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Addressing Obstacles in Following Prescribed Medication Regimens in Patients With Type 2 Diabetes Mellitus

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ADDRESSING OBSTACLES IN FOLLOWING PRESCRIBED MEDICATION REGIMENS
IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Cristina Sarro

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Abstract

Background. Type 2 diabetes is the ninth leading cause of death in the United States. Micro/macro vascular complications are common in diabetes. **Purpose.** To implement an evidence-based protocol addressing obstacles for patients with type 2 diabetes in following their prescribed medication regimens to reduce glycosylated hemoglobin levels. **Evidence.** Failure to follow treatment plans increases diabetes complications. Perceptions and complexities of treatment plans, side effects of therapies, and cost contribute to patients not taking their medications as prescribed. **Goals.** To increase the number of patients with type 2 diabetes who follow their prescribed medication regimen and reach their targeted glycosylated hemoglobin. To increase referrals for patients with glycosylated hemoglobin greater than 8.4 g/dL to the optimization clinic. **Methods.** Patients with diabetes were asked to complete a medication adherence and diabetes knowledge questionnaire identifying obstacles to taking prescribed medications. Providers adjusted treatments according to clinical practice guidelines to address the identified obstacles. **Results.** A total of 61 patients completed the questionnaire and received educational information. All 22 patients with glycosylated hemoglobin's above 8.4% were referred to the optimization clinic. Common barriers reported were cost (14%), side effects (31%), and forgetfulness (55%). Patient advocates were used to address cost, alternative therapies were provided for side effects, and mail-in delivery services were offered for forgetfulness. The project ended before three-month follow-up glycosylated hemoglobin levels were obtained. **Practice Implications.** Early recognition of obstacles that interfere with patients taking their medication provides an opportunity to address these barriers thereby reducing the risk of complications from diabetes.

Keywords: diabetes mellitus, medication adherence, glycosylated hemoglobin, glycemic control, barriers to treatment

Addressing Obstacles in Following Prescribed Medication Regimens in Patients With Type 2 Diabetes Mellitus

Medication adherence is an ongoing problem throughout all disciplines in outpatient settings (Adams & Stolpe, 2016). However, this is particularly the case for patients with type 2 diabetes mellitus (T2DM) (Polonsky & Henry 2016). Primary care providers are at the frontlines of all preventative care, educating patients about their chronic diseases and monitoring them closely for health-related issues. Most patients require some sort of medication regimen as part of their preventive care (e.g., statins and metformin), while others may require medications to control their disease progression and/or complications associated with the disease state (Adams & Stolpe, 2016). A major problem encountered with patients who are prescribed medication is their failure to take medications as prescribed. Patients who do not take their medications as prescribed have more adverse health outcomes, increased hospitalizations, and health care costs (Adams & Stolpe, 2016).

Texas has had a significant increase in health disparities from 1990-2019 and has had a higher obesity rate compared to the United States overall (Texas Oral Health Coalition, 2022a). Obesity is one of the major risk factors for diabetes, which suggests that the rate of diabetes mellitus is likely to increase due to the growing surge of individuals at high-risk of diabetes (e.g., obesity, hypertension, prediabetes, sedentary lifestyle) (Johnson et al., 2019). In 2017, an estimated 2,323,220 people in Texas had diabetes, representing 11.4% of the adult population, and 23.8% of these individuals were not aware that they had diabetes (Johnson et al., 2019). According to the Texas Demographic Center, the number of persons with diabetes is projected to quadruple to nearly 8 million by 2040 (Texas Oral Health Coalition, 2022b). This rise in diabetes mellitus means that primary care providers must take a proactive approach to managing chronic

diseases, including becoming familiar with patient barriers to following prescribed treatment regimens and patients' needs, including environmental factors (e.g., literacy and cognitive function), social and community factors (e.g., access to providers and pharmacy), health care system factors (e.g., patient interactions with healthcare systems, trust, prior authorization, fragmentation of healthcare), and health insurance policies (e.g., coverage of medication) (Bosworth et al., 2016). Primary care providers must also be aware that provider factors, such as complicated treatment regimens and limited office time, are patient barriers to following prescribed treatment regimens (Bosworth et al., 2016).

The role of providers and staff is imperative in assessing patients' backgrounds and developing realistic, affordable treatment plans for managing type 2 diabetes while acknowledging and addressing barriers that limit patients' abilities to take their medications as prescribed. Current clinical guidelines provide many options for managing type 2 diabetes that allow providers to address many of the common barriers identified in literature. The lack of a systematic approach to managing patients with T2DM, or unfamiliarity with current practice guidelines, can play a role in the providers themselves becoming a barrier to patients not taking their medications as prescribed.

Current Guidelines

According to the American Diabetes Association (ADA) (2020a), the criteria for diagnosing T2DM includes at least one of the following characteristics: a fasting plasma glucose greater or equal to 126 mg/dl, a two-hour plasma glucose equal to or greater than 200mg/dl during a glucose tolerance test, glycosylated hemoglobin (HbA1c) equal to or greater than 6.5%, or classic symptoms of hyperglycemic crisis presenting with random glucose levels equal to or greater than 200 mg/dl on two separate occasions. The first-line treatment for managing T2DM

is meal planning, exercise, and weight loss (ADA, 2020b). In some cases, lifestyle modifications are not enough and therefore required medication management. According to ADA (2020b), an HbA1c greater than or equal to 6.5% requires the first-line treatment of lifestyle modifications previously mentioned. If the first-line treatment does not lower HbA1c levels below 7.5%, patients will require medication such as metformin, in conjunction with lifestyle modifications (ADA, 2020c). It is important that providers review the patient's understanding of T2DM, the patient's willingness to follow prescribed treatment regimens, and the patient's ability to obtain and take prescribed medications. Additionally, providers should schedule routine follow-up appointments to monitor the patient's progress in lowering their glucose levels. According to the ADA (2020b), this should occur every 3-6 months. Initiating medication therapy is beneficial when lifestyle modifications fail to lower HbA1c levels. According to the ADA (2020c), diabetic medications can reduce HbA1c levels by 1 to 1.5%.

A patient-centered approach should be used to guide the choice of pharmacologic agents considering hypoglycemia risk, impact on weight, cost, the risk for side effects, and patient preference (ADA, 2020c). The first line pharmacological therapy for T2DM is metformin (ADA, 2020c). For patients who do not tolerate metformin due to its side effects (gastrointestinal upset is the most reported side effect), it is recommended that they be prescribed metformin extended release to minimize side effects. Other strategies to reduce side effects include gradual dose titration (ADA, 2020c). If metformin is not tolerated or is contraindicated, other medications should be considered such as sulfonylureas, meglitinide, sodium-glucose cotransporter-2 inhibitors, glucose-like peptide-1 receptor agonist, dipeptidyl peptidase-4 inhibitors, and thiazolidinedione (ADA, 2020c).

Patients with HbA1c levels greater than 7.5% who do not achieve glycemic control while on metformin after three to six months should start combination therapy (ADA, 2020c). Insulin is suggested when patients present with persistent hyperglycemia and elevated HbA1c equal to or greater than 9%. The use of combination therapy, such as insulin and oral therapy, might be indicated when HbA1c levels continue to increase and have been shown to decrease HbA1c by 1.3 to 5.2% (ADA, 2020c). According to the ADA (2020d) if metformin is not tolerated, the use of a sulfonylurea may be an option due to its low cost and efficacy of lowering blood sugar and HbA1c. While the use of GLP-1RAs may provide substantial reductions in HbA1c and help with weight reduction, these medications have an increased burden of cost (ADA, 2020c). The cost of medications for the treatment of T2DM can be a significant barrier for patients taking medications as prescribed (Polansky & Henry, 2016).

The American Association of Clinical Endocrinology (2022) reports that patients without concurrent serious illness and with a low hypoglycemia risk should maintain an HbA1c equal to or less than 6.5%. Patients with concurrent serious illness who have a high risk for hypoglycemia should maintain a HbA1c greater than 6.5% but less than 7.5%. Monotherapy is indicated for patients with persistent elevated HbA1c equal to or greater than 7.5%, while triple therapy is recommended for patients with elevated HbA1c between 7.5 to 9%. Early initiation of insulin therapy is recommended for patients with evidence of HbA1c at 9% or greater (ADA, 2020d).

Statement of the Problem

During my assessment of the Northwest family practice clinic in which this study was carried out, the quality metrics revealed an ongoing issue with patients diagnosed with T2DM taking their medications as prescribed. While the clinic's goal for medication adherence in patients with diabetes was 89% or greater, indicating a five-star rating, the clinic ranged between

86% and 88% each quarter and had been unable to attain scores greater than 89%. The clinical staff informed me that reports on patients taking their medications as prescribed were based on several factors, including the time it took for electronic prescriptions to be delivered to pharmacies by the provider and the number of days patients took to pick up their medications from the pharmacies. The pharmacies send reports to the patients' insurance companies, who generate reports that are sent to the clinic. The clinic management then distributes metric reports to each provider's staff. The metrics are guided by the healthcare effectiveness data and information set (HEDIS), which is a set of national performance metrics to ensure quality of care. Metrics are received weekly and may vary according to insurance companies. The clinic's medical assistants (MAs) reported that some of the data may be inaccurate, due to the time it takes the pharmacies to notify the insurance companies and the time it takes for the clinic's reports to be generated. If patients do not pick up their medications from the pharmacies, the patients are reported as nonadherent. Furthermore, patients' HbA1c levels indicate whether they have been taking their prescribed medications as directed. When patients' HbA1c levels are greater or equal to 8.4%, patients are referred to the optimization clinic to help get the HbA1c levels closer to recommended levels, before being referred back to the primary care provider. Unfortunately, most of the patients referred to the optimization clinic failed to attend because they felt that they would lose the care established with their primary physician and the optimization clinic was not located on the Northwest campus.

Background and Significance

Medication adherence is critical to the patient's overall health, particularly in patients with diabetes. Patients who do not take their medications as prescribed are at risk for elevated HbA1c and random blood glucose levels that can increase the likelihood of patients developing

microvascular and macrovascular complications such as cardiovascular disease, stroke, retinopathy, nephropathy, and neuropathy (ADA, 2020c).

According to the ADA (2020c), patients not taking their medications as prescribed accounts for approximately half of the patients with chronic diseases, resulting in billions of dollars spent and an increased number of inpatient and emergency care visits. Educating patients about complications that can occur with uncontrolled diabetes, identifying obstacles that impact patients taking medications as prescribed, and addressing those obstacles is key to optimizing the care of patients with diabetes (ADA, 2020a).

My observations within the Northwest family practice clinic detected no in-house processes to identify the barriers patients were experiencing that interfered with their ability to take their medications as prescribed. There was also no guidance nor written patient education resources on the complications associated with uncontrolled diabetes mellitus. Additionally, there were limited adjustments to patients' medications for diabetes mellitus, despite the fact that elevated HbA1c levels were above the ADA recommended clinical practice guidelines. These factors may be contributing to the inability of the clinic to reduce the number of patients with T2DM who do not take their medications as prescribed. Uncontrolled diabetes mellitus is associated with increased macrovascular and microvascular complications as well as increased HbA1c levels. The ADA (2020a) suggests an HbA1c of 7 to 7.5% in adults with no comorbidities or few comorbidities. An HbA1c of 8 to 8.5% is suggested for older adults with multiple comorbidities or a decreased life expectancy due to the risk for hypoglycemia (ADA, 2020d).

The facility in which this project was implemented serves a large number of patients with diabetes mellitus. A total of 6,111 patients are seen within the facility annually, with 5,633 of

these patients having T2DM. The physician provider in this institution's Northwest family practice clinic sees the greatest number of these patients, accounting for 699 patients annually. Of these 699 patients, 244 have T2DM. The physician provider ranks number one within the institution for the number of patients with an HbA1c greater than 10%, which accounts for 26 patients out of the 244 patients with diabetes. The physician provider also ranks number one with the number of patients with diabetes with known heart disease and ranks third out of 36 providers with the most reported amputations. Table 1 shows the number of patients at the Northwest family practice clinic with HbA1c levels greater than 7%.

Table 1

HbA1c Levels Above 7%

HbA1c Levels (Percentage)	N = 244
15% or greater	0
14 - 14.9%	0
13 - 13.9%	6
12 - 12.9%	0
11 - 11.9%	3
10 - 10.9%	17
9 - 9.9%	46
8 - 8.9%	56
7 - 7.9%	116

Assessment

The clinic is part of a large medical group that serves the Northwest and Southside of San Antonio. My project site is located within the Northwest institution, providing care to thousands of patients. More than 100 individuals are employed at this facility, including physicians of different disciplines, physical therapists, chiropractors, nurse practitioners, licensed vocational nurses (LVNs), MAs, receptionists, greeters, laboratory technicians, and patient advocates. The facility does not employ registered nurses (RNs) as part of the healthcare team. The Northwest family practice clinic where this project was implemented is a specialty clinic within the larger Northwest institution.

The primary care physician I coordinated with for this project works with one nurse practitioner with less than a year of experience and four MAs. The physician provider sees an average of 18-22 patients a day. The nurse practitioner sees an average of 10-14 patients daily, not including telephone visits that average 3-5 patients per day. Patients are booked in 15 to 30 minute intervals, depending on their health status. Most visits are allotted 15 minutes and those with a comprehensive background are allotted up to 30 minutes. Usually, the comprehensive patients have been recently discharged from the hospital.

