

2022

Evaluation of a Comprehensive Diabetes Mellitus Protocol at a Rural, Federally Qualified Health Center in Southern West Virginia

Hannah D. Davis

West Virginia University, hdhellems@mix.wvu.edu

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Evaluation of a Comprehensive Diabetes Mellitus Protocol at a Rural, Federally Qualified Health
Center in Southern West Virginia

Hannah Davis, APRN, FNP-C

Doctor Nursing Practice Project submitted to the
School of Nursing at West Virginia University
in partial fulfillment of the requirement for the degree of
Doctor of Nursing Practice

Dr. Ubolrat Piamjariyakul, PhD, RN, Faculty of Record

Dr. Kesheng Wang, PhD, MA, BS

Dr. Kendra Barker, DNP, APRN, FNP-BC

Dr. Jessica Workman, PharmD, CDCES

Dr. Pamela Edens, DNP, APRN, FNP-BC

Department of Nursing

Morgantown, WV

2022

Keywords: type 2 diabetes mellitus protocol, evaluation, provider behaviors, rural health

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Abstract

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Background: Diabetes mellitus is a chronic disease that affects nearly 34 million Americans. In rural Appalachia, the population is affected disproportionately at a rate of 14% compared to the national average of 10%. Diabetes is a lifelong, chronic condition managed best by a multidisciplinary team-based approach to achieve optimal disease control. Best practices in the care of diabetes support the use of evidenced based care protocols and leveraging technology to decrease the burden of disease. Type 2 diabetes mellitus (T2DM) is the most common type, making it the focal population for evaluation.

Purpose: The purpose of this project was to evaluate the impact of a standardized diabetes mellitus protocol for patients with T2DM at a rural federally qualified health center (FQHC) in rural southern West Virginia. Program evaluation completes the care cycle. This information can inform stakeholders about a protocol's effectiveness, thus leading to recommendations for change to improve T2DM education and outcomes in healthcare delivery.

Intervention and Methods: Program Evaluation was completed using a retrospective chart review and a provider survey. Objective 1 was to evaluate the diabetes protocol using seven core quality measures (hemoglobin A1c, blood pressure, low density lipoprotein [LDL] cholesterol, diabetes self-management education (DSME), annual urine microalbumin, retinopathy, and neuropathy exams) over three years (pre-protocol T1 and post-protocol T2 and T3). Objective 2 utilized a provider survey to determine behaviors regarding Type 2 Diabetes Mellitus (T2DM) protocol and diabetes education team awareness and utilization.

Results: Results for Objective 1 found statistically significant improvement at T3 for diastolic blood pressure and annual microalbumin, but not for other metrics. Overall, most metrics noted improvement or stabilization over all time periods despite the evaluation taking place during the COVID-19 pandemic. Results for Objective 2 found that majority of providers were aware of the T2DM protocol and utilized the diabetes education accreditation program (DEAP) team regularly.

Conclusion: The evaluation provided valuable insight on the current efforts to reduce the burden of diabetes mellitus at the facility in rural West Virginia. Over half of all core quality measures met facility benchmarks, however measures for DSME referral, A1c, retinopathy and neuropathy exams are still lower than expected. All providers agree that COVID-19 had a negative impact on patient care. Recommendations for improvements in practice include a patient-individualized approach to care with increasing utilization of the DEAP team, and continuous provider support of DSME in the management of patients with T2DM.

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Background

Problem Description

Diabetes mellitus is a chronic disease that affects nearly 34 million Americans (Centers for Disease Control and Prevention [CDCP], 2019a). Type 2 diabetes mellitus (T2DM) is the most common form of diabetes; 90% of all cases are type 2. T2DM is defined as the decrease in beta cell function that limits insulin production, or the decreased cellular response to insulin, called insulin resistance (CDCP, 2019b). This leads to insulin deficiency and resultant hyperglycemia, which when uncontrolled may result in increased morbidity and mortality.

The Problem of Diabetes Mellitus in WV

Diabetes affects individuals in rural Appalachia disproportionately; when compared to the national average of around one in ten individuals, more than one in seven individuals (approximately 15%) in West Virginia (WV) have a diagnosis of T2DM (National Institute of Diabetes and Digestive and Kidney Disease [NIH], 2020; WV Department of Health and Human Resources [DHHR], 2018). Diabetes is more prevalent among individuals over age 65 years, persons that completed lower than a high school education, and those with an annual household income of less than \$15,000. It is estimated that diabetes costs an estimated \$2.5 billion in WV each year, which includes the costs of serious complications such as heart disease, stroke, kidney disease, and amputations (Allen, 2019).

Attention must be paid to cultural nuances and external forces on the people of WV for a thorough understanding of the population. The entire state of WV is in central Appalachia, a rural mountainous region in the eastern United States. While rugged and beautiful, the economy has been depressed for years with over 16% of West Virginians living below national poverty levels (O'Leary, 2020). Median per capita income for West Virginia was \$27,446 in 2019, about

\$8,000 lower than the national levels (US Census Bureau, 2020). Specifically in the local region for this clinic, per median income is even lower at \$23K. Overall, WV has one of the highest high school graduation rates in the nation at 92% however; the rate of graduation for the county of interest for this project is only 83%. Six percent of residents do not advance past the ninth grade. (Open Data Network, 2018). Other healthcare and social disparities that contribute to a higher burden of disease include a shortage of primary care providers, poor transportation infrastructure, and housing, food, and financial insecurity (Beverly et al., 2020).

Culturally, Appalachians are typically described as very independent, close to nature and with a deeply held belief in God. They are friendly, kind, and helpful, known for taking care of the needs of others. Carpenter and Smith (2018) describe Appalachians as self-determined and self-reliant. Appalachians also have a strong sense of what is right and what ought to be. They have a deep mistrust of anyone who is new, or anyone who is identified as a stranger. Appalachian culture is noted for resistance to change (Hilly, 2015). Understanding the social factors and the strong influence of Appalachian culture on health, wellness and disease management is important to improving population health.

