes management, and DSM behaviors predict glycemic control in patients with type 2 diabetes?	Cross-sectional research of face to face interviews Sample: Jordanian adults with type 2DM who sought care between July 15, 2008, and September 16, 2008 Age: >25 years and mentally competent with verbal communication and informed consent Exclusion included pregnant women with gestational diabetes, cognitive impairments, or significant diabetes complications. Interviews were structured using three questionnaires (DSMES, SDSCA, and Physiological measurement)	The mean of self-efficacy subscale was calculated for the DSME: a higher score indicated a higher level of self-efficacy. Descriptive statistics analyzed the sociodemographic and clinical demographics Multivariate regression analyzed the relationship with the demographics and clinical characteristic The highest efficacy score for efficacy to carry out the prescribed medical treatment, and the lowest score was efficacy to exercise. 2. For the levels of DSM behaviors, blood sugar testing was less frequently reported, and the most frequent was washes feet and oral hypoglycemic agents.	**Qualitative Level V** **High quality (A)**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
				4 of the five subscales self-efficacy was statistically significant of respective DSM behaviors using univariate logistic regression .Participants who received stronger dietary self-efficacy were more likely to have lower value HbA1c	
Harrington, C., Carter-Templeton, H. D., & Appel, S. J. (2017). Diabetes self-management education and self-efficacy among African American women living with type 2 diabetes in rural primary care. *Journal of Doctoral Nursing Practice, 10*(1), 11-16. https://10.1891/2380-9418.10.1.11	none	To evaluate the effectiveness of a DSME intervention in AA women with T2DM and how SE can improve self-care behavior (management) of diabetes	Descriptive pilot study Sample: n=15 African American women participants age 25-65 years of age Location: rural clinic in Southeastern US Who received 4 hr DSM class. Exclusion: visual disturbance/blindness, physical or cognitive issues, mentally ill or pregnant	Stanford Self efficacy for Diabetes management – structured questionnaire Pre and post-intervention imported into excel then downloaded into SPSS The pre and post-SES scores were statistically significant between the two variables, $p<0.001$. indicating the program demonstrated a significant difference in pre and -post-intervention	**Level V** **Good (B)**
Heisler, M., Bouknight, R., Hayward, R., Smith, D., & Kerr, E. (2002). The relative importance of physician communication, participatory	None	The study assessed the influence of patients' evaluation of their physician	The sample was composed of 2000 veterans receiving diabetes care at 1 of 25 VA medical centers.	The interclass coefficient was near zero and did not approach	**Cross-sectional**

Citation	Theoretical Conceptual Framework	Research Question /Hypothesis	Methodology	Analysis and Results	Level of Evidence
decision making, and patient understanding in diabetes self-management. *Journal of General Internal Medicine: JGIM, 17*(4), 243-252. https://10.1046/j.1525-1497.2002.10905.x		participatory decision-making style, rating of physician communication, and reported understanding of diabetes self-care on their self-reported diabetes management	Approval of IRB. Study Variables included patient self-management, provider participatory decision-making (PDMstyle), Provider communication (PCOM), and Patient understanding(understanding)	significance, indicating that self-management and evaluation of provider styles did not vary significantly by facility The standardized coefficient that compared the independent variables (2 providers and the Understanding to combined models. Alo the magnitude of the association between the respondent's evaluation and the provider participatory decision-making style of their provider communication **Results:** The PDMsytle was a highly significant positive predictor of overall self-management and provider communication in multiple linear regression and all logistic regression model	**Quality is Good, **