During my assessment of the family practice clinic, quality metrics revealed an ongoing issue with patients diagnosed with T2DM taking their medications as prescribed. According to Curkendall et al. (2013), patients with diabetes have one of the lowest medication adherence rates at 65% to 85%. The clinic's goal for medication adherence in patients with diabetes is 89% or greater, indicating a five-star rating. The clinic was ranging between 86% and 88% each quarter and had been unable to attain scores greater than 89%. The clinical staff informed me that reports on patients taking their medications as prescribed are based on several factors,

including the time it takes for the electronic prescriptions to be delivered to pharmacies by the provider and the number of day's patients took to pick up their medications from the pharmacy.

The pharmacies send reports to the patients' insurance companies which then are generated and sent to the clinic. Clinic management then distributes metric reports to each provider's staff.

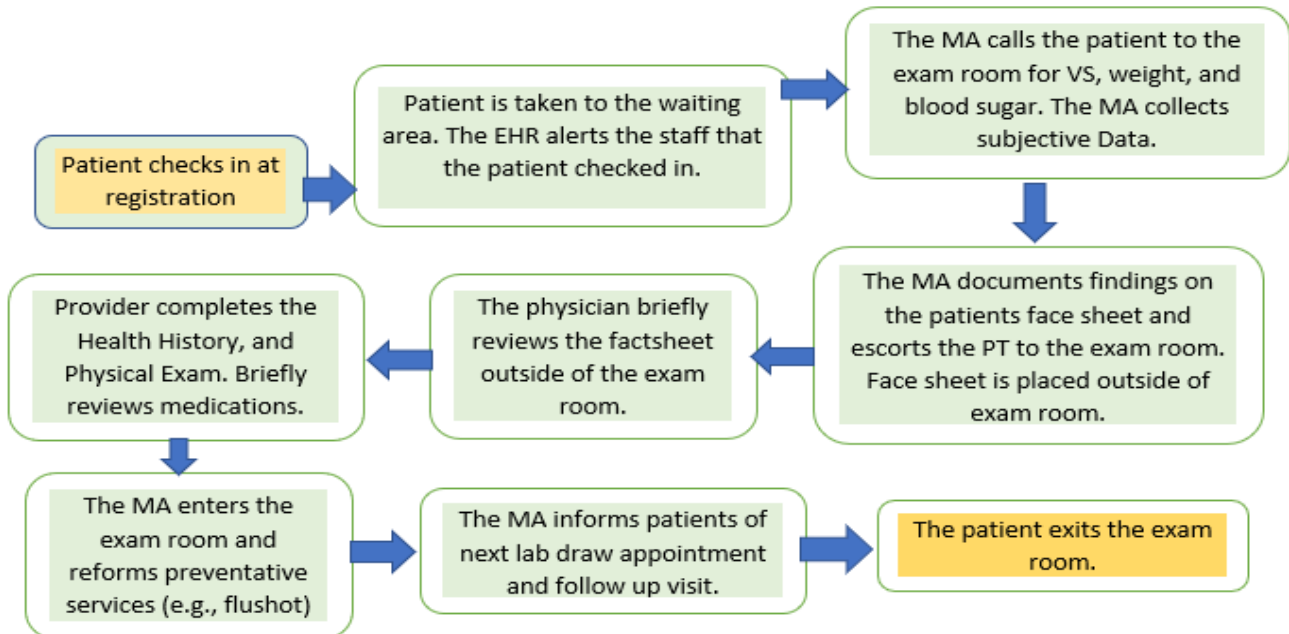
HEDIS metrics are received weekly and may vary according to insurance companies. The MAs report that some of the data may be inaccurate due to the time it takes the pharmacies to notify the insurance companies and the time it takes for the reports to be generated. If patients do not pick up their medications from the pharmacies, the patients are reported as nonadherent.

Furthermore, patients' HbA1c levels indicate whether patients have been taking their medications as prescribed. When patients' HbA1c levels are greater or equal to 8.4%, patients are referred to the optimization clinic to help get the HbA1c levels closer to recommended levels before being referred back to the primary care provider. The optimization clinic consists of an endocrinologist, a nurse practitioner specializing in T2DM, and a diabetic educator. The optimization clinic offers services that are evidenced-based and educate individuals based on their individualized needs in order to empower patients with the skills needed to self-manage their T2DM, thus helping to prevent the development or worsening of complications associated with uncontrolled T2DM. These sessions are held individually or in groups. Unfortunately, most of the patients referred to the optimization clinic failed to attend because they felt that they would lose the care established with their primary physician. Additionally, the optimization clinic was not located at the Northwest clinic.

Current Intake-to-Discharge Process

Patients enter through the main lobby and check in with the receptionist. Once cleared, patients are taken back to the waiting area. The electronic health record (EHR) will reflect

“waiting” at this point, letting the MA know that the patient is ready to be taken into an examination room, where the MA obtains vital signs, weight, and blood glucose level before reviewing the medications patients are currently taking and obtaining the patient’s chief complaint. The MA writes down this information on the patient’s face sheet that is placed outside the patient’s examination room. The MA then changes the patient’s statuses to “ready” on the EHR and verbally communicates metric needs and individual patient requirements in order to assist in fulfilling preventative requirements according to clinic metrics with the provider. The provider briefly screens the EHR, laboratory results, and the need for any medication refills. Once the provider enters the examination room, the provider briefly reviews abnormal laboratory results with the patient, discusses the patient’s chief complaints, performs a focused physical assessment, and discusses any follow-up plans. If the patient is interested in learning about their disease process (e.g., T2DM), the provider will offer some brief education regarding medication management and lifestyle modifications. After the provider exits the room, the provider debriefs the MA to identify if patients need follow-up laboratory studies or preventative screenings scheduling (e.g., retinal examinations or monofilament foot assessments). The MA enters the patient’s examination room and provides the patient with discharge instructions, any changes in the plan of care, and follow-up appointments. Currently, there are no processes for educating patients on complications associated with uncontrolled T2DM and the importance of taking diabetes medications as prescribed to reduce these risks. Regardless of risk factors, patients are usually scheduled for 3- to 6-month follow-ups. It is recommended that patients visit with the healthcare team at least twice a year and more often if they are having complications reaching blood glucose goals. Figure 1 provides an overview of the current intake and discharge processes.

Figure 1*Overview of Current Intake and Discharge Processes***Setting/Population**

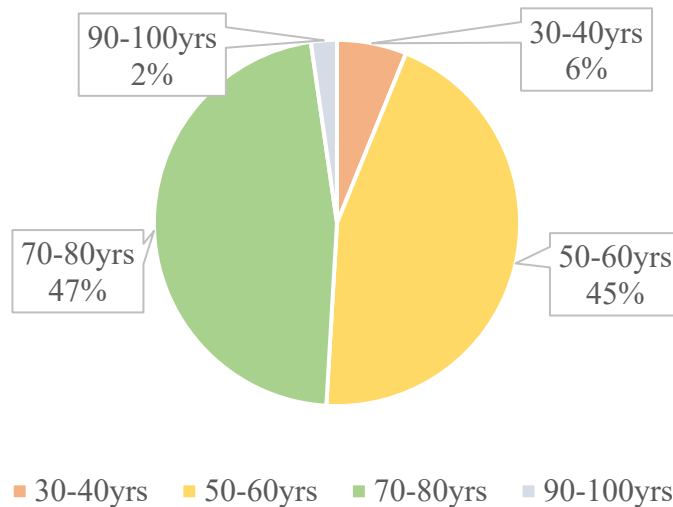
The Northwest internal medicine clinic serves a diverse population. Most patients are Hispanic, but the clinic also serves White and Black patients. The clinic is located in the 78251 zip code, serving residents from neighboring zip code areas and the surrounding community. According to UnitedStatesZipCodes.org (2019), the zip code area has approximately 49,435 residents. The most common age group of people that reside in this area ranges from 20-44 years old that account for 16,352 (33%) of the residents. The number of seniors aged 65 years or older is relatively small in comparison accounting for 2,430 (12.3%) residents. The average median household income in this zip code is \$62,482. People living in this area are primarily white (35.3%) or Hispanic or Latino (64.7%), with a smaller number of Black individuals (10.1%). The

majority of residents (53.3%) 25 years or over have a high school diploma followed by 21% with a bachelor's degree (21%).

Most of the patients that my clinical mentor sees come for routine preventative services and chronic care management. Next door to my clinical mentor's area is the in-house urgent care clinic that provides emergent non-life-threatening care (e.g., infections, common colds, and fractures). The clinic is open Monday-Friday from 8 a.m. to 5 p.m., with urgent care available Monday-Sunday from 8 a.m. to 8 p.m. The clinic has over 68 providers from a variety of disciplines (e.g., oncology, endocrinology, rheumatology, rehabilitation services, and urgent care services). The laboratory is located onsite and is shared with the urgent care clinic. Patients who are seen in this clinic have their laboratory studies performed by appointment and most patients can receive this service after their initial appointment with the provider. The onsite laboratory can run their own laboratory studies the same day of the appointment or by appointment on a different day from the initial provider visit. There is a radiologist on site who performs radiology studies such as x-rays. Results are available to the patient and provider within 48 to 72 hours. In addition, the clinic provides nursing visits led by the LVNs. The LVNs manage the wound care for patients with and without a diagnosis of diabetes.

My clinical mentor is the facility's medical director and cares for 699 patients, of which 244 have been diagnosed with T2DM. This is consistent with the literature, where more than one-fourth of adults aged 65 years and older were identified as having diabetes, and this population is increasing (Srijan et al., 2018). At least 45% of patients with a diagnosis of T2DM fail to achieve glycemic control of an HbA1c of < 7% (Srijan et al., 2018).

Patients seen at the Northwest family practice clinic range from 30 to 100 years. Figure 2 shows how this age range is distributed.

Figure 2*Age Distribution at the Clinic*

The ethnic makeup of the patients seen at the clinic are as follows: 81.5% Hispanic, 18.3% non-Hispanic or Latino, 14% Black, 4.3% White, and 0.1% other or undetermined. The primary language spoken by the patients is English, accounting for 87% of the patients, while 12.6% of the patients speak Spanish. All of the patients are insured, with 215 patients (30.8%) having private insurance such as Aetna, Blue Cross/Blue Shield, and Tricare; 315 patients (45.1%) having Medicare advantage; and 169 patients (24.2%) having traditional Medicare. The top three diagnoses reported for the Northwest family practice clinic are T2DM, heart disease (e.g., hyperlipidemia, dyslipidemia, stroke), and kidney disease.

HEDIS Measures

All of the patients seen at the clinic are enrolled in healthcare plans that report HEDIS measures. HEDIS measures guide clinicians in meeting national standards and encourages preventative healthcare screenings, thereby ensuring the delivery of quality care. Clinic metrics are reviewed weekly and are driven by HEDIS guidelines. Every Monday, clinic metric results

are reported to the staff. Overall, this clinic does an excellent job of meeting its clinic metrics. However, after tracking the clinic metrics for a couple of weeks, the information gathered revealed that the clinic had an issue with patients with T2DM taking their medications as prescribed and all patients taking their statin medications as prescribed. This project centered on patients with T2DM taking their medications as prescribed.

Quality measures during the first quarter of 2021 revealed that 244 (36.7%) of the 699 patients seen at the clinic had T2DM. These quality measures also reported that a significant number of patients with T2DM seen at the clinic were not meeting the clinic metrics in relation to taking their medication as prescribed nor meeting their target HbA1c levels. The clinic metric goal for medication adherence was greater than 89%. Recent metric reports indicated that the clinic did not meet the 89% or greater targeted goal. Of the 244 patients with diabetes seen at the clinic, 67 (27.46%) patients had HbA1c levels greater than 7.5%. The most recent metrics report showed an 86% medication adherence rate. Clinic metrics also revealed that of the 699 patients seen at the clinic, 244 patients had T2DM. My clinical mentor had the highest HbA1c levels among the primary care providers in the clinic since he saw the greatest number of patients. Out of the 244 patients with diabetes seen at the clinic, 26 (10.6%) patients had a HbA1c greater than 10%. The provider also ranked number one with the number of patients with diabetes that also had known heart disease and ranked third out of 36 providers with the most reported amputations.

Organization's Readiness for Change

The institution had indicated a desire to change medication adherence rates in patients with T2DM. Both administration and the clinical healthcare team acknowledge that medication adherence needed to improve. The healthcare team at the Northwest family practice clinic were

eager, committed, and willing to participate in this project in order to improve medication adherence rates. A collaborative relationship existed between the staff and the clinical manager. All the MAs had verbalized a commitment to working together closely to help manage patients taking their medications as prescribed. The clinical manager had set up mandatory quarterly meetings to review medication adherence scores. MAs from each pod attended the meetings and proactively asked questions on how to improve their current processes. Initially, the clinical manager was skeptical of the project interventions; however, after taking more time to more thoroughly review the project, she was eager to begin implementation of the project and offered her support.

From the providers' perspective, the clinic works hard to improve patient care and the providers were willing to implement the project interventions including providing additional resources to patients and families. A patient advocate was located within the facility to assist patients with financial applications that could help cover the cost of medications and other medical equipment. Additionally, the facility utilizes a designated NP who specializes in the care of patients with diabetes. The NP comes to the Northwest family practice clinic location weekly to assist patients whose blood glucose levels areas not controlled and need further guidance with medication management. Having these resources readily available demonstrated the organization's readiness for improvement. A clinical letter of support was obtained from my clinical mentor from the Northwest family practice clinic (Appendix A).

Potential Barriers

There were a few potential barriers to the successful implementation of this project. First, time was of significant concern. The high volume of patients seen within the clinic dictated the amount of time that could be allotted for each patient visit. The interventions had to be stream

lined in order not to extend patient visits significantly. Second, there were no unoccupied examination rooms that could be used for patients who required additional teaching. Therefore, interventions were designed to work within the current process flows, negating the need for special space allocation. Third, availability of prescription delivery service was limited by proximity of patients to participating pharmacies. Many pharmacies required that patients live within a 10-mile radius to qualify for delivery services. Additionally, many pharmacies also required patients to have access to electronic devices such as smartphones in order to use the pharmacies applications.