Managing Diabetes with an Evidence-Based Protocol in a Primary Care Clinic in WV

Protocol driven care based on best practices has been shown to improve chronic disease management. Protocols drive provider decisions, provide clear patient expectations, and prevent morbidity and mortality (Kurdi, 2015). The ADA and the AACE are two expert bodies that author clinical practice guidelines (CPG) to guide treatment. Updated periodically, these bodies promote evidenced based, cost effective, cost efficient, patient centered care, delivered by a multidisciplinary clinical team. The use of decision support tools and patient registries are recommended to improve care. Diabetes self-management education programs (DSME) feature

prominently in both CPG's. Strategies are designed to reduce the morbidity and mortality of diabetes, reduce the overall burden of disease, and maximize the patient's health and functional status. While care is delivered at the individual patient level, both groups recommend the use of systematic data collection and monitoring of the entire diabetes population to better understand how the larger population is being impacted. Said another way, does the health of the community improve as the health of the individual improves? (ADA, 2020; AACE 2015). The clinic site of this evaluation adopted a standardized protocol to direct the care of patients with diabetes, which incorporates the American Diabetes Association (ADA) and American Association of Clinical Endocrinology (AACE) elements (see Appendix A for detailed protocol). The diabetes protocol at the facility was created with a focus on rural health with an understanding of the social and cultural norms of the community it serves. This aided in the successful creation of a diabetes program to improve the health and outcomes of patients in rural Appalachia of WV.

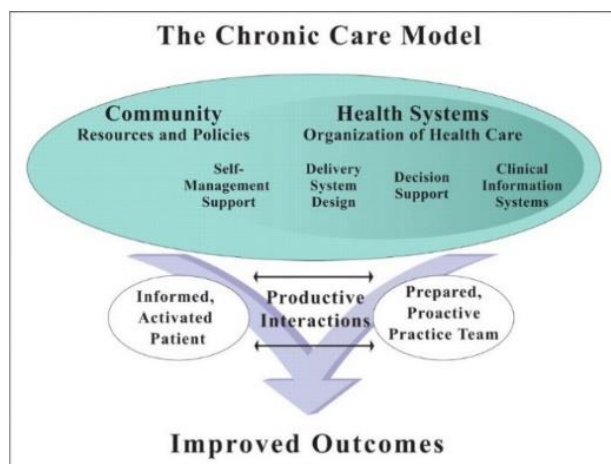
The clinic in this evaluation is a federally qualified health center (FQHC) facility located in southern WV serving over 16,000 patients. The leadership team sought to improve the care approach to more than 1,700 patients that have a diagnosis of T2DM. These patients had suboptimal outcomes in numerous areas; in addition to uncontrolled diabetes, many had multiple coexisting comorbidities such as cardiovascular and kidney disease. Initially, the agency did not have a formal DSME program. Leadership was concerned not only for the health of their patients and the greater community, but that these poor patient outcomes could lead to therapeutic inertia in the clinicians. Karam et al (2020) characterize these care burdens as a failure to screen, escalate treatments, make appropriate referrals, and manage risk factors and complications. For these reasons, leadership felt compelled to devote resources that would improve the care of

people with diabetes. The Chronic Care Model (CCM) was used to direct initial quality of care program at the facility and will be discussed below.

Conceptual Model used for the Integration of the Evidence Based Diabetes

Evaluation and Management Protocol. The Chronic Care Model (CCM), developed in the U.S. in 1990, was designed to restructure healthcare interactions, particularly regarding chronic conditions, between health systems and communities. The aim of the CCM is to improve the use of existing resources while creating new ones that allows improved health and empowered patient interaction (Baptista et al., 2016). Current trends support aggressive screening for early identification of disease and the use of team-based care such as that employed in the CCM (ADA, 2018).

The CCM incorporates a proactive, evidence-based, and patient-centered approach to care (Grover & Joshi, 2014). It is composed of intersecting components which are essential to driving down the burden of chronic disease. These elements include integrating community resources and policies, redesigning health care delivery, increasing self-management support, leveraging clinical information systems to improve communication and patient engagement. Evidence-based change concepts within each element, in combination, foster productive interactions between informed patients, who take an active part in their care, and support providers with resources and expertise. See Figure 1.

Figure 1*Chronic Care Model (Wagner, 1998)*

When used to guide diabetes care, the CCM has been attributed with decreasing patient morbidity and mortality. Cardiovascular disease declined by 57%, microvascular complications by 12%, and mortality by 66% (ADA, 2020). When used appropriately and in full context, the CCM has promising implications for improving diabetes outcomes and cost savings of over \$7,000 per patient (ADA, 2020). The CCM, already in use at the facility, allows an exchange of healthcare information between providers and patients, with a result being a higher degree of patient engagement and better diabetes control.

The CCM incorporates traditional Appalachian values of independence and seeing themselves as capable and able to direct their own health care. An individualized teaching plan can be specifically adjusted to accommodate low literacy. When the care team is composed of community members, their neighbors, and friends, who share the same values and disposition, patients are more likely to make adjustments that promote a healthy lifestyle and control a challenging disease such as diabetes.

The Development of Diabetes Education Accreditation Program (DEAP) Team

Leading the Evidence Based Diabetes Evaluation and Management Protocol Integration.

The initial plan by the stakeholders of the facility was to create a diabetes work group that would ultimately position the facility to achieve full accreditation as a DSME provider. The work group led a small pilot study with a volunteer receiving DSME provided by one employee of the agency over six months. The pilot needed to show improvement in at least two focus areas (ex. weight loss, Hgb A1c improvement, etc.), which was achieved. The workgroup also completed a Health Resources and Services Administration (HRSA) review that identified areas for improvement in T2DM management. Numerous other data were collected including demographics of the service population and the expected reduction in the burden of disease. Capital resources and cost associated with startup of a DSME program were determined. The impact on clinic flow was analyzed; the economic impact in terms of revenues to the facility was projected. Steps to ensure sustainability were also identified. This work resulted in administrative approval for the new program. National accreditation was granted in February 2018. (S. Ward, personal communication, July 20, 2021).

With accreditation achieved, the diabetes provider team became the Diabetes Education Accreditation Program (DEAP) leaders for the facility, and the membership was expanded in accordance with CDC recommendations to include a certified diabetes educator (CDE), two clinical pharmacists, an advanced practice nurse practitioner (APRN), and a registered nurse (RN). At the recommendation of the facility Board of Directors, an oversight committee was formed to provide ongoing management of patient care. This committee consists of the DEAP team, a physician, the director of nursing (DON), a facility board member, and a community

member. The DEAP established their mission: “To improve the education and care of diabetes patients at the facility.”