Stakeholders and Stakeholder Engagement

This project can have an impact on improving patient outcomes by preventing and decreasing microvascular and macrovascular complications associated with uncontrolled T2DM. Alshehri et al. (2020) noted that complications associated with T2DM that lead to increased healthcare cost and hospitalizations are related to patients not taking their medication as prescribed. The prevention of healthcare complications can be assessed by simply investigating barriers to why patients do not take their medication as prescribed (e.g., side effects and cost). By detecting these barriers, it is likely that patients will take their medication as prescribed. After reviewing all the data from administration and clinic management, a plan was created in order to implement evidence-based practice guidelines using effective and cost-effective interventions in order to improve patient outcomes. The stakeholders for his quality improvement project consisted of a diverse interdisciplinary team. The project included engagement by the patients, families, caregivers, clinic administration, clinical managers, MAs, and providers.

Patient involvement in the management of T2DM was fundamental. In order to adhere to taking their medications as prescribed, patients had to be willing to take the initiative in

managing their own care and willing to participate in learning about lifestyle modifications, medications, and complications associated with T2DM. Subrashree et al. (2016) reports that patients should recognize that physicians assist in managing T2DM, but patients are responsible for self-management and making decisions to control diabetes. Family members of the patients with T2DM also play an integral role in the success of patients taking their medications as prescribed. The vast majority of the patients seen in the clinic are Hispanic. In Hispanic culture, the family serves as the center of the social unit that serves as a support system and helps to maintain the well-being of individual members. Thus, having the family involved when patients sees the providers helps to ensure that the patients are more likely to take their medications as prescribed.

Providers and staff have provided input for ways to increase medication adherence and knowledge about T2DM in patients diagnosed with T2DM. This includes the MAs initiating the medication compliance questionnaire and knowledge questionnaire, assisting the patients in completing the surveys, and asking patient-centered questions to identify barriers to taking their medication as prescribed (e.g., side effects, cost, and forgetfulness). The MAs' role was crucial because the information gathered during the intake process was reported to the providers. The educational pamphlet (Appendix B) was also provided to the patients by the MAs during the intake process. After the appointment the MAs also assisted patients with obtaining their medication via mail in delivery. This process varied according to the patient's preferred pharmacy. For example, if the patients selected HEB pharmacy, the patients must meet the pharmacy requirements, such as downloading the phone application, live within a 10 mile radius and the medication must be able to be delivered via mail.

The providers' role was to further explore barriers and assist the patients in overcoming barriers that contribute to patients not taking their medication as prescribed, such as changing medication regimen due to side effects, offering low-cost medications, and educating the patients of complications associated with T2DM for patients who report forgetfulness. The providers offered mail delivery and reinforced educational information with patients about risk factors and complications associated with T2DM. Subashree et al. (2020) stated that providers play a considerable role in providing cost effective, safe, and effective medications.

Project Identification

Purpose

The purpose of this project was to implement an evidence-based protocol according to the ADA clinic practice guidelines to address obstacles to following prescribed medication regimens for patients with T2DM, and to enhance patients' understanding of complications associated with uncontrolled T2DM in order to reduce patients' HbA1c levels.

Objectives

The objectives for this project were:

1. 100% of patients with T2DM would receive an educational brochure on the complications associated with uncontrolled T2DM.
2. Increase the number of patients with T2DM who follow their prescribed medication regiment from 86 to 95%.
3. Decrease the number of patient with T2DM that have a HbA1c of greater than 8g/dl from 52 to 40%.
4. Increase the number of patients with a HbA1c > 8.4g/dl that are referred to the optimization clinic from 50 to 100%.

Anticipated Outcomes

The anticipated outcomes for this project were:

1. Staff members would receive a 30 minute in service training of the complications in T2DM prior to the start of implementation of the project.
2. 100% of patients would receive educational brochures and obtain a medication adherence survey during the triage process. By increasing the percentage of patients who receive the education brochure and complete the medication adherence survey, a greater number of patients were more likely to express medication adherence concerns (e.g., cost, side-effects, and mail delivery) during their encounter with the providers.
3. Patients that report poor adherence based on questionnaires will then be flagged for the providers to address the identified obstacles. Addressing obstacles to taking medications as prescribed will help improve patient outcomes and reduce morbidity and mortality rates.

Summary and Strength of the Evidence

A review of literature was done by conducting a search using key search terms in the following databases: Cochrane Library, PubMed Central, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Medline. Keywords used for the search were diabetes mellitus, medication adherence, glycosylated hemoglobin, glycemic control, and barriers to treatment. There were more than 142 articles found. In order to narrow the search, additional key terms used were side effects, barriers, cost, and adherence. I conducted a review of various qualitative, quantitative, and current clinical practice guidelines from professional associations. A total of 20 articles were used for this project. See Appendix C for the evidentiary table.

The level and strength of the evidence was evaluated using the Melnyk and Fineout-Overholt (2015) system. This system consists of seven levels and is based on a combination of quality, validity, and applicability of the evidence to a specific patient environment (Melnyk & Fineout-Overholt, 2015). Table 2 provides a summary overview of the rating system.

The quality of the evidence was evaluated using the Johns Hopkins Nursing Evidence-Based Practice system (Dang & Dearholt, 2018). This system consists of four levels and uses a lettering system A, A-B, B, and C to note the quality of evidence. The quality of evidence is based on a combination of study design, sample size, scientific evidenced reviewed, appropriateness of recommendations, and generalizability (Dang & Dearholt, 2018). Table 3 provides a summary of the rating system for quality of evidence.

Table 2

Level of Evidence

Level of Evidence	Study Design
I	Systematic reviews and meta-analysis of randomized controlled studies
II	Single, randomized controlled studies
III	Quasi-experimental studies and non-randomized controlled studies
IV	Cohort or case-control studies
V	Systematic review or meta-synthesis of qualitative or descriptive studies
VI	Single, qualitative or descriptive studies
VII	Expert opinion of authorities and/or reports of expert committees

Factors Associated with Adherence

Polonsky and Henry (2016) conducted a cross-sectional study and found that 45% of patients failed to achieve glycemic control ($HbA1c < 7\%$). One of the main contributing factors

for this was poor medication adherence. Key factors to medication adherence are perceived treatment efficacy, treatment

Table 3

Quality of Evidence

Quality of Evidence	Criteria
A	High: Conclusive, consistent, sufficient, generalizable; sufficient sample size for study design; adequate control, definitive conclusions, consistent recommendations based on comprehensive literature review that includes thorough references to scientific evidence.
A-B	High-Good: Fairly conclusive, consistent, sufficient evidence. Meets some criteria from both A and B levels.
B	Good: Reasonably conclusive, consistent results, sufficient sample size for study designs; reasonably consistent recommendations based on fairly comprehensive literature review that includes references to scientific evidence. However, there may be some conflicting evidence.
C	Low: Inconclusive, inconsistent, insufficient evidence, insufficient sample size for the study design, inconsistent results, little references to scientific evidence. Conclusions cannot be drawn.

complexity, convenience, and cost of medications, medications beliefs, and physician trust.

Patients not taking their medication as prescribed are also linked to non-patient factors (e.g., lack of integrated care in many health care systems, clinician burnout among healthcare professionals), patient demographic factors (e.g., young age, low education level, low-income level), patient's beliefs about their medications (e.g., treatment inefficacy), and perceived patient burden regarding obtaining and taking their medications (e.g., treatment complexity, out-of-pocket costs, hypoglycemia) (Polonsky & Henry 2016).

Subashree et al. (2016) found that of the 387 patients who participated in the study (68.5%) reported adhering to their medications, while 122 (31.5%) reported that they did not adhere to their T2DM treatment. The most common reasons for non-adherence was forgetting to take their medication (82 patients, 67.21%), fatigue from taking medications for a long time (61 patients, 50%), the complexity of their treatment (49 patients, 40.16%), lack of family support (47 patients, 38.52%), adverse side effects from medication (43 patients, 35.24%), interference with their meal planning (43 patients, 30.32%), feeling that their dose was too high (37 patients, 30.32%), and lack of finances (16 patients, 4.13%). Subashree et al. (2016) implemented two questionnaires (medication compliance questionnaire and a knowledge questionnaire) to assess barriers and patients' knowledge of risk factors and complications. Subashree et al. (2016) identified a weak relationship between knowledge and adherence (poor and very poor) and glycemic control. Subashree et al. (2016) showed that the patients' understanding of risk factors, treatment, and complications of diabetes was very low. This stresses the need for creating awareness of and intensifying education on diabetes among the general population and patients diagnosed with T2DM. Knowledge about all the factors influencing adherence can be improved by educating patients using media, educational handouts, and small group programs about the importance of achieving good glycemic control and preventing complications. Healthcare providers also have an important and significant role in initiating and altering treatment plans as barriers arise.

Unintentional Non-adherence

Non-adherence begins as early as when a new medication is prescribed to the patient and the patient fails to pick it up from the pharmacy for various reasons (e.g., forgetfulness, lack of transportation) (Adams & Stolpe, 2016). Providers, pharmacies and insurance companies have

worked together to increase prescription usage when prescribed by the providers by switching to electronic prescription methods. Electronic prescriptions have improved the rate of patients picking up their medication by 10%, when compared to written prescriptions; however, one in five new prescriptions are never filled and those who do take medications do so incorrectly for various reasons (e.g., time, dose frequency, forgetfulness), which accounts for 50% of patients (Centers for Disease Control and Prevention [CDC], 2017). Alshehri et al. (2020) reported that the most common reason for non-adherence was forgetting to take medication by the patients (67.21%), feeling that the dose of the medication was too high (30.32%), and feeling that the treatment was not effective (24.59%). During a yearly comprehensive wellness examination Guerard et al. (2018) reported that barriers that affect patients' abilities in taking their medications varied throughout the years. Forgetting to take medication and missed doses related to medication complexity were consistently reported as barriers by a large group of patients over a five-year period (Guerard et al., 2018).

In addition to comprehensive wellness examinations, assessing obstacles during patient encounters is essential, because patients with T2DM are seen by their provider every 3-6 months. During this time patient needs such as income, insurance, place of residence, pharmacy, or progression of T2DM might change. Guerard et al. (2018) reported that barriers to adherence are multifactorial and include the cost of medications, side effects, and forgetfulness. Therefore, they should be assessed frequently. Guerard et al. (2018) identified forgetfulness as a common barrier in patients taking their medication as prescribed. Patients reported that they did not take their medication because of treatment complexity (e.g., several scheduled oral doses, frequent insulin requirements) and general forgetfulness.

Social and Economic Factors

The CDC (2010) estimates that the number of Americans without health insurance is growing, affecting low-income and middle-income Americans. Hsu et al. (2012) conducted a study investigating income in poor-income, low-income, middle-income, and high-income people with T2DM. They concluded that low-income patients suffered more T2DM complications than middle-income and high-income people and were more likely not to receive follow-up care. Moreover, low-income patients were less likely to recognize worsening signs of T2DM and tended to be older, live in rural areas, and suffer from more chronic diseases (Hsu et al. 2012). Further, Hsu et al. (2012) reported that the increase cost of diabetic agents (approximately \$15 a month) led to an 11% increase in medication non-adherence in the low-income and older populations. However, He et al. (2021) stated that younger patients suffered from T2DM barriers (e.g., cost) more than older patients. In both studies, lower income status and lack of insurance coverage create increased risk for medication non-adherence. Capoccia et al. (2016) conducted a systematic review that explored the risk factors associated with medication non-adherence, investigating demographic data including age, race, health beliefs, medication cost, insurance coverage, and health literacy. They concluded that high adherence was associated with improved glucose control, fewer hospitalizations, fewer emergency department visits, and lower medical cost. In patients 65 years and older it was concluded that Black and Latino patients were less adherent when compared to Whites. Further, Srijan et al. (2018) conducted a cross-sectional study of 116 adult patients with a diagnosis of T2DM. This study assessed knowledge about complications of patients diagnosed with T2DM and the relationship of taking their medications as prescribed. Srijan et al. (2018) used the 8-item Morisky Medication Adherence Scale (MMAS-8), a scale used to identify barriers and behaviors

in patients taking their medication as prescribed. The most common reasons identified were forgetfulness when away from home or while traveling and difficulty in adhering to medication plans due to busy work schedules (e.g., frequent insulin). Some patients stopped taking medications because they believed their diabetes was under control and they were not experiencing symptoms of hyperglycemia. Counseling sessions were implemented to assess whether education on the barriers had an impact on patient adherence to medications. The study concluded that the counseling sessions on diabetes and adherence to medication did, in fact, enhance changes in adherence levels with 18 patients (15.51%) having reached high compliance and 77 patients (66.37%) achieving medium adherence. However, 21 patients (18.1 %) had low adherence because of financial burden, lack of support, and personal beliefs on how they perceived their T2DM diagnosis (Srijan et al., 2018).