The DEAP system intervention adopted a standardized protocol for the care of patients with diabetes at the facility, drawn from the ADA (2018) and AACE (2015) clinical practice guidelines. See Appendix A for the fully detailed outline of the standardized protocol, which is approximately ten pages in length. Over a series of meetings, staff was educated on the protocol and data storage in the electronic health record (EHR) for future data retrieval and program evaluation. Patients and the greater community were informed of the new care approach via flyers posted in the clinic and internet marketing. Following the successful pilot program, the standardized protocol was formally implemented in January 2020 with integration as a linked document into the EHR. Prompts were later installed into the EHR for a simplified referral process for patients with a T2DM diagnosis.

Literature Review and Synthesis

This literature review is limited to the research on program evaluation and the metrics commonly used to measure T2DM control. A comprehensive literature search was performed using PubMed, Medline, and CINAHL from December 2020 through March 2021 using the following question in Population, Intervention, Comparison, Outcome (PICO) format: How does the adoption of a standardized diabetes mellitus protocol affect core quality measures for T2DM patients, and provider perceptions over a two-year period (from January 2019 to December 2021)?

The databases were searched utilizing keywords from the PICO in addition to relevant terms for core quality measures including self-management education, and terms relative to the clinic setting including rural health and the chronic care model. The results yielded over 500

articles for review. Articles were excluded if they were published before 2010, not of English language, and if the article included persons less than 18 years of age. A total of over 40 articles were reviewed and synthesized to compile a list of best practices for evaluating the provision of care for patients with diabetes. Diabetes is a complex disease process that requires a comprehensive medical approach for the management and prevention of its comorbidities. The ADA Standards of Medical Care in Diabetes clinical practice guideline (2018) and AACE clinical practice guideline (2015) support the use of a comprehensive medical evaluation to confirm diabetes diagnosis, evaluate comorbidities, review treatments, and formulate a self-management plan. From this thorough literature review and using the information from these guidelines, best practices for diabetes care were evaluated and synthesized in the following section into the categories of Screening and Diabetes Management.

Best Practices for Diabetes Care Synthesis

Screening. The first best practice in T2DM care begins with early recognition of at-risk populations. Screening of diabetes in adult patients begins at age 45 and is repeated every three years for those with normal findings (ADA, 2018). Screening should begin earlier if the patient is overweight or obese with a body mass index (BMI) ≥ 25 , or if Asian American a BMI ≥ 23 , and has at least one other additional risk factor such as: (a) maternal history of diabetes or gestational diabetes (GDM) (b) family history of T2DM in a first or second degree relative, (c) ethnic backgrounds (Native American, African American, Latino, Asian American, Pacific Islander) or (d) insulin resistance (acanthosis nigricans, hypertension, hyperlipidemia, polycystic ovarian syndrome, or small-for-gestational-age birth weight). Type 2 diabetes mellitus is diagnosed by the confirmation of two abnormal screening tests on two different occasions. The four accepted screening tests and diagnostic measures are:

- Fasting plasma glucose ≥ 126 mg/dL
- 2-hour plasma glucose ≥ 200 mg/dL during oral glucose tolerance testing (OGTT)
- Hemoglobin A1C $\geq 6.5\%$
- Random plasma glucose ≥ 200 mg/dL, with classic symptoms of hyperglycemia; polyuria, polydipsia, polyphagia

Once the diagnosis is confirmed, it is critical that the patient's chart reflects a diagnosis of T2DM. Accurate recording of pertinent medical facts ensures that the patient will have access to proper monitoring and care.

Diabetes Management: Seven Core Measures. The following section describes the seven most common core measures evaluated in this study per the ADA 2018 and AACE 2015 national guidelines. These seven core measures review glycemic control, assess the provision of a self-management plan through some form of diabetes education, evaluate for comorbidities, and gauge treatment efficacy.

- ***Hemoglobin A1c Monitoring and Management.*** Hemoglobin A1c is a test that measures the amount of glucose attached to hemoglobin, which is the part of the red blood cell that carries oxygen to the body (U.S. DHHR, 2020). Hemoglobin A1c is an indirect measure of the glucose average over three months (ADA, 2018), which should be evaluated every 3 months for uncontrolled T2DM patients, and every 6 months for controlled T2DM patients. This glucose measure is widely utilized, due to its ease of use, lack of need for fasting, greater pre-analytical stability, and less variations with illnesses. A hemoglobin A1c less than 7% reduces the risk of microvascular and macrovascular complications.

- ***DSME Utilization.*** The use of DSME improves care and decreases poor outcomes (ADA, 2018). Although extremely successful, DSME can be limited in use due to lack of knowledge, availability, and feasibility related to cost. Canada, Shah & Booth (2009) found that DSME was utilized by only 25-30% of the T2DM population. Lower use of DSME was noted for older adults, immigrants, people with lower socioeconomic backgrounds, and individuals with other physical or mental health conditions (Cauch-Dudek, Victor, Sigmond, & Shah, 2013). Poor patient compliance with DSME were found to be related to decreased awareness, scheduling conflicts, and inconvenient locations (Gucciardi-et al., 2012). Primary care providers also were found to have a low referral rate due to low awareness and limited access (Gucciardi et al., 2011). Despite low DSME utilization, Gucciardi (2020) reported on the successful use of onsite nurse-dietician led education interventions, which resulted in a lowering of hemoglobin A1c. Positive impact of DSME was described in a systematic review by Chrvala et al. (2016). One hundred twenty papers, all randomized control trials, were included, examining a broad variety of DSME interventions (118) and their associated impact on A1c values. Nearly 70% of the interventions showed an improvement in A1c values, specifically in persons receiving more than 10 hours of education in a group setting having the best outcomes. Those with higher A1c values (>9 percent) had the most significant lowering with DSME. Nearly 84% achieved reduction in A1c levels, further providing evidentiary support of DSME.
- ***Blood Pressure Monitoring and Management.*** Blood pressure control is an important step in preventing cardiovascular disease. Elevated blood pressure,

specifically a sustained pressure over 140/90 mmHg, is a common comorbidity found in uncontrolled patients with diabetes. Studies have shown a positive relationship between insulin resistance and hypertension. When insulin levels are high, the body retains salts and fluids, creating an increased vascular volume. Over time the vessels become stiff, resulting in high blood pressure. Insulin resistance and hypertension double the likelihood that the patient will go on to develop cardiovascular disease (Jovinally, 2020).

- ***Dyslipidemia Assessment and Control.*** Cholesterol is a naturally occurring substance in the body, important to overall health. Lipoproteins include high-density lipoprotein (HDL) (good cholesterol), low-density lipoprotein (LDL) (bad cholesterol) and triglycerides. When cholesterol levels are too high, plaque builds up on blood vessel walls, causing a narrowing or blockages. When combined with hypertension, as discussed above, this dramatically increases the risk of developing atherosclerotic cardiovascular disease (ASCVD) such as coronary artery disease, chest pain, myocardial infarction, stroke, transient ischemic attacks, and peripheral vascular disease (AHA, 2016). Elevated levels of (LDL) cholesterol are directly linked to ASCVD (AACE, 2015). The burden of disease related to dyslipidemia in WV is notable. The state has the highest rate of myocardial infarction (7.5%) and coronary heart disease (8%) in the nation (WV DHHR, 2018).

Increased LDL cholesterol is commonly seen in poorly controlled diabetes and is related to a multitude of factors such as diet, elevated glucose, and adiposity (AHA, 2016). High LDL is associated with poor outcomes in diabetes (AACE,

2015). To improve outcomes and reduce progression of cardiovascular disease, a lipid blood panel should be annually assessed in patients with diabetes with a goal of achieving an LDL <100 mg/dl.

- ***Urine Microalbumin or Albumin to Creatinine Ratio Testing for Diabetic***

Nephropathy. Over time, poorly controlled diabetes contributes to a condition called diabetic nephropathy, a decline in kidney function that often leads to kidney failure. Decreased kidney function also plays a role in the development of hypertension. Studies have shown that 9 in 10 individuals are unaware that they have a diagnosis of chronic kidney disease (CDC 2019a). Furthermore, The National Kidney Foundation (2016) has reported that 35% of all patients with diabetes have chronic kidney disease; this is projected to increase to 50% by 2025. Dialysis is a mainstay treatment option for end-stage kidney disease, which is not only costly but has a negative impact on quality of life. The average annual cost for one year of hemodialysis is around \$72,000 and about \$53,000 for peritoneal dialysis (Johnson, 2014).

Early detection of declining kidney function can be accomplished with urine microalbumin testing, which looks at the albumin to creatinine ratio. This is an easy to obtain test in the primary care setting. A normal albumin/creatinine ratio is defined as less than 30mg/g (ADA, 2018). Treatment includes strict glyceemic control and the use of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) (ADA, 2018). Both the ADA and AACE recommend annual microalbumin screenings.

- ***Foot Screenings for Diabetic Neuropathy.*** Uncontrolled diabetes can also lead to the damage of peripheral nerves, resulting in impaired or complete loss of sensation, typically in the feet. Loss of sensation can lead to ulcerations, infections, and in some cases, amputations. Nearly 50% of patients will have some form of diabetic neuropathy (Zimmerman, 2016). In 2010, 73,000 adults with diabetes underwent amputation (McDermott, 2018). While foot screenings for patients with diabetes have reduced amputations by over half in the last 20 years, the number of individuals with complications is still a concern (McDermott, 2018). This high risk of complications, cost, and long-term care can be positively impacted through foot exams.
- ***Annual Dilated Eye Exam Screening for Diabetic Retinopathy.*** Overtime, T2DM can cause damage to blood vessels in the eye due to hyperglycemia. It is the leading cause of new cases of blindness in people ages 20-74 years; most of these are preventable (Research to Prevent Blindness, 2016). It is estimated that as many as 40% of T2DM patients on insulin and 24% of patients taking oral hyperglycemic medications will develop retinopathy after five years (Zimmerman, 2016). This number greatly increases to 84% and 53%, respectively, after 15 to 19 years (Zimmerman, 2016). The annual diabetes eye examination is key to early recognition of retinopathy (ADA, 2018).

Rationale for Study

The Healthy People 2030 initiatives align with the rationale of the evaluation to improve the care of patients with T2DM. The Healthy People 2030 initiatives (U.S. Department of Health and Human Resources [DHHR], 2020) recommend:

- An increase in the proportion of people with diabetes who get formal diabetes education, with a target goal of 55.2 percent.
- An increase in the proportion of adults with diabetes who have a yearly eye examination, with a target goal of 67.7 percent.
- The reduction in the rate of foot and leg amputations in adults with diabetes with a target of 4.3 percent.

The Healthy People 2030 initiatives and core quality metrics align with the facility's vision, philosophy, and the T2DM protocol. The facility's philosophy is to provide patient care that includes individual, family, and community wellness, regardless of payment in a rural, underserved community (Rainelle Medical Center, 2020). The facility's overarching goal is to improve the health of the individuals with T2DM through care process change. The facility had a goal to increase the number of T2DM patients who receive DSME, an annual retinal examination, and annual diabetic neuropathy screenings to prevent complications. The recommendations provide feasible and accurate goal setting when evaluating the current core quality measure outcomes.

A project's strengths, weaknesses, opportunities, and threats (SWOT) analysis was performed to provide the facility with a snapshot of the internal and external factors that may help or harm this evaluation project (Appendix B). The strengths of the evaluation were multiple including increased provider awareness and improved core quality measure outcomes via protocol driven care. The evaluation was feasible and cost neutral that was supported by key stakeholders. Weaknesses included lack of provider use of the standardized protocol with resultant poor outcomes of CQM's. Opportunities for improved care for patients with T2DM were substantial. These included data driven support for T2DM program expansion, leading to

improved patient access to care. This in turn reduced comorbidities related to T2DM and improves population health. Threats to the evaluation included the COVID-19 pandemic, as this has delayed the evaluation from 12 to 24 months. Diabetes education staffing was relocated to other positions due to facility need and staffing shortages, creating a strain for DSME.