Insurance Coverage and Cost

Cohen and Cha (2019) concluded that adults under the age of 65 with a diagnosis of diabetes mellitus were less likely to take their medications because of cost than those over the age of 65. Patients under the age of 65 reported that they were likely to take their medications if lower-cost medications were an option. He et al. (2021) said that among Medicare beneficiaries aged 65 years and older with type 2 diabetes, 10.3% reported medication non-adherence related to cost. Also, patients between the ages of 18-64 who were uninsured reported not taking their medications due to cost and patients who did report taking their medications as prescribed requested low-cost medications (He et al., 2021). Van Alsten and Harris (2020) concluded that in adults with type 2 diabetes, 25% reported using less than the prescribed insulin in the previous year to manage costs, 3.2% reported limiting insulin on a daily basis, and 40% reported not discussing the underuse of insulin with their physician. The most common form of cost-related

non-adherence was delaying medication doses, taking less than prescribed, and skipping doses (Van Alsten & Harris, 2020). Furthermore, Kennedy-Martin et al. (2017) reviewed multiple articles published between 2006-2015 assessing compliance, adherence, or persistence and treatment in patients with T2DM. Kennedy-Martin et al. (2017) identified that most of the financial burden was related to emergency visits and hospitalizations in patients with uncontrolled T2DM. They also identified that adherence and persistence of taking medication as prescribed was linked to reduce healthcare complications and cost.

Health Provider Related Factors

Acute or chronic disease management is managed in a primary care setting. Important factors contributing to managing the disease are for the providers, staff, and patients to establish a trusting relationship to explore barriers to adherence. Renaldi et al. (2021) conducted a qualitative study investigating interpersonal relationships between patients and healthcare workers. They concluded that healthcare workers have a direct effect on patient treatment compliance and behavior. Therefore, an interdisciplinary approach between the patient, pharmacist, diabetic specialist, and clinical staff is needed to reinforce lifestyle changes and prevention of complications. Muñoz-López et al. (2020) conducted a cross-sectional study amongst 180 Mexican patients assessing the management of T2DM, including diet, exercise, medication, attending medical visits, and seeking social support for T2DM self-care. There was a significant correlation between adherences to medical treatments when ongoing consultation was provided to the patient at every visit. Fan et al., (2016) identified that individualized diabetic education plays a pivotal role in managing T2DM when compared to group sessions. However, social support beyond the clinical staff was also reported as a considerable aspect in Mexican culture; having direct caregiver involvement strengthened medication management and attending

medical visits. The study identified that individualized diabetic education and caregiver involvement did not impact diet or promote weight loss. Most patients (91.2%) reported eating home-cooked meals compared to those who ate fast food (8.8%), especially in the low-to-medium income bracket. However, there was no evidence that home-cooked meals enhanced healthy eating habits, because most of the foods that patients were accustomed to cooking were high in carbohydrates (e.g., tortillas, beans, rice, corn, cheese), which should be monitored to reduce blood sugars and, ultimately, HbA1c (Muñoz-López et al., 2020).

A few caregivers reported difficulty understanding nutritional labels at the grocery store because they could not read the print in English (Muñoz-López et al., 2020). Therefore, primary care providers and diabetic educators should be aware of cultural barriers and address these obstacles during visits. Husdal et al. (2021) concluded that patients who are able to self-manage have a good support system that involves a caregiver, proactive staff, and trust between the provider and the patient. However, patients require guidance and motivation from healthcare staff to encourage self-management (Husdal et al., 2021). An important factor in managing diabetes mellitus is the start of treatment, when patients' HbA1c levels are equal to or greater than 6.5% (ADA, 2020c). Providers' awareness of patients' risk factors and increasing HbA1c should trigger providers to begin addressing lifestyle modifications early on in the course of managing diabetes, including essential lifestyle modifications such as diet management that includes incorporating healthy food options, portion control, and daily exercise. These treatment options go hand in hand with medication therapy.

According to ADA (2020c), an HbA1c greater than or equal to 6.5% requires a first-line treatment, such as metformin. Monotherapy is indicated for patients who present with persistent elevated HbA1c equal to or greater than 7.5%, while triple therapy is recommended for patients

with elevated HbA1c between 7.5 and 9%. Insulin is suggested when patients present with persistent hyperglycemia and elevated HbA1c equal to or greater than 9%. Combination therapy, such as insulin and oral therapy, might be indicated when HbA1c levels continue to increase, these therapies have been shown to decrease HbA1c by 1.3 to 5.2% (ADA, 2020c). According to ADA (2020c), early intervention, and intense control of HbA1c levels lead to a reduction in complications. A HbA1c of 7% or less led to a 50% reduction in microvascular complications (ADA, 2020c). Lin et al. (2017) found that therapy and lifestyle modifications early in the disease process helped patient's better control T2DM and reduced complications. Reinforcing the use of diabetic clinical practice guidelines in patients with diabetes who have increasing HbA1c levels should improve blood glucose levels and reduce HbA1c. Lin et al. conducted a retrospective cohort study amongst 2,463 newly diagnosed patients with T2DM. The patients who did not take their medication as prescribed had an increase in HbA1c by 0.4% over two years, were likely to be hospitalized, and had more emergency department visits than those who were adherent to medication regimens.

Survey Tools

Subashree et al. (2016) led a cross-sectional study in 100 patients diagnosed with diabetes mellitus. The purpose of this study was to assess knowledge, risk factors, and medication compliance utilizing two questionnaires. This valid tool assisted the staff in assessing barriers within the clinic. The first questionnaire consisted of 10 questions assessing knowledge and risk factors for diabetes containing both open-ended and close-ended questions. Patients reported that the most commonly affected organs were the kidneys (49.1%), eyes (43.4%), nerves (41.5%), feet (32.1%), lungs (24.5%), heart (22.6%), stomach (20.8%), brain (17.0%), hand (1.9%), and other organs (1.9%). Out of 100 patients, only 64 (64 %) knew about the risk factors (e.g.,

obesity, hypertension, lack of exercise) for diabetes, with the remaining 36 patients (36 %) not aware of the most common risk factors. Subashree et al. (2016) identified patients with lack of understanding of risk factors for non-adherence had a tendency to consume more sweets (76.5%), lacked physical activity (46.8%), were overweight and had high blood pressure (34.3%). Additionally, these individuals had a previous family history (14.3%) of diabetes and experienced mental stress (4.8%). Another segment of the questionnaire contained seven questions to assess adherence to the medications. This study defined good adherence as a score of 27 out of 28 possible points and poor adherence was defined as a score of 22–26 and very poor adherence was defined as a score of less than 18. No patients obtained a score of 27-28 points. Poor adherence was identified in 19 patients and very poor adherence was identified in 81 of the patients. Study results showed that there was a weak relationship between knowledge (poor) and adherence to medications (very poor) and glycemic control. The most common reasons for non-adherence were forgetting to take medications and stopping taking medication due to side effects. Subashree et al. (2016) showed that the knowledge of study participants regarding risk factors, treatment, and complications of diabetes was very low. This stressed the need for creating awareness and intensifying education on diabetes among the general population and for patients diagnosed with diabetes. Subashree et al. (2016) identified that improving knowledge about all the factors influencing adherence could be improved through education. Furthermore, it was determined that educational handouts and individual or group sessions about the importance of achieving good glycemic control was essential in the management and prevention of T2DM. Healthcare providers also had an important and significant role in continuing T2DM management (Subashree et al., 2016).

Methods

Project Framework

As a standard quality-improvement process, the Plan-Do-Study-Act (PDSA) cycle helps introduce new programs into complex environments such as primary care (Coury et al., 2017). The PDSA model for clinical improvement served as a framework for this quality improvement project. The topic for this project was chosen after a detailed needs assessment was conducted, revealing a gap in interventions that could help alleviate obstacles to patients with T2DM taking their medications as prescribed. The Northwest family practice clinic had a large patient population with T2DM, with many of these patients having HbA1C levels above the current recommended ADA clinical practice guidelines, despite being prescribed medications. The clinic did not have any formal processes in place to help with direct management of patients with T2DM, including a means to determine why patients were not taking their medications as prescribed, written educational materials on the complications associated with uncontrolled diabetes mellitus, or use of current ADA clinical practice guidelines. As part of the ongoing evaluation of care, the clinic had set a goal for medication adherence in patients with diabetes at 89% or greater, which would indicate a five-star rating, prior to the implementation of the project. However, the clinic was ranging between 86% and 88% each quarter and had been unable to attain scores greater than 89%. A screening tool to identify barriers to taking medications as prescribed was identified from a review of the literature, and, in collaboration with the providers and staff, an assessment process and treatment plan was created. Once these processes were finalized, staff and providers were educated on the processes and the project was implemented over a 10-week period (Do). Throughout implementation of the project, I monitored staff and provider compliance with the agreed-upon plan. My clinical mentor, who also was the owner of

the clinic, was updated on a regular basis to assist in identifying any areas that needed to be adjusted or addressed (Study). When there were incidences of straying from the agreed-upon plan, each incidence was evaluated to determine if revisions needed to be made to the plan or if re-education on the project plan needed to occur (Act). This help to ensure that real-time evaluation of progress occurred, thus maximizing success in achieving patient outcomes. The PDSA cycle helped to uncover obstacles that needed to be discussed in order to ensure sustainability of the project over time. This would be necessary to fully evaluate whether the interventions had a significant impact on patient outcomes.

Project Intervention

The initial intervention for this project was providing an educational session to the providers and staff on the goals for the project and the agreed-upon assessments and treatment plans that would be used for the project. Providers and staff were given a walkthrough of the T2DM algorithm (Appendix D), the educational brochure (Appendix B) that would be provided to the patients, and the screening tools that would be used to evaluate obstacles to patients taking their medications as prescribed. The medication adherence questionnaire (Appendix E) used by Subashree et al. (2016) was an easy-to-use valid screening tool that evaluates potential reasons why patients are not taking their medications as prescribed. The screening tool did not require a high level of literacy to complete and consisted of just seven questions, preventing fatigue during the check-in process. The knowledge questionnaire (Appendix F) used by Subashree et al. (2016) was another easy-to-use screening tool that determines patients' understanding about diabetes mellitus and the potential complications that can develop from failure to manage the disease process. Similar to the medication adherence questionnaire, the knowledge questionnaire did not require a high level of literacy to complete and consists of just 11 questions, thus preventing

form fatigue during the check-in process. One additional question was added to the knowledge questionnaire, asking patients how often they do not take their medications because of cost. This was important since neither questionnaire addressed cost of medications as a barrier yet cost of medications was a significant finding noted from the review of the literature. Once this educational session was completed, the project was implemented for patients.

When patients with T2DM presented to the Northwest family practice clinic, the receptionist checked them in. Once the check-in process was complete, the patients were taken back to the waiting area. The MA verified each visit to confirm the patient had an existing diagnosis of T2DM. The EHR reflected “waiting” at this point, letting the medical MA know that the patient was ready to be taken into the examination room, where the MA obtained pre-assessment screenings, including vital signs, weight, chief complaint, blood glucose levels, and review of medications patients were currently taking. During this time the questionnaires were initiated by the MA. The first questionnaire was the knowledge questionnaire, which consisted of 11 questions, and the second questionnaire was the medication adherence questionnaire, which consisted of seven questions. Also, during the pre-assessment screenings, the MA provided the patient with a brochure from the John Hopkins Diabetes Prevention and Education Program that discussed the complications associated with uncontrolled T2DM. These brochures were available in both English and Spanish.

Once the patient had completed the questionnaires, the MA reviewed and collected the patient’s completed questionnaires. The MA assisted patient with tallying up scores, if needed, and answered any questions patient had about the questionnaires. Scoring of the medication adherence questionnaire was as follows: one point was given for each question answered (not often, seldom, rarely, sometimes, and often). A score of 0-2 was determined to be good

adherence, a score of 3-5 was considered poor adherence, and a score of 6-7 was considered very poor adherence. The MA highlighted areas where patient was not taking their diabetes medications as prescribed, which required attention by the providers. The completed surveys were then attached to patient's face sheets and placed in folders outside of the examination room for the provider to review. Before entering the examination room, the provider briefly examined the questionnaires, identifying any barriers that were preventing patients from taking their diabetic medications as prescribed, in order to determine how to discuss these barriers with patient during their office visit. During the provider's examination, they investigated the barriers identified by patient and planned care based on specific barriers patient identified, using the algorithm found in Appendix C. The interventions on the algorithm followed ADA clinical practice guidelines and utilized current clinic resources. These interventions were summarized as follows:

- If cost was a barrier, the provider identified whether a lower cost alternative medication was available, such as metformin or sulfonylureas (glipizide, glimepiride, or glyburide), or the provider referred the patient to the onsite patient advocate for financial assistance. Patients who qualified for the onsite patient advocate were those who had managed-care United Health plans. The MA provided information about Good Rx to all the other patients who did not qualify for the onsite patient advocate.
- If patient indicated that side effects were a barrier to taking medication as prescribed, then the provider altered the dose of the medication (e.g., lowering the dose of metformin), changed the medication to an extended-release formulation (e.g., metformin ER instead of metformin), prescribed additional medications to address the side effects (e.g. simethicone or dicyclomine), or had patient take the medication with food. Patients

who wanted to discontinue the medication were offered other options, such as weekly subQ injections or other oral anti-diabetic agents, if appropriate.

- If patient answered that forgetfulness, intentionally/unintentionally not taking medications, travel, or running out of medications were the barriers to taking medication as prescribed regardless of the number of days or doses missed, then the provider offered mail-in delivery service as an option and reinforced patient education on the complications associated with uncontrolled T2DM.
- Once the provider completed the office visit, they debriefed with the MA regarding disposition and follow-up details. The plan of care was then finalized, and the MA entered the examination room and provided discharge instructions to the patient and any recommended follow-ups that needed to be scheduled. Documentation of changes to plans of care were entered into the EHR by the provider and the MA.