A Framework for Quality Improvement for System Level Change

This system evaluation study utilized the CDC Framework for Program Evaluation in Public Health (FPEPH). Evaluation is defined as a systemic method that determines the effectiveness of a program or service, based on specific criteria developed by stakeholders. Program evaluation is infrequently utilized in most practices; however, it is a vital aspect to program sustainability (Moule et al., 2017). While various metrics were identified to evaluate the impact of the standardized protocol at the facility, the DEAP team did not expressly select an evaluation model. Various evaluation models exist; one of the most well-known and studied models is the CDC Framework for Program Evaluation in Public Health (FPEPH). Multiple papers were reviewed applying this model to diabetes program evaluation. The author recommended this tool to guide facility evaluation as it is easy to follow with proven results that can effectively assist with strategy and program improvement.

The FPEPH uses a systematic six step approach to improve and account for public health actions by steps that are useful, feasible, ethical, and accurate (Figure 2) (CDC 2017). A brief synthesis of the activities conducted at the facility for each step are described in the evaluation plan section.

Figure 2

CDC Framework for Program Evaluation (CDCP, 2017).



FPEPH Step 1: Engage Stakeholders. The first step of FPEPH is the engagement of stakeholders. Stakeholders include persons involved in program operations (sponsors, administration, staff), those served or affected by the program (patients, communities, skeptics), and primary users of the evaluation (CDCP, 1999). Stakeholder values and perspectives drive the program from inception; without their consideration and engagement, a program may fail to meet stakeholder expectations. The risks could be that evaluation results may be ignored, discounted, or rejected.

FPEPH Step 2: Describe the Program. In the second step, the program is described in terms of need, results, and resources needed for implementation. Program descriptions convey the mission and desired outcomes of the program being evaluated (CDC, 1999). A clear and logical description of the program, agreed on by all stakeholders, ensures that program evaluation results will have maximal application. Specifically, program need, expected results, activities of the program, resources needed, and context are considered. A logic model is often used to illustrate the various components in this stage.

FPEPH Step 3: Focus the Evaluation Design. In step three of the FPEPH, the design of program evaluation is determined. The selected design should be useful, feasible, ethical, and accurate (CDCP, 1999.) It must be efficient (easy to execute), evidence-based, and reflect the highest priorities of the stakeholders. The evaluation metrics link program purpose and stakeholder values. In this step, the methodology is determined by asking what data do we need and how will we collect it? Other considerations in this phase include consideration of patient safety and confidentiality, minimizing any patient risk.

FPEPH Step 4: Gather Credible Evidence. Compiling information for stakeholders is an important aspect of evaluation. The goal of this step is to collect information that gives a rigor of comprehensive evidence-based program evaluation. In addition to selecting metrics as described in Step 3, it is essential to determine the statistical significance of the program evaluation and how much data is needed to answer such questions. How big will our sample size be? What level of confidence do we need? Is there adequate power to detect effect? For clinical and practical significance, the stakeholders need to engage in the program evaluation from the design through interpretation of the results and dissemination, as they lend credibility and increase the likelihood results will be accepted. Engaging stakeholders are essential for successful program evaluation, sustainability, and continuous improvement.

FPEPH Step 5: Justify Conclusions. Activities in this step consider what the findings mean and their significance to the overall program. The results will guide stakeholders' decisions on what to do with the results. For stakeholders to decide that the conclusions are justified, great care must be taken with the process of data analysis and synthesis. Statistical and clinical significance will be determined. When the results align with stakeholder values and expectations,

stakeholders are likely to accept the conclusions. Considerations in this step include discussing bias, study limitations, and unexpected findings.

FPEPH Step 6: Ensure Use and Share Lessons Learned. Activities involved in the final step of the evaluation model revolve around disseminating the results and creating mechanisms to use the results. Stakeholders must ensure that the evaluation is adequately portrayed and share lessons learned. Strategic work must be done in this phase, with special attention paid to not only sensitively communicating the results, but to also with a consideration of how stakeholders should translate the new information into practice. Steps must be taken to ensure that the results are not misused. Involving stakeholders from the design of the study through dissemination will enhance the positive outcomes of the program evaluation. Team-based and co-learning approach through continuous quality improvement lens will prevent emotionally charged of declining morale or inertia.

Specific Aims

The specific aim of this program evaluation was to lead the FQHC in rural, WV through the first evaluation and quality improvement (QI) project of their standardized approach to the care of people with T2DM, with a focus on population health, identifying program/care strengths and gaps, and informing future practices for the agency. Two primary objectives were identified to be explored.

Objective 1: Are there significant differences on core quality measures (hemoglobin A1c, B/P, LDL, DSME, annual microalbumin, eye exam and foot exam) between baseline (2019) and 1- and 2-years follow-up (2020, 2021)?

Objective 2: What are the perceptions and acceptability of the DEAP team as measured by the provider questionnaire? What are the recommendations from providers to improve the management of T2DM at the facility?

Methods

Context

The facility's T2DM evidence-based protocol had not been formally evaluated since implementation of the protocol. After having the protocol in place for two years, a formal program evaluation is timely to evaluate whether the protocol needs revision to meet the needs of the staff and an underserved population of patients with T2DM in rural Appalachia. This is the first evaluation after implementation of a T2DM protocol and DEAP team to provide high-level, evidence-based practices to the rural area. These services were previously not available or were limited in access to patients in the community and surrounding areas. The results of the study will be used for future continuous quality improvement.

Timeline for the T2DM Protocol Program Evaluation Study

An evaluation of the current diabetes protocol was completed in the spring of 2022. This program evaluation project was the culmination of doctoral work for a nursing practice degree that exemplified an area of interest by a clinic staff provider supportive of the T2DM protocol and the work of the DEAP team. The following timeline and description of activities are as follows:

Time	Task
Fall 2020-21	Engagement with FQHC stakeholders to explore the potential for T2DM Protocol Program Evaluation
January 2022	WVU Institutional Review Board (IRB) approval for the DNP Program Evaluation study
February 2022	Chart Review completed
March 2022	Provider survey completed
April – May 2022	Data analysis completed
Summer 2022	Data write up and presentation

Interventions

This program evaluation study used a retrospective chart review one-group pretest–posttest design to determine the effects of the DEAP intervention on the measures outlined in Objective 1. The benefit of this design is justifiable when only one group of participants (T2DM patients) is available and when creating a control group is not possible or unethical (Creswell & Creswell, 2017). A cross-sectional survey was used to address Objective 2 to determine provider behaviors related to the T2DM protocol and DEAP use.