Ethical Considerations

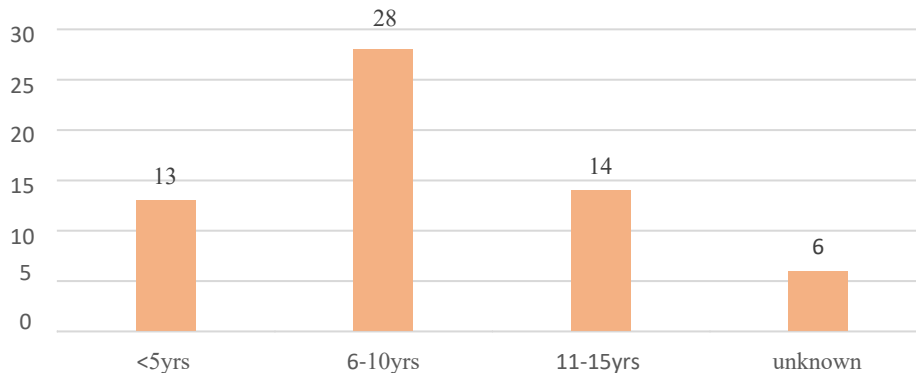
There were no potential risks to the patients, staff, or providers in implementing this quality improvement project, which followed current evidence-based clinical practice guidelines from the ADA. The use of clinical practice guidelines should help to improve overall HbA1c levels in patients with T2DM. Additionally, the clinic had enhanced EHR security that complied with all federal guidelines related to the Health Information Portability and Accountability Act. This quality improvement project was submitted to the University of the Incarnate Word Institutional Review Board for review and was deemed to be non-research. My clinic mentor and project advisor both deemed that this quality improvement project was in compliance with current established clinical practice guidelines. By reducing obstacles to patients with T2DM

taking their medications as prescribed, there should be a reduction in overall HbA1c levels, which in turn should decrease the risk of complications associated with uncontrolled T2DM.

Results

A total of 103 patients agreed to participate in the quality improvement project, but only 61 patients completed the questionnaire. The remaining 42 patients were excluded due to incomplete questionnaires. Demographic data was collected at the start of each office visit by the MA to determine how many patients had a diagnosis of T2DM. An average of seven patients with T2DM were identified on a daily basis, with an average of three of these patients being screened per day. The patients that were not screened were missed because of the high volume of patients seen in the clinic. The MAs reported that there was not enough time for patients to complete the surveys during triage. There were several occasions where the MAs would assist the patients in completing the survey to expedite the process by reading the questions and filling out the surveys for them. Patients ranged from 30 to 100 years of age, with 67% being male and 33% being female. The majority of the patients were Hispanic (62%), and the rest of the patients were black, non-Hispanic (26%), and white, non-Hispanic (12%). All of the patients seen at the Northwest family practice clinic were insured (58%), primarily using Medicare and Medicaid, and the remaining (42%) had private insurance (e.g., Aetna, BCBS, and Tricare). Of the 61 patients in the study, 13 were diagnosed with T2DM for less than 5 years, 28 patients had diabetes for 6-10 years, 14 patients had been diagnosed for 11-15 years, and 6 patients reported that they were unaware of how long they had T2DM. Patients who reported an unknown diagnoses date were between the ages of 68 and 74 years (Figure 3).

The knowledge questionnaire assessed patients' knowledge of T2DM risk factors. Of the 61 patients in the study, 23 reported lack of activity, 61 reported candy consumption, two

Figure 3*Duration of Diabetes Amongst Participants***Duration of diabetes amongst participants (N = 61)**

reported mental stress, 47 reported family history, 31 reported elevated blood pressure, and 54 reported overweight/obesity as risk factors for diabetes (Figure 4). Of the 61 patients in the study, 53 reported awareness of eyes, 27 awareness of heart, four awareness of lungs, seven awareness of stomach, 58 awareness of kidneys, 61 awareness of feet, 0 awareness of brain, 21 awareness of hands, and 41 awareness of nerves as organs affected by diabetes mellitus (Figure 5). Patients reported that T2DM could be prevented by diet (71%) and exercise (8%), but approximately one-third of the patients (21%) were unsure how either intervention could help reduce their chances of T2DM or how either intervention could improve their HbA1c.

Educational Brochures

All 61 (100%) patients with T2DM received the educational brochure. English speaking patients received the John Hopkins University (n.d.) educational brochure and Spanish-speaking patients received the Centers for Disease Control and Prevention (2020, December 6) educational brochure. Education was provided in the intake room by the MAs as they obtained subjective data while the patients completed the questionnaires. In some cases, the questionnaires

were not completed in the intake room because patients required additional time to complete the questionnaires. Patients were then taken to the examination rooms to complete the questionnaires

Figure 4

Patient Knowledge of Risk Factors

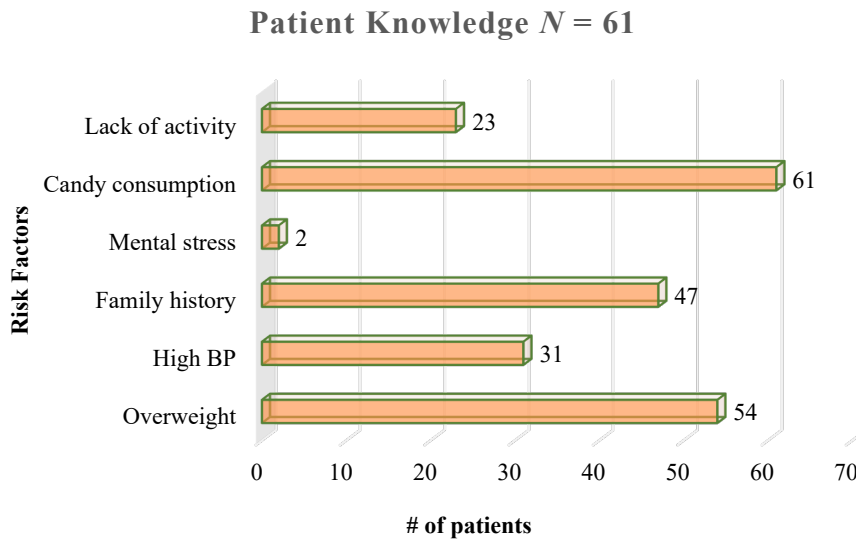
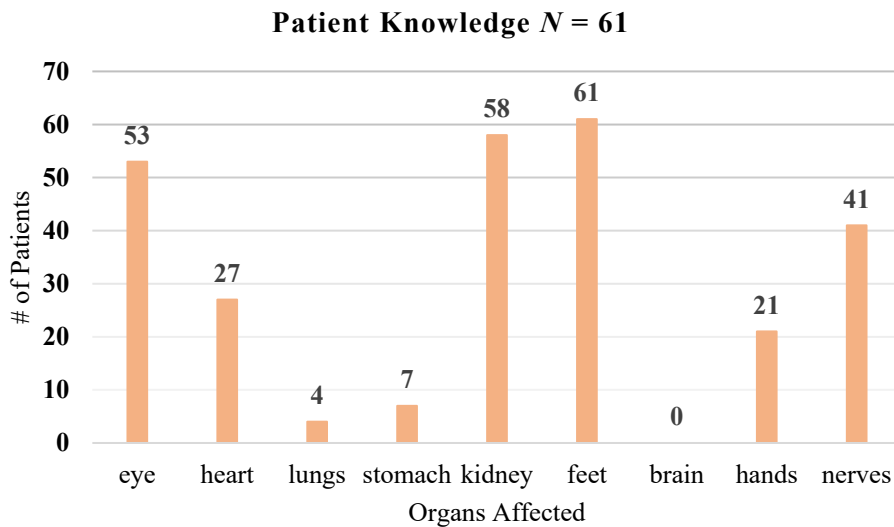


Figure 5

Patient Knowledge of Organs Affected



and review the educational literature as they waited for the providers. The MAs then checked in with the patients to assist with the questionnaires that, once completed, were placed outside the of examination rooms for the providers to review. The educational brochures provided opportunities for the patients to ask questions related to microvascular and macrovascular complications associated with diabetes. Of the 61 patients, 36 patients required additional education on prevention and maintenance of T2DM. The most common questions patients had related to the information found in the brochures was the frequency of foot care exams, hyperglycemia and hypoglycemia management, nutrition, and eye exams.

Forgetfulness/Running Out of Medications

The providers reinforced education from the educational brochures addressing complications associated with T2DM, explained in detail the importance of medication therapy, and required that the patients use the teach-back method to validate that the patients understood the information. Mail-in delivery was also suggested for patients who reported inability to access their medications because they were not able to drive themselves or were forgetful about picking up their medications. The MAs worked with patients and their pharmacies to receive their medication via-mail delivery. Twenty-one patients forgot to take their medications and 12 patients reported that they forget to pick up their medications from the pharmacy, missing 1-2 days of medications. Patients who reported forgetfulness and ran out of medications were considered for medication delivery service; eight patients agreed to enroll in the mail-in delivery program and three patients were successful in completing the mail-in delivery application. Five of the patients agreed but did not successfully enroll into the mail-in program offered by their pharmacy (HEB, CVS). The barriers identified for patients enrolling in this service were that patients had to self-enroll in the programs by using an application from their phone. The MAs

could not do it for the patients since the application was necessary for validating information and the majority of patients did not have phones that could download this application. Also, delivery times varied (e.g., Monday-Friday 8 a.m. – 3 p.m., Saturday 10 a.m. – 2p.m.) in selected locations and there were no delivery options on Sunday. The times and dates were not convenient for patients and their caregivers. Some insurance plans restricted coverage for home delivery, even when the same prescription was covered for in-store pick up. Finally, patients had to live within a 10- to 20-mile radius of the pharmacy in order to qualify for these services.

Side Effects

Of the 61 patients, 20 (31%) reported side effects being a barrier to taking their medication as prescribed and were switched from metformin immediate release (IR) 500mg twice daily to metformin extended release (ER) 1000mg daily. These patients' HbA1Cs ranged from 6.8% to 8.5%. The three patients who reported not being able to tolerate metformin due to gastrointestinal upset were switched to liraglutide daily subcutaneous injections. Two patients were started on semaglutide weekly subcutaneous injections. Seven patients chose to stop taking metformin because of gastrointestinal side effects and try lifestyle modifications such as diet and exercise before considering an alternative treatment. These patients' HbA1Cs were also assessed to ensure this was a safe option. Their HbA1Cs ranged between 6.9% to 7.6%.

Cost

Eight (14%) patients who reported cost as a barrier to taking their medication as prescribed. These patients were given resources within the clinic if they qualified. According to the onsite patient advocate department, patients who had United Health Managed Care insurance were able to receive financial assistance within the clinic. Other patients who had private insurance were referred to GoodRx. Six patients who had United Health Managed Care were

referred to the onsite patient advocate center and were assisted with financial applications. Two patients who had private insurance, (e.g., BCBS, Aetna) were referred to Good Rx.

Optimization Clinic

Of the 61 participants in the study, 21 were identified as having an HbA1C greater than 8.4%. All of these patients were referred to the optimization clinic. The MAs ensured that each patient secured an appointment with the optimization clinic prior to discharge. It was not known if patients followed through with future appointments due to the length of this project.

Overall Objective Outcome Results

Three of the four objectives for this project were met. As previously mentioned, 61 patients out of 103 patients with T2DM that presented to the clinic completed the questionnaires. However, all of the 103 patients received the educational brochure on the complications associated with uncontrolled T2DM. Thus objective 1 was met.

The goal of the clinic was to achieve a weekly score of 95% or greater for patients with a diagnosis of T2DM who followed their prescribed medication regimens. The clinic was able to achieve this goal for 7 of the 10 weeks. The first two weeks of the project had several issues developed that affected the ability to reach the 95% weekly score. Short staffing and current experienced staff members training new staff resulted in no designated staff assigned to initiate the surveys. During this time there was also an unusually high volume of patients that had to be seen. All of these issues combined with the new workflow process resulted in less than optimal implementation of the project. Educational sessions were held every morning to review the project objectives and processes at the beginning of each week. This helped improve performance allowing the clinic to meet their goal of 95% or greater for most of the remaining weeks of the project. However, during week 10 the staff reported that they were not able to meet

their goal because of similar issues that occurred in week 1 and week 2 as well as the primary provider being absent from the clinic that week. Overall objective 2 was met except for week 1, week 2, and week 10.

Of the 61 participants in the study, 21 were identified as having an HbA1C greater than 8.4%. All of these patients were referred to the optimization clinic. The MAs ensured that each patient secured an appointment with the optimization clinic prior to discharge. Thus objective 4 was met.

Objective 3 was to decrease the number of patients with T2DM who had a HbA1c of greater than 8g/dL from 52 to 40%. This goal was not met. Since HbA1c levels are done every 3 to 6 months, it was impossible to determine if the interventions had improved any of the patients' HbA1c levels. This objective should be re-evaluated at the end of one year of implementation of the project to determine if any changes occurred as a result of the interventions. No correlations can be made at this time.

Discussion

During my assessment of the Northwest family practice clinic, it was evident that the providers and staff all recognized that their current processes were not meeting organizational goals and that patients lacked education and guidance in managing their diabetes. This placed several of the patients at risk for developing complications associated with uncontrolled diabetes mellitus. The willingness of the staff and providers to participate in this quality improvement project was essential in meeting three of the four objectives developed to determine success of the project. Involving the staff and providers in the development of the interventions based on current evidence helped to ensure that the new processes were followed. The algorithm that was developed for this project was easy to follow and assisted the staff and providers with the steps

needed to assist patients in addressing the barriers the patients identified when they came into the Northwest family practice clinic. By streamlining the processes and the medical interventions, patients were able to easily follow the prescribed treatment plan, particularly the medication therapy. Simplifying the processes helps to decrease the complexity of treatment plans which was one of the obstacles identified by Guerard et al. (2018), Polonsky and Henry (2016), and Subashree et al. (2016).