Study Participants

Inclusion Criteria.

Objective 1

- (1) Patients with a diagnosis of T2DM (ICD-10 code - type 2 diabetes mellitus), non-pregnant, between the ages of 18 and 75, having at least one primary care visit for the treatment of T2DM in the three periods (2019, 2020, and 2021)
- (2) Eligible clinic providers included those family practice physicians, physician assistants (PAs), or nurse practitioners (NPs) that were full-time primary care clinicians were employed by the facility during the entire time frame of the study.

Objective 2

All providers, regardless of type or status, were invited to complete the survey regarding behaviors on T2DM protocol and DEAP use with recommendations for T2DM management.

Exclusion Criteria.**Objective 1**

Pediatric clinicians were excluded, as their patient population does not meet age related inclusion criteria. Nephrology patient data was also be excluded due to its subspecialty population and inclusion of patients outside of the facility. Chart review exclusions also included pregnancy, deceased patients, and type 1 diabetes mellitus codes.

Objective 2

Pediatric and subspecialty providers were also excluded from the provider survey.

A total of five physicians and three PAs met inclusion criteria and the retrospective chart review was planned for charts completed by these specific providers. Patient care data from the team champion nurse practitioner was excluded to minimize bias. Twenty-seven providers received an email for the anonymous survey.

Setting

The protocol evaluation was conducted at a FQHC facility in rural WV. The implementation of the protocol served as an educational intervention for family practice providers to guide care to over 1,700 T2DM patients at the facility. This project was determined to be congruent to the facility's strategic plan to improve the care of patients with T2DM by utilizing an evaluation model including 7 CQM's and a provider survey.

Budget

Evaluation of the T2DM protocol was budget neutral and was affordable. The work of the doctoral student, including conducting program evaluation, represents no additional cost to the agency. The student is not a member of the DEAP team; however, as a provider her compensation included administrative time for QI projects. Data collection, retrieved by the student represents a usual and customary function of this department. Appendix D outlines estimated costs including the hourly wage of the team champion nurse practitioner and DEAP staff members during meeting times and data collection. Much further downstream are potential cost savings expected to result by reducing the burden of disease.

Evaluation Plan

Operationalizing the FPEPH

As noted previously, the FPEPH model was used to structure this program evaluation. Each step of the framework was systematically operationalized to assess whether the T2DM Protocol at the FQHC was effective based on the specific criteria of the objectives noted above. A brief synthesis of the activities conducted at the facility for each step are described in the following section.

FPEPH Step 1: Engage Stakeholders

Facility stakeholders were greatly concerned for the health status of those with diabetes, their families, and the larger community. They valued providing care that was highly individualized, using a team approach with community partners. They wanted to reduce the burden of disease and improve the client's functional status. Persons served by the program also shared this value. Patients with diabetes wanted to feel good, be able to work and enjoy activities with family and friends. They wanted to live longer, eat better, and spend less money on health

care. They wanted to take fewer medications and spend less time in doctor's offices and hospitals. They valued knowledge and the skills to be able to care for themselves. The users of the evaluation results value a cost-effective, cost-efficient delivery system. An investment in resources to improve the health of this specific population could yield a high return, reducing costs associated with chronic disease. A well-run efficient diabetes program could elevate the status of the facility in the community, demonstrate their care is evidenced based, increase sources of funding based on high quality care, possibly free up resources to develop programs for other disease states, and increase provider job satisfaction.

The key stakeholders involved in the T2DM protocol evaluation included: The team champion nurse practitioner, DEAP providers, advisory committee, administration, primary care providers, support staff (i.e., nursing), information technology (IT), patients, and members of the doctoral capstone committee. The specific stakeholders involved in the aims and results of the evaluation are the administrators, DEAP team, and advisory committee.

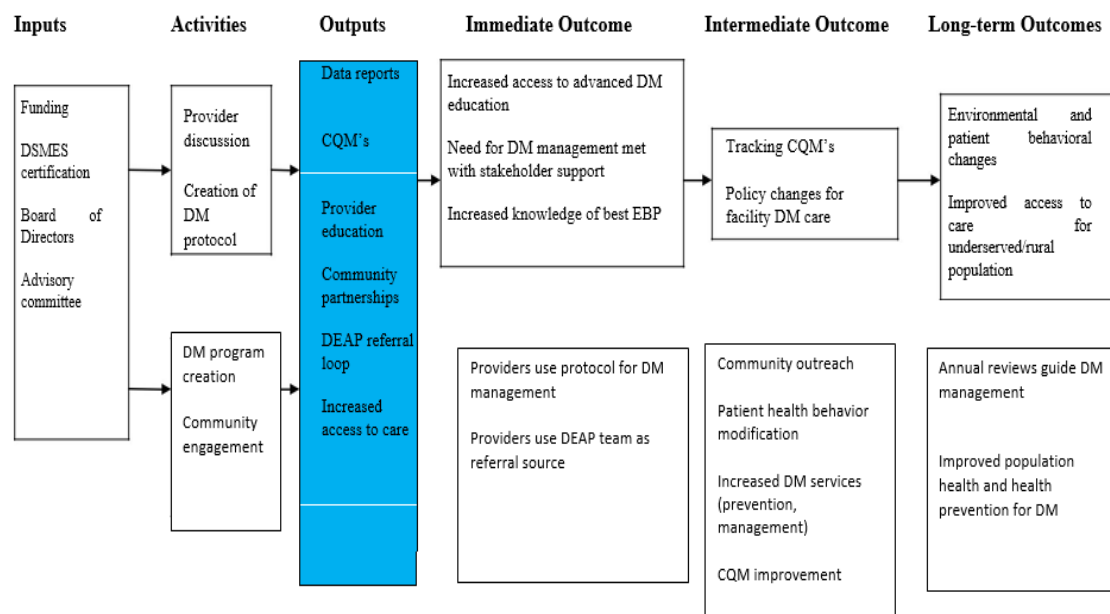
The team champion nurse practitioner led the initial discussion for protocol evaluation with the DEAP team in October 2020. This work group was primarily responsible for conducting the evaluation. The evaluation produced two important pieces of information. It provides information regarding the health of the facility's patient population before and after adoption of the standard protocol. It also provides opinion information about the providers who utilize the standardized protocol. With these main objectives in place, the author engaged additional stakeholders in the agency, including the Chief Executive Officer (CEO). Full approval was received in January 2021, to proceed with no adjustments being made (Appendix E).

The process used for data retrieval was established during a meeting in late 2021. Originally, there was a plan to pull data after 12 months of data. However, due to confounding

factors of the COVID-19 pandemic, a cumulative report of 12 and 24 months of data will be analyzed. The team leader extracted the initial report from the data analysis base, AZARA, and then used a manual chart review from the EHR for 12- and 24-months' data. The author created the provider survey with assistance from the DEAP team and members of the doctoral capstone committee. The team champion nurse practitioner worked with IT to create an emailed survey for provider questionnaire disbursement using Qualtrics. The team champion nurse practitioner led regular meetings with the DEAP team starting in January 2022 for data collection and analysis. The team discussed CQM's and provider questionnaire outcomes. The team overseen all evaluation operations and communicated updates to stakeholders.

FPEPH Step 2: Describe the Program

The standardized protocol adopted for the facility was drawn from clinical practice guidelines produced by experts in the field (See Appendix A for standardized protocol). Many patients with T2DM did not enjoy optimal control of their diabetes and suffered significant consequences in the form of co-morbid diseases, creating program necessity. The expected results were better disease management, and a more engaged, self-sufficient patient population. Resources, human and technical, were in place and are easily allocated. There was energy and enthusiasm to create a new way of doing things. The DEAP team looked forward to a much more visible role in the care of patients with diabetes; providers welcomed additional support in the care of complex patients. Figure 4 illustrates a logic model of the diabetes program at the facility, its inputs, activities outputs and goals.

Figure 4*Protocol Logic Model*

Over the course of several meetings in late 2019, a DEAP provider and medical director wrote the standardized protocol to guide the care of persons with T2DM (S. Ward, personal communication, July 20, 2021). The DEAP team provided a written copy of the typed standardized protocol to providers during a routine meeting in late 2019. The standardized protocol is not currently housed within the electronic health record (EHR). The standardized protocol is divided into three diagnostic groups (type 1, type 2, and pre-diabetes); however, T2DM was the focus of this evaluation. Providers can review the standardized protocol with major themes of care including:

- History and physical
- DSME

- Pharmacologic management
- Biometrics (A1C, BP, LDH)
- Preventive health screenings (vaccines, foot exam, eye exam, etc.)

The protocol is accessible to all providers via an emailed, typed form. The seven core quality measures provide objective data in evaluating outcomes. All providers have been oriented to the standardized protocol with an expectation of its use to guide diabetic patient care. DSME is one facility core quality measure that is of particular importance due to the referral process. Providers are urged, but not required to refer all T2DM patients to the DEAP team for DSME. Referral reasoning may include but are not limited to uncontrolled diabetes, new-onset diabetes, change in medication, need for diet and exercise education, or annual follow-up. Referrals are submitted electronically in the EHR. Patients not affiliated with the facility are also eligible for DSME care; however, these patients are excluded from the program evaluation. The patient's last chart notes and reasoning of referral is sent to the DEAP receptionist for scheduling.

Once admitted for DSME, the patient is invited to six individual visits over 3 months. The educational content is standardized, reflecting care recommendations from specialty groups and national guidelines. The DEAP providers can make recommendations to the patient's plan of care, communicated electronically with the referring provider. The provider has the final decision regarding changes in patient management. Common care recommendations from the DEAP team include medication adjustments, use of continuous glucose monitoring (CGM), as well as reminders for scheduled screenings.

The seven core quality measures are objective; however, analyst interpretation may vary results. We know that Hgb A1C, LDL, urine microalbumin, and dilated retinal and neuropathy

exams each have acceptable test reliability and validity. These tests use physiologic metrics commonly used to measure diabetes control. However, patients may not comply with testing and referral recommendations. If we are unable to demonstrate an improvement in any of these metrics, it may speak more to patient behaviors or challenges accessing specialists rather than as a limitation of the test itself.

Blood pressure is influenced by multiple factors including technique, clinician interpretation, time of collection, and patient factors such as anxiety. The program evaluation cannot currently average readings for a cumulative percentage. Diabetes education in the patient's chart may also be subject to variations based on provider documentation and EHR retrieval. By establishing limitations, the team champion nurse practitioner and stakeholders can better understand the evaluation metrics and associated outcomes.

FPEPH Step 3: Focus the Evaluation Design

The aim of the facility was to improve the care of patients with T2DM. A comprehensive team-based approach was adopted, and it was determined the standardized protocol would best be measured by collecting specific quantitative data. While literally hundreds of metrics could have been chosen for the first evaluation cycle, seven core measures provide a reasonable snapshot of the population. Aggregate data was extracted from the electronic health record. This represents an efficient use of time. The student and team leader of the evaluation team was proficient at running data reports. The project lead had the support of a statistician and SPSS software to conduct data analysis. As evaluation drew nearer, some stakeholders wanted to learn more about the clinicians charged with delivering the care. They decided to add an electronic survey to the evaluation design, collecting quantitative data on thoughts and beliefs regarding the

use of a standardized protocol. The quantitative data was easily retrieved from the EHR; the provider survey was delivered via email and manually processed.

To narrow the evaluation, we will discuss utility, feasibility, propriety, and accuracy. The four standards that were used to guide the 6-step program evaluation were utility, feasibility, propriety, and accuracy.

Utility. Utility discerns what stakeholders need from the evaluation and how it will be used. The purpose of the evaluation of the T2DM protocol is to understand the impact of a standardized approach to care on patient population health. Biometric measures informed the facility on the health of the population. Care gaps were identified, and data driven decisions can be made regarding program priorities. Clinician perspectives were appreciated and incorporated to strengthen how care is provided.

Feasibility. Feasibility involves cost, time, and skill needed to complete the evaluation. Cost for the evaluation is minimal, as the DNP student and team leader involved in the evaluation project was based on regular salary. Time spent in data collection and analysis was brief, as charts can be directly pulled from AZARA and EHR. The data was analyzed using an ANOVA discussed later in study design. The results are timely, as this will be the first evaluation completed after the creation of the DEAP team and T2DM protocol within two years of creation. The skills needed to complete the evaluation include basic EHR comprehension for chart review and email use for provider questionnaires. Data analyzation skills include the use of an ANOVA at the guidance of a statistician.