Identifying the obstacles that prevented patients from taking their medications as prescribed and offering alternative medications or resources to assist the patients in addressing these specific barriers demonstrated that the Northwest family practice clinic was concerned about the well-being of its patients and increased trust in the healthcare team. Trust is an essential component to patients improving their self-care management of their diabetes (Husdal et al., 2021; Polonsky and Henry, 2016). Believing that the treatments are appropriate increases the likelihood that patients will follow the prescribed plan.

The obstacles identified by the patients at the Northwest family practice clinic were consistent with similar findings in the literature. Forgetfulness, side effects of medications, and cost were all obstacles identified in this project that effected patients taking their medications as prescribed. Side effects from the medications accounted for 31% of the patients that did not take their medications as prescribed. Forgetfulness accounted for 20% of the patients that did not take their medications as prescribed. Cost accounted for 14% of the patients that did not take their medications as prescribed.

Healthcare providers are acutely aware that anytime medications are prescribed and administered to patients there is the risk of patients developing side effects. Several of the medications that treat diabetes are notorious for causing side effects ranging from gastrointestinal

distress to hypoglycemia. The ADA (2020c) highlighted this fact in the clinical guidelines for managing diabetes by stating that providers should consider alternative therapies if side effects are unable to be managed. Side effects from medications is highly correlated to patients not taking their medications as prescribed (Alshehri et al., 2020; Guerard et al. 2018; Polonsky and Henry, 2016; & Subashree et al., 2016). Failure to address these side effects decreases the likelihood that patients will take their medications as prescribed and erodes trust between patients and the providers. Findings from this project correlate with what is found in the literature. Side effects from medications was the most identified barrier for patients not taking their medications as prescribed at the Northwest family practice clinic accounting for 31% of the barriers.

Hargis and Castel (2018) reported that patients over the age of 65 are likely to take more than five medications regularly, which can contribute to forgetfulness in taking their medications, especially when medications are taken in the evening. Forgetfulness was the second most common barrier for patients not taking their medications as prescribed at the Northwest family practice clinic accounting for 20% of the barriers. Adams and Stolpe (2016), Guerard et al. (2018), and Srijan et al. (2018) identified forgetfulness as a significant contributor to patients not taking their medications as prescribed. While Hargis and Castel (2018) suggest that aging may contribute to increased levels of forgetfulness in taking prescribed medications, this trend was not specifically noted in the literature regarding forgetfulness in patients with T2DM. Despite the fact that forgetfulness was identified as the second most common barrier to taking medications as prescribed at the Northwest family practice clinic, there was no correlation with this barrier being identified by particular age range of patients.

Cost was the third most common barrier to taking medications as prescribed at the Northwest family practice clinic accounting for 14% of the barriers. Historically, cost of prescription medications has been an ongoing concern for patients. This is particularly true for those patients who are underinsured or uninsured. Polonsky and Henry (2016) reported that higher costs for antidiabetic medications are linked to poor adherence. Specifically, Polonsky and Henry (2016) found that patients with low income who were uninsured, underinsured, or on Medicaid had poor medication adherence rates, while the older population who are typically on Medicare tended to take their medications as prescribed because they were found to have lower out-of-pocket costs. Findings from this project revealed no significant difference between those with private insurance, Medicaid, or Medicare when identifying cost as a barrier to taking their medications as prescribed. Affordability of prescription medications is essential to improved adherence rates. When patients with T2DM take their medications as prescribed, there is usually better control of glucose levels, more optimal HbA1c levels, decreased complications, and less need for hospitalization thereby reducing the overall healthcare cost burden to patients.

The literature supports that fact that there are multiple risk factors affecting patients taking their medication as prescribed but ultimately patients not taking their medications as prescribed leads to complications and adverse health outcomes. Diabetes is a disease that is strongly associated with both microvascular and macrovascular complications such as retinopathy, nephropathy, and neuropathy as well as macrovascular complications such as ischemic heart disease, peripheral vascular disease, and cerebrovascular disease that results in organ and tissue damage in approximately one-third to half of people with diabetes (Cade, 2008). These complications can place a substantial financial burden on patients. According to the CDC (2010), approximately 17 million emergency department visits were reported in people with

diabetes over the age of 18. Of the 17 million, 248,000 were treated for hyperglycemia crisis and most of these patients were also reported to have concurrent comorbidities directly associated with the diabetes such as cardiovascular disease (1.87 million), ischemic heart disease (440,000), stroke (334,000), and lower extremity amputation (154,000).

Instituting measures that will address patient barriers to taking their medications as prescribed will help to improve overall patient health. Therefore, providers must stress the importance of non-pharmacologic interventions, such as diet modification, weight control, and regular exercise, in addition to pharmacological interventions when developing plans of care to treat patients with T2DM. Due to time constraints, I was not able to collect data that showed the project interventions improved overall HbA1c levels. HbA1c levels are done every 3 to 6 months, therefore it was impossible to determine if the interventions had improved any of the patients' HbA1c levels since none of the patients were eligible for a repeat HbA1c level following the intervention. The earliest patients could have their HbA1c levels repeated would have been 12 weeks after the interventions were implemented. Providers should continue to monitor the patients' HbA1c levels over the course of the next year to determine if any changes occurred as a result of the interventions. Failure to stabilize glucose levels increases the likelihood that these patients will develop complications from T2DM, will accrue a heavier financial burden, will have increased hospitalizations, and will have higher morbidity and mortality rates compared to those patients with T2DM that have well controlled glucose levels.

Limitations

Four factors were identified as limitations for implementation of this project. These include completion rates of surveys, willingness of patients, staff, and providers in implementing the interventions, length of project implementation, and COVID-19.

As with any self-survey there is a chance for inaccurate or incomplete data based on the thoroughness of the individuals completing the survey. Despite the fact that the questionnaires used in this project were short and written at grade level that most adult patients could understand, almost one-third of the patients with T2DM that presented to the clinic did not complete the questionnaires. This limited the ability of the providers to address any potential barriers that interfered with these patients taking their medications as prescribed. If patients needed assistance in completing the questionnaires, answers might have been skewed based on interpretation of the questions by family members and staff.

The willingness of patients, staff, and providers in implementing the interventions had a direct effect on the success of project. During the first two weeks of the project, it was necessary to work with the staff to implement the project interventions as planned. The high volume of patients seen at the clinic and the shortage of available staff impacted the willingness of the staff to make these interventions a priority. It was important to note that patients needed to be afforded adequate time to complete the questionnaires in order to ensure that the providers had all the relevant information to address any obstacles that were identified by the patients. This issue seemed to resolve itself by the third week when the staff and providers had integrated the interventions into their routines.

COVID-19 infection rates directly impacted the processes that were implemented by the Northwest family practice clinic as processes had to be adjusted to account for interventions that would decrease COVID-19 transmission rates. Primarily this involved changing some of the face-to-face appointments to telemedicine visits. Telemedicine visits were not as conducive for patients completing the questionnaires as face-to-face appointments. Therefore, this may have affected the questionnaire completion rates.

Finally, this project was implemented over a ten-week period. As previously mentioned, I was unable to obtain post intervention HbA1c levels to determine if the interventions actually had a significant impact on patients' overall glucose management. However, it can be surmised that improvements in patients with T2DM taking their medications as prescribed should result in improved glucose regulation and thereby improve overall HbA1c levels and reduce complications associated with uncontrolled T2DM. This information would need to be tracked over a period of time to ensure whether this assumption panned out.

Recommendations

The use of two questionnaires made the check-in process lengthy. Completion of both the medication adherence questionnaire and the knowledge questionnaire to approximately 15 to 30 minutes to complete. In the future it would be best to utilize one questionnaire, preferably the medication adherence questionnaire, that could be completed within 5 to 10 minutes. Findings from this project revealed that most patients are unaware of the scope of complications that can arise from uncontrolled T2DM. Based on these findings, I would recommend that all patients with diabetes be provided the educational resources that discusses these complications. This would negate the need for the knowledge questionnaire. It might also be beneficial to make this questionnaire available through the patient portal so patients could complete the questionnaires at home and bring the completed questionnaires to their appointment.

If budget allowed, designating a dedicated staff member that could assist patients with completing the questionnaire would help to ensure all questions were answered, potential improve the time it takes to complete the questionnaire, and decrease the number of incomplete questionnaires. This measure would have an impact on the clinic budget and staffing. By improving the time it takes to complete the questionnaire there would be an improvement in

overall intake process times, thereby allowing more time for patients to review educational materials in the examination rooms prior to being seen by the providers. This extra time to review educational materials could help patients feel better prepared to discuss their concerns with the providers.

Finally, I would recommend tracking patients HbA1c levels over the course of the next year to determine whether the project interventions improved overall glucose management. This will assist the providers in determining whether additional interventions are needed based on trends in HbA1c levels.

Sustainability

Berta et al. (2019) states that sustainability refers to the extent that an evidence-based intervention can continue to deliver its benefits over time once the project donor support ends. In the case of this project, sustainability refers to the ability of the Northwest family practice clinic to continue to the project interventions once my role in the project has ended. In effect, the interventions are being transferred from an academic project requirement to the Northwest family practice clinic as an integrated component of treating patients with T2DM. Many factors can influence whether interventions are sustainable. One of the influential factors is continued interest in the interventions by the Northwest family practice clinic both from the staff and provider viewpoint as well as the patient viewpoint. Granger (2020) stresses the importance of confirming an ongoing commitment to the clinical outcome. In short, does the improvement in practice remain a priority for the patient, provider, and institution. In this case, I believe there is significant institutional interest in increasing the number of patients with T2DM that take their medications as prescribed. This improves the overall metrics that are used for reimbursement purposes but also potentially lowers the resources that are needed for patients with T2DM since

complications from uncontrolled glucose levels are reduced. Furthermore, patient satisfaction should improve as patient self-management improves, and glucose levels are better managed. Ongoing assessment of successful intervention implementation is necessary to ensure that deviation from established plans are minimized. Granger (2020) advocates that one to two key process factors should be audited in order to determine if process drift is occurring. Additionally, Granger (2020) stated that EHR data should be examined for auditing purposes periodically along with re-evaluation of workflow processes. As previously mentioned, I recommended that the Northwest family medicine clinic continue the interventions for a 1-year time frame in order to determine if the interventions were making a difference in patients' HbA1c levels. This 1-year time frame would also afford the Northwest family clinic an opportunity to look for trends in improvement of patients' self-management of their T2DM during follow-up visits. This data could be obtained via the EHR as the staff and providers document patients' progress in implementing treatment plans. The staff and providers could also use the institutional metrics to track patient adherence rates in taking medications and trends in complications for patients with T2DM that was mentioned in the assessment section to see if any improvements were noted. At the conclusion of the one-year time period, the staff and providers at the Northwest family practice clinic could make a determination if the interventions were useful in improving patient outcomes and which interventions, if any, should be revised or discontinued. At the time I ended my involvement with the project, the Northwest family practice clinic was continuing the project interventions.

Relevance to DNP Prepared Nurse Practitioner

The Doctor of Nursing (DNP) nurse practitioner is prepared to combine nursing science with knowledge of ethics, and the biophysical, psychosocial, analytical, and organizational

sciences, as the foundation for the highest level of nursing practice (American Association of Colleges of Nursing, 2006). The DNP nurse practitioner develops an understanding of how to evaluate existing clinical problems and incorporates new practice approaches based on nursing theories using current evidence-based practice guidelines. As a DNP prepared nurse practitioner, it is essential to understand how to evaluate a clinical problem and implement evidence-based practice into the organization. Implementing change within a clinic, and ultimately within the organization, can be challenging and requires educating staff and providers of current practice evidence-based guidelines that are proven to enhance care for patients, families, and the community. During my project, the DNP essentials served as a reference point in completing the project, focusing primarily on essential 1: scientific underpinnings for practice. This essential prepares the DNP student to integrate nursing science with other sciences to determine the nature and significance of a health care delivery phenomenon in order to develop and evaluate new practice approaches based on this scientific knowledge to improve the health care delivery (American Association of Colleges of Nursing, 2006). For example, prior to implementing the quality improvement project, the staff and providers did not have an established process in place for assessing and addressing barriers to patients with T2DM taking their medications as prescribed. By developing a practice change plan with an accompanying algorithm based on established national clinical practice guidelines I was able to assist the providers and staff implementing the plan in order to address barriers to patients taking their medications as prescribed and improving patients' understanding of complications associated with uncontrolled diabetes mellitus. Quality improvement is an ongoing process that requires continuous assessment, intervention, and evaluation of practice performance. This affords the advanced practice nurse a plethora of opportunities to improve patient outcomes and workflow processes.

This project also afforded me the opportunity to address DNP essential II: organizational and systems leadership for quality improvement and systems thinking. This essential requires the advanced practice nurse to employ principles of business, finance, economics, and health policy to develop and implement effective plans for practice level initiatives that will improve the quality-of-care delivery and to analyze. It also requires the advanced practice nurse to analyze cost-effectiveness of practice initiatives accounting for risks and improvement of health care outcomes while also demonstrating sensitivity to diverse organizational cultures and populations including patients and families. In this case, the project plan needed to work within the current structure of the Northwest family practice clinic without the need to add additional staff or providers. The clinic served a primarily Hispanic population, so the interventions had to be accessible for patients speaking both English and Spanish. Additionally, the reading level of the questionnaires needed to be at a level appropriate for this community since the majority of the community members had obtained a high school diploma as the highest level of education. Modifications of lifestyle choices also needed to fit within the context of the cultural identity of the patients, particularly related to nutrition. It was also important that the project interventions were compatible with the patients' insurance plans in order to cover the cost of medications. As with any business, it was essential that the project plan limited extra costs and time expenditures for the staff and providers while still maintaining the appropriate standards of care.

Current demands within the healthcare environment influence how the DNP essentials will evolve over time. Regardless of the changes that may occur to the essentials over time, it is important that advanced practice nurses remain abreast of current clinical practice guidelines, trends in the healthcare environment, and new developments in technology in order to better serve our patients.

Conclusion

Although the Northwest family practice clinic initially demonstrated some minimal resistance to the change process, overall, the staff and providers supported the project plan implementation and were able to incorporate the new processes into their daily workflow. By identifying the barriers that contribute to patients with T2DM not taking their medications as prescribed, the staff and providers were able to implement measures to address these barriers and education patients on the complications that can arise when T2DM is not managed effectively. While we were able to meet three of the four outcome objectives for the project, time will tell if these interventions had any significant effect on patients' overall HbA1c levels.

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Appendix A

Letter of Support

Dear University of the Incarnate Word,

On behalf of the northwest family practice clinic, I am writing this letter of support granting permission for Mrs. Cristina Sarro, a DNP student, to conduct her DNP project at the [name of clinic]. I understand this project aims to improve medication compliance in patients with diabetes that are seen at the [name of clinic]. I understand that Mrs. Cristina Sarro will be working closely with patients and staff. This project is consistent with the mission of the [name of clinic] by helping to improve the management of chronic disease and overall improving patient care and outcomes.

As an institution of higher learning, you have demonstrated a commitment to improving patient care and helping to educate nurse practitioners. We appreciate your efforts and enjoy a continued partnership with the University of the Incarnate Word in precepting and mentoring DNP students. This Doctoral project will begin January 2022 and end at the conclusion of August 2022. Dr. Michael D. Moon will serve as the UIW Faculty project advisor and is available to answer any questions that may arise regarding the project. He can be reached at (210) 283-5054.

The [name of clinic] is happy to participate in this DNP project and contribute to this important work. Therefore, as the Medical Director of the [name of medical group], I agree that Cristina Sarro's — DNP project may be conducted at our facility.

Dr. Vincent Gonzaba- Medical Director
Northwest family practice clinic
Address, San Antonio, TX Zip Code

Appendix B

Educational Brochure

Diabetes Education – #28

Must Know Health Info

Health Information from the Experts at Johns Hopkins Medicine



Nine Ways to Avoid Diabetes Complications

Managing your diabetes means more than just getting blood sugar in control; it doesn't stop there. Follow these tips. They will help you reduce your chances of long term problems from diabetes. They will also help you improve your overall health.

1. **Control your blood glucose.** Keep your blood sugars within a healthy range. This is the best way to prevent long term problems from diabetes. Here is what the ADA (American Diabetes Association) recommends. Have an A-1-c test ("hemoglobin A1c") at least twice a year. If your A1c is under 7%, that is good control. Your blood sugars:
 - should be in the in the 90-130 mg/dL range
 - should be less than 180 mg/dL after you eat.
 Keep a record of your blood sugar levels. Share it with your doctor or other health care team members. Work out a care plan for good blood sugar control.
2. **Eat healthy.** Follow a food plan that includes all food groups:
 - Vegetables
 - Fruits
 - Dairy
 - Protein
 - Whole grains.
 This is the best way to eat for health. Limit foods that are high in bad fats ("saturated fat") and cholesterol. Drink plenty water and other drinks that do not have sugar.
3. **Be sure to be active every day.** When you exercise on a routine basis, it pays off; it can help you control your blood sugar with less medicine.

Diabetes Education – #28

4. **Control your blood pressure.** High blood pressure makes you more prone to heart and kidney disease, and stroke. Exercise, lose weight, and eat a low salt diet. Doing these will help you control your blood pressure. And, these may reduce your need for blood pressure medicine.
5. **Be sure to keep your cholesterol low.** High blood cholesterol makes you more prone to heart disease and stroke. If you have diabetes, keep your LDL ("bad" cholesterol) low; it should be less than 100 mg/dL. Ask your doctor about the best methods for meeting this goal.
6. **Check your feet every day.** Diabetes can damage nerves and cause pain or loss of feeling. Often this happens in the legs and feet (called "peripheral neuropathy"). This can increase the risk of foot infections. Your doctor should examine your feet for early signs. Wear well-fitting shoes and always wear socks. Check your feet every day. See your doctor for signs of infection, a cut, or sore on your foot that doesn't heal.
7. **Know the signs of heart disease.** If you have diabetes, you may have common signs of heart disease. These include chest pain or shortness of breath. But, you may also have signs that are not common: pain in the jaw, shoulder, or abdomen; pain down the arm; nausea and dizziness.
8. **See your eye doctor yearly.** Diabetes can damage the small blood vessels in the eye ("retinopathy"). Often, the first symptom you will notice is poor vision. And, it even leads to blindness. An eye doctor ("ophthalmologist") can find problems early. This doctor can examine the back of the eye. This will detect signs of damage before your sight is impaired.
9. **Quit smoking now!** If you smoke, you are more prone to heart and kidney disease, stroke, and nerve damage. So, if you do smoke, quit. It's one of the most vital things you can do to prevent these diseases.

****Authored by Johns Hopkins University and Johns Hopkins Health System****






Cómo controlar la diabetes: Cobertura y recursos de Medicare

10 pasos para las personas que viven con diabetes

-  **Coma bien**
Encuentre consejos, estrategias e ideas para comer saludablemente.
-  **¡Haga ejercicio!**
Haga actividad física para mantenerse en control.
-  **Mantenga un peso saludable**
Aprenda cómo alcanzar un peso saludable (y cómo mantenerlo).
-  **Controle el azúcar en la sangre**
Conozca sus números y cómo mantenerse enfocado en el objetivo.
-  **Evite complicaciones**
Aprenda cómo evitar o retrasar problemas de salud relacionados.
-  **Maneje los días de enfermedad**
Adopte medidas para proteger su salud.


Encuentre un proveedor de servicios de Medicare
Visite [es.medicare.gov](https://www.medicare.gov) para encontrar y comparar proveedores de servicios médicos en su zona.


-  **Incluya en su calendario el control de la diabetes**
Incluya en su calendario tanto los cuidados diarios como las visitas a su médico.
-  **¡Prepárese!**
Piense por adelantado cómo manejar las emergencias.
-  **Descubra la conexión entre la diabetes y la salud mental**
Descubra cómo están relacionadas.
-  **Obtenga educación y apoyos**
Aprenda sobre la capacitación para controlar la diabetes por su cuenta.


Conozca más acerca de los [10 pasos](#).




Cobertura de Medicare

 **Pruebas y suministros:**
Averigüe si Medicare cubre su prueba de diabetes, sus productos o su servicio.
Descargue la aplicación de Medicare "What's covered" ("Qué está cubierto") disponible en el *Apple Store* o en *Google Play Store*.


 **Medicamentos:**
Inscríbese en Medicare Parte D con cobertura de medicamentos recetados que incluya suministros para la diabetes.

 **Capacitación sobre autocontrol de la diabetes:**
Encuentre clases en su zona que le ayuden con los 10 pasos de los CDC para las personas que viven con diabetes.

Ayuda con los costos

 **Beneficio Adicional:**
Si sus ingresos son limitados, este programa puede ayudarle a cubrir los costos del programa de medicamentos recetados de Medicare.

 **Programas de ahorros de Medicare:**
Puede obtener ayuda en su estado para pagar sus primas de Medicare.

 **Programas de las compañías farmacéuticas para asistir a los pacientes:**
Es posible que pueda obtener ayuda si la compañía que fabrica sus medicamentos ofrece programas de asistencia a pacientes.



Necesita ayuda?

Llame al **1-800-MEDICARE**
(1-800-633-4227)
Los usuarios de teléfono de texto pueden llamar al **1-877-486-2048**
o visite la página **[es.medicare.gov](https://www.medicare.gov)**
o escriba a:
Medicare Contact Center Operations
PO Box 1270
Lawrence, KS 66044
Also available in English:
[Medicare.gov/publications](https://www.medicare.gov/publications)

Appendix C

Evidentiary Table for Summary of Evidence

References	Purpose	Setting Design	Findings/Implications	Quality of Evidence	Level of Evidence
Adams and Stolpe (2016)	The purpose of the study was to explore poor medication adherence. Medication nonadherence has been increasingly recognized as a major public health issue.	Primary care setting, Medicare beneficiaries Systematic literature review	Lack of standardized definitions and measurements makes it difficult to study medication nonadherence. The development of consistent measures and quality measures from a consensus is an important step in further investigating this issue.	B	V
Alshehri et al. (2020)	The purpose of the study is to assess adherence to T2DM medications and investigating the reason patients are nonadherent.	Primary care health setting. Cross sectional design	Incorporating pharmacist in patient medication planning. The provider can collaborate closely with the pharmacist to explore ways to address medication nonadherence. The provider needs to explore the barriers to medication adherence with patients during wellness exams	B	III

<p>American Diabetes Association (2020)</p>	<p>The American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” includes the ADA’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care.</p>	<p>The clinical practice guidelines are developed through a systematic review of research and consensus from experts in the field. The clinical practice guidelines cover the care of patients with diabetes from primary care to acute care settings.</p>	<p>The clinical practice guidelines are divided into specific sections to address the depth of caring for patients with diabetes. The sections utilized for this project addressed glycemic targets, obesity management, pharmacological management, and the older adult with diabetes from the primary care perspective</p>	<p>A</p>	<p>I</p>
<p>Bosworth et al. (2016)</p>	<p>The purpose of this study was to demonstrate key skills such as motivational interviewing, counseling, and shared decision-making for clinicians interested in providing patient-centered care in efforts to improve medication adherence.</p>	<p>Primary care health setting Case study</p>	<p>A patient and provider centered relationship is fundamental. Aspects of this person-centered approach include agreeing on the problem and prioritizing patient goals</p>	<p>B</p>	<p>IV</p>

Capoccia et al. (2016)	The purpose of this systematic review was to synthesize the evidence of risk factors associated with nonadherence to prescribed glucose-lowering agents, the impact of nonadherence on glycemic control and the economics of diabetes care, and the interventions designed to improve adherence	Systematic review	Age, race, health beliefs, medication costs, healthcare costs, insurance coverage, health literacy significantly affected adherence to treatment plans. Phone interventions, health coaching, case managers, pharmacists, education, and point of care testing improved adherence rates. Higher adherence rates resulted in better glycemic control, fewer emergency department visits, decreased hospitalizations, and lower costs.	AB	I
Curkendall et al. (2013)	The purpose is of those review was to synthesis risk factors in patients with a known diagnoses of T2DM and the effect of lower cost medications.	Cross sectional study. Primary care	Identified risk factors can guide medical professionals in their attempts to increase the likelihood of patient adherence to drug treatment regimens. Adherence was higher among patients who were male, older, or residing in non-Southern states. Adherence was better with mail-order use and lower levels of cost sharing.	AB	I
Fan et al. (2017)	Evaluate the effect of individualized education in patients with type 2 diabetes mellitus.	N = 280 participants in a primary care setting. Randomized clinical trial	Individualized diabetes education is more effective than group education in facilitating the control of type 2 diabetes.	AB	II
Guerard et al. (2018)	The purpose of this study was to assess whether a comprehensive	N= 291,326 participants from 2010-2015 who had	Short provider visits results in providers being unaware of patients' adherence statuses. Care	B	III

	<p>wellness assessment (CWA) program helps improve medication adherence for oral diabetic medications, statins, angiotensin-converting enzyme inhibitors, ir angiotensin II receptor blockers.</p>	<p>Medicare and Medicaid. Focused on the primary care setting. Retrospective panel study</p>	<p>coordination, education, and collaboration using a team based approach can help improve adherence rates. Providers need to discuss adherence with patients to identify solutions to managing chronic disease states.</p>		
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<p>Hargis and Castel (2018)</p>	<p>To assess and understand the complexity of medication regimens by improving memory, promote metacognitive accuracy which is likely to increase adherence.</p>	<p>Randomized</p>	<p>Memory and metacognitive factors help explain why patients across the life span may not understand or follow prescribed regimens. These factors include difficulties in remembering confusing information, patients' and practitioners' potential overconfidence in memory, and misunderstandings about memory.</p>	<p>A</p>	<p>II</p>
<p>He et al. (2021)</p>	<p>To examine associations between factors (i.e., drug coverage satisfaction and cost-reducing behavior) and medication nonadherence among Medicare beneficiaries with type 2 diabetes</p>	<p>N =1,430 The population included Medicare beneficiaries aged 65 years and older with reported type 2 diabetes Retrospective design</p>	<p>Medication nonadherence was defined as skipping a dose of medication or taking a dose of medication smaller than what was prescribed. 10.3% of the patients reported medication nonadherence. The risk for medication nonadherence was higher among those who were dissatisfied with the amount they paid for medications compared with those who were satisfied. Those who spent less on basic needs to save for medications were more likely to report medication nonadherence than those who did not.</p>	<p>B</p>	<p>III</p>

<p>Hsu et al. (2012)</p>	<p>To explore the discrepancy of diabetes incidence and care between socioeconomic statuses in nations with universal health coverage.</p>	<p>N = 600,662</p> <p>Patients from the National Health Insurance program seen in primary care in Taiwan were followed for over a 5-year period.</p> <p>Representative cohort design</p>	<p>The incidence of type 2 diabetes in the poor population was 20.4 per 1,000 person-years compared with their middle-income counterparts. The adjusted odds ratio for the poor population incidentally identified as having diabetes through hospitalization was 2.2. Poor persons with diabetes were less likely to visit any diabetes clinic. The odds ratios for the poor population with diabetes to receive tests for glycated hemoglobin, low-density lipoprotein cholesterol, triglycerides, and retinopathy were 0.6, 0.4, 0.5, and 0.4, respectively.</p> <p>Poverty is associated not only with higher diabetes incidence but also with inequality of diabetes care in a northeast Asian population, despite universal health coverage.</p>	<p>AB</p>	<p>IV</p>
<p>Husdal et al. (2021)</p>	<p>To gain a deeper understanding of how people with T2DM perceive Swedish primary diabetes care and self-management support</p>	<p>N = 28</p> <p>Diverse group of Swedish patients with diabetes seen in a primary care setting. Diversity was based on age, sex, diabetes duration, and HbA1C levels.</p> <p>Qualitative focus group design</p>	<p>. Following national standards for management of diabetes improved self-management skills. Communication, trust, and consistency must be ongoing between the primary care provider and patient.</p>	<p>B</p>	<p>VI</p>

Kennedy-Martin et al. (2017)	To explore published evidence on health care costs associated with adherence or persistence to antidiabetes medications in adults with T2DM.	A total of 4,662 de-duplicated abstracts were identified and 110 studies included in the wider review. Systematic review	Nineteen studies reported an association between adherence (n=13), persistence (n=5), or adherence and persistence (n=1), and health care costs. All studies were retrospective, with sample sizes ranging from 301 to 740,195. Medication possession ratio was the most commonly employed adherence measure (n=11). The majority of adherence studies (n=9) reported that medication adherence was associated with lower total health care costs	AB	V
Lin et al. (2017)	To explore newly diagnosed patients with T2DM and barriers that led to medication adherence.	N = 2,463 Patients managed in the national healthcare group in Singapore with newly diagnosed diabetes. Retrospective cohort study	The prevalence of medication adherence (PDC \geq 80%) was 65.0% among newly diagnosed diabetes patients in Singapore. Male, Indian, or patients without hypertension or dyslipidemia were associated with poorer medication adherence. The HbA1c level of poor adherent patients (PDC < 40%) increased by 0.4 over the two years and they were also more likely to have hospitalization or emergency department visit compared with the fully adherent patients.	AB	IV

<p>Munoz-Lopez et al. (2020)</p>	<p>To validate a culturally appropriate instrument directed towards the Mexican population that measures patient's level of adherence to their T2DM management. t</p>	<p>N = 200 Patients seen in a outpatient clinic in order to manage their T2DM. Cross-sectional design</p>	<p>The transtheoretical model of behavior change to simultaneously identify patient motivation to change their lifestyle, is valid and reliable tool. The highest correlations were between adherence to medical treatment and social support, between change in dietary habits and adherence to physical activity and exercise, between prevention of complications and adherence to physical activity and exercise, and between changes in dietary habits and social support.</p>	<p>B</p>	<p>V</p>
<p>Polonsky and Henry (2016)</p>	<p>The purpose of this study was to exam the scope of poor medication adherence and its key contributors in patients with T2DM.</p>	<p>Systematic review design</p>	<p>Patients who have a regimen that benefits their overall health i.e., weight loss, HbA1c reduction, minimal side effects is likely to adhere to their medication regimen. Key contributors to poor medication adherence include perceived treatment efficacy, hypoglycemia, treatment complexity, cost/belief in medications, and MD trust.</p>	<p>AB</p>	<p>V</p>

<p>Renaldi et al. (2021)</p>	<p>To identify various interpersonal relationship problems between patients and healthcare workers that can affect their treatment compliance behavior.</p>	<p>N = 20 Patients with T2DM who had been confirmed by the Community Health Center and healthcare workers consisting of doctors, pharmacists, nutritionists, and nurses. Qualitative study</p>	<p>The results showed that most of the patients (76%) followed the advice given by healthcare workers. Trust arises from the convenience of interaction between the two parties. Providing adequate information will increase patients' understanding and encourage them to take appropriate action for themselves. Patients tend to comply with treatment if they already trust and feel comfortable with the health workers who handle them.</p>	<p>AB</p>	<p>VI</p>
<p>Selvaraj et al. (2016)</p>	<p>This study was conducted to assess the medication adherence among type II diabetic patients.</p>	<p>N= 236 Cross sectional</p>	<p>Improving medication adherence enhances patient safety. It is crucial for the health care professionals to assess risk factors and foresee the possible causes of non-adherence to achieve best health outcome.</p>	<p>B</p>	<p>V</p>

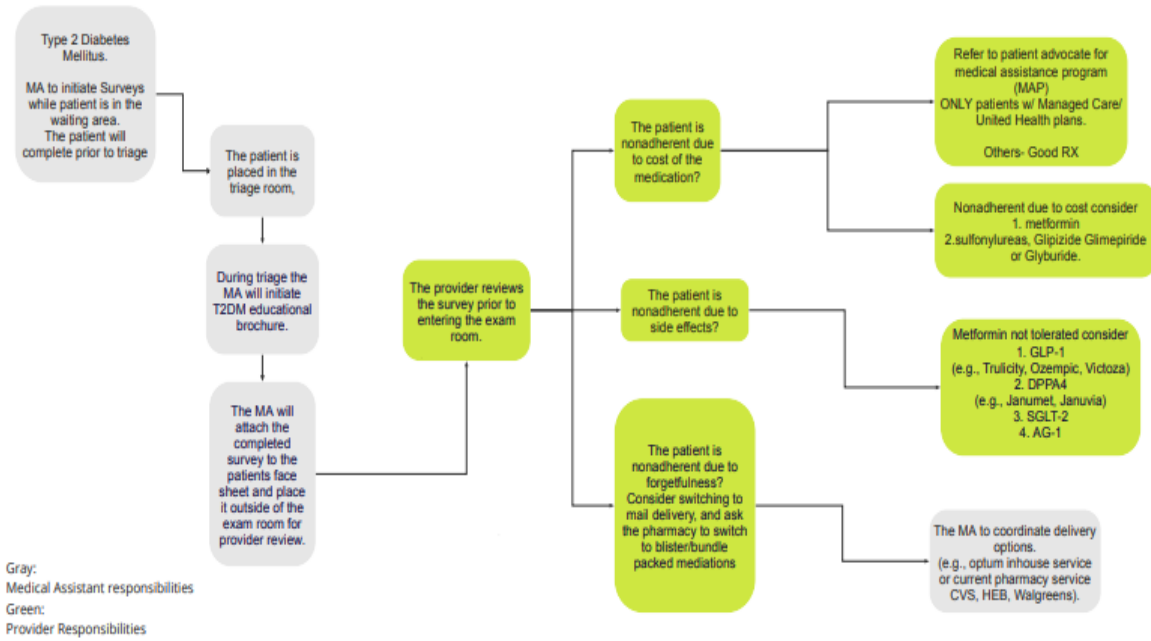
Srijan et al. (2018)	To explore medication adherence in patients with T2DM...	<p>N = 116</p> <p>Patients with T2DM seen in a tertiary hospital over a 6 month period.</p> <p>Cross sectional observation design</p>	<p>Medication adherence was assessed.. Eighty-four (72.41%) patients had low adherence, and 32 (27.58%) patients had medium adherence with none of them having high adherence before the counselling session. After receiving a counselling session on diabetes and adherence to medication, a significant change in adherence levels occurred with 18 (15.51%) patients having reached high adherence, 77 (66.37%) patients having reached medium adherence and 21 (18.10%) patients having low adherence.</p>	AB	V
Subashree et al (2016)	To assess the knowledge and adherence status among patients with T2DM on treatment	<p>N = 100</p> <p>Patients seen in a tertiary teaching hospital.</p> <p>Cross-sectional design</p>	<p>Fifty-eight (58.0%) participants were male and 42 (42.0%) participants were female. Fifty-three (53%) participants scored at a medium knowledge level for T2DM. 47 (47%) scored at a low knowledge level for T2DM. Only 32 participants believed that T2DM could be prevented with 12 identifying diet as a means to preventing T2DM, 15 exercise, 5 identifying other methods such as controlling sweets or taking medications. Only 53 participants were aware that T2DM affected other organs Sixty-four of the participants knew about risk factors for T2DM. None of the participants</p>	AB	III

			<p>showed good medication adherence in controlling their T2DM resulting in poor therapeutic outcome as evidenced by uncontrolled HbA1c level. There is a weak relationship between knowledge and adherence resulting in the failure of long-term glycemic control. Hence along with improving knowledge by educational aids like media, SMS, handouts, and educative programs with removal of impending factors for adherence are suggested for achieving good glycemic control and avoiding the complications where healthcare providers have an important role</p>		
<p>Van Alsten and Harris (2020)</p>	<p>To determine if cost related nonadherence (CRN) is associated with higher all-cause and disease-specific mortality among patients living with diabetes and cardiovascular disease in a representative sample of U.S. adults.</p>	<p>N = 39,571 patients with diabetes N = 61,968 patients with cardiovascular disease N = 124,899 patients with hypertension</p> <p>Patient data from the 2000 through 2014 releases of the National Health Interview Surveys.</p> <p>Retrospective design</p>	<p>On average, 15% of the sample reported CRN in the year before the interviews. After adjusting for confounders, CRN was associated with 15% to 22% higher all-cause mortality rates for all conditions (diabetes hazard ratio [HR] = 1.18; 95% CI, 1.1–1.3; cardiovascular disease [CVD] HR = 1.15; 95% CI, 1.1–1.2; hypertension HR = 1.22; 95% CI, 1.2–1.3). Relative to no CRN, CRN was associated with 8% to 18% higher disease-specific mortality rates (diabetes HR = 1.18; 95% CI, 1.0–1.4; CVD HR = 1.09;</p>	A	IV

			95% CI, 1.0–1.2; hypertension HR = 1.08; 95% CI, 0.9–1.3).		
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Appendix D

Algorithm for Project



Appendix E

Medication Adherence Questionnaire

English

Medical Assistant Initial:

Check boxes

Questionnaire complete/given Educational Brochure given

<p>Medication Compliance Questionnaire: Type 2 Diabetes Mellitus Patient Name:</p>
1. How often do you forget to take your medication?
2. How often do you decide not to take your medication?
3. How often do you miss taking your medication because you feel better?
4. How often do you decide to take less of your medication?
5. How often do you stop taking your medications due to side effects?
6. How often do you take your medication when traveling?
7. How often do you not take your medication because you run out?

Subashree, S, Revathy, S., & Dipali, M. (2016). Knowledge and compliance status among diabetes mellitus patients in a tertiary care teaching hospital. *Journal of Pharmaceutical and Biomedical Sciences*,6(1), 51-59.

Spanish

Medical Assistant Initial:

Check boxes

Questionnaire complete/given Educational Brochure given

Cuestionario de cumplimiento de medicamentos	
Nombre:	
1.	¿Con qué frecuencia se olvida de tomar su medicamento?
2.	¿Con qué frecuencia decide no tomar su medicamento?
3.	¿Con qué frecuencia omite tomar su medicamento porque se siente mejor?
4.	¿Con qué frecuencia decide tomar menos de su medicamento?
5.	¿Con qué frecuencia deja de tomar sus medicamentos debido a los efectos secundarios?
6.	¿Con qué frecuencia toma su medicamento cuando viaja?
7.	¿Con qué frecuencia no toma su medicamento porque se le olvida?

Appendix F

Knowledge Questionnaire

Medical Assistant Initial:

Check boxes

Questionnaire complete/given

Educational Brochure given

<u>Knowledge questionnaire</u>	
1. Have you heard of a condition called diabetes?	
	Yes
	No
	I do not know
2. If so, do you think more and more people are affected by diabetes?	
	Yes
	No
	I do not know
3. Duration of diabetes mellitus	
	Less than 5 years
	5-10 years
	11-15 years
4. Do you know what treatment you're in?	
	Oral and diabetic medication
	Insulin
	Both
	I do not know
5. Do you think diabetes can affect other organs?	
	Yes
	No
	I do not know
6. If so, which organs?	
	Eyes, heart, lungs, stomach, kidney, feet, brain, hands, nerves, others
7. Do you know the risk factors for diabetes?	
	Yes
	No
8. What are the risk factors for diabetes?	
	Overweight, High Blood Pressure, Family History, Mental Stress, Candy Consumption, Lack of Activity
9. Do you know that diabetes can be prevented?	
	Yes
	No
	I do not know
10. If so, how can it be prevented?	
	Diet, exercise, others
11. How often do you not take your medication because of the cost?	

Subashree, S, Revathy, S., & Dipali, M. (2016). Knowledge and compliance status among diabetes mellitus patients in a tertiary care teaching hospital. *Journal of Pharmaceutical and Biomedical Sciences*,6(1), 51-59.

Medical Assistant Initial:

Check boxes

 Questionnaire complete/given Educational Brochure given

Questionario de conocimientos	
1. ¿Has oído hablar de una condición llamada diabetes?	
	Sí
	No
	No sé
2. Si es así, ¿crees que cada vez más personas se ven afectadas por la diabetes?	
	Sí
	No
	No sé
3. Duración de la diabetes mellitus	
	Menos de 5 años
	5-10 años
	11-15 años
4. ¿Sabes en qué tratamiento te encuentras?	
	Medicamentos orales y para la diabetes
	Insulina
	Ambos
	No sé
5. ¿Crees que la diabetes puede afectar a otros órganos?	
	Sí
	No
	No sé
6. Si es así, ¿qué órganos?	
	Ojos, corazón, pulmones, estómago, riñón, pies, cerebro, manos, nervios, otros
7. ¿Conoces los factores de riesgo para la diabetes?	
	Sí
	No
8. ¿Cuáles son los factores de riesgo para la diabetes?	
	Sobrepeso, PRESIÓN Arterial Alta, HX Familiar, Estrés Mental, Consumo de Dulces, Falta de Actividad
9. ¿Sabes que la diabetes se puede prevenir?	
	Sí
	No
	No sé
10. Si es así, ¿cómo se puede prevenir?	
	Dieta, ejercicio, otros
11. ¿Con qué frecuencia no toma su mediación debido al costo?	