Propriety. Propriety determines who needs to be involved in the evaluation. The team champion nurse practitioner will lead the evaluation. The faculty of record serves to guide the evaluation and provide feedback. The content expert led the discussion on diabetes in rural Appalachia.

The preceptor served as a clinical liaison and DEAP member for the diabetic community. The statistician was able to aid in analysis of core quality measures and provider questionnaires for accurate and meaningful data. Stakeholders were involved in results to provide feedback for future evaluations and DEAP use.

Accuracy. The final component, accuracy, defines what evaluation will lead to accurate information. Each of the standards serve an important role in focusing the evaluation of the T2DM population. Accuracy was achieved by creating modifiers, utilizing data reporting systems that can pull entries correctly from the corresponding EHR, and by setting statistical significance parameters for analysis. Transferring accurate data into SPSS software led to reliable conclusions on T2DM patient management.

FPEPH Step 4: Gather Credible Evidence

The sample size of T2DM patients at the facility for objective 1 included 168 randomized patients. Patient demographics, inclusion, and exclusion factors were based on national ADA 2018 and AACE 2015 clinical guidelines. A probability value (p -value) is a number describing how likely the data is true or occurred by random chance. The p -value is considered statistically significant if the value is less than or equal to 0.05% (McLeod, 2019). This p -value is used in the study to provide reliable and statistically relevant results. Systematic random selection of the medical record reviews reduced selection biases and enhance credible results. The facility evaluation gathered credible evidence from multiple sources. We compared evidence-based core quality measures collected prior to the adoption of the standardized protocol and after two years of use for objective 1. The evaluation also included provider responses to an electronic survey composed of Likert style questions and open-ended questions as previously discussed for objective 2.

Data Collection Procedure. For Objective 1. This proposed study used a retrospective chart review to collect seven core quality measures across three periods (Baseline (2019) and 2 years follow-up of post T2DM protocol and DSME implementation at T2 (2020), and T3 (2021).

Sample Size Estimation. Patients' medical records were reviewed using a data analytics and quality improvement reporting module, AZARA, and the EHR for data retrieval. AZARA was used to input inclusion and exclusion data for each of the eight providers. From the sample size, 21 patients were randomly selected by simple randomization of every other chart. Each medical record number was then de-identified using case ID such as 001, 002, etc. The case ID was utilized for manual chart review to follow the patients forward in T2 and T3. Repeated measured Analysis of Variance (ANOVA) for 7 outcomes variables with 3 repeated measures (baseline, T2, and T3), using G*Power v.3.1.9.7 on repeated measure ANOVA were conducted. Given $\alpha=0.05$, moderate effect size (0.25), power of 80%, for 7 outcomes with 3 measurements, correlation among repeated measures (0.50), a sample size of 168 was required.

Numerical data including Hgb A1c, blood pressure, and LDL was collected using the patient's most recent level collected during each period. Diabetes self-management education, retinopathy, nephropathy, and neuropathy exams were reported by a positive or negative finding in the chart for the specified periods. The evidence was safeguarded by using a discrete provider login to the EHR and AZARA, so protected health information (PHI) is controlled, and all Health Information Portability and Accountability Act (HIPAA) rules apply. Data collection was completed by the DNP student. An example of the medical record review can be found in Appendix F.

Step 5: Justify Conclusions

The DNP student engaged stakeholders in data analysis to interpret findings based on clinical significance. A statistician aided in determining statistical significance with use of SPSS software. Data was easily interpreted by using percentages for change. Based on findings and review of studies regarding diabetes education in similar populations, conclusions can be drawn to lead future implications. Stakeholders can then decide how to proceed with changes in T2DM care to foster improved outcomes in keeping with facility benchmark goals and national guidelines. Results that align with the overarching goal of the facility and the DEAP team, conclusions are likely to be accepted as accurate. Reviewing the limitations of the study sample (rural, elderly, and underserved population) and missing data were essential for justification of conclusions. The results will be used for future continuous quality improvement projects.

Step 6: Ensure Use and Share Lessons Learned

Dissemination of results of this program evaluation is being planned in multiple ways beginning with a meeting with administration and eventually continuing to include all members of the agency. Conclusions drawn based on data analysis will aid in making key global recommendations based on the findings. It will, however, be at administration's discretion to guide us in releasing the results, whether this will be staged or in entirety. Process changes will lie with the DEAP team and specific parties they deem essential to setting priorities, modifying care pathways, delivering continued training, and so forth.

The DNP graduate student reported findings to the DEAP team monthly, or more frequently as necessary. One or two scheduled meetings are being made to disseminate results to stakeholders. Due to COVID-19 restrictions, these meetings may take place in the form of video conferencing or via emails. Slide presentations and print literature may be used to convey the

results of the program evaluation. Full dissemination of results take place in late summer of 2022.

In summary, the CDC FPEPH provides a useful roadmap to evaluate the adoption of a standardized approach to T2DM care at the facility. It is easy to follow and allows for accurate assessment and reliable results.

Measures

Objective 1

The measures for Objective 1 included core quality measures per clinical guidelines (ADA, 2018; AACE, 2015). See Table 1. These core quality measures evaluated at the facility are relevant and have been agreed upon by the DEAP team and advisory committee. All the core measures in Aim 1 have been used with patients with T2DM populations. These have published mean scores/SDs identifying clinically significant differences and are sensitive to compare change over time.

Table 1

Facility Core Quality Measures

Core Quality Measures	Percentage of Compliance	Type of Data
Average hemoglobin A1C <7%	50%	Continuous
Documented self-management counseling within the last year	50%	Dichotomous
BP controlled <140/90	50%	Continuous
LDL <100mg/dL	50%	Continuous
Yearly microalbumin	50%	Dichotomous
Dilated eye exam in the past year	50%	Dichotomous
Comprehensive foot exam documented at all routine follow-up appointments	85%	Dichotomous

Objective 2

An anonymous survey with open-ended questions data was collected via an electronic survey sent to all provider via secured Qualtrics. The survey questions included a 5-point Likert scale and binary response of yes or no. Two open-ended questions were used to solicit providers' perceptions on COVID-19 negative impact to diabetes care management and obtain recommendations on how to improve the management of T2DM patient care in the facility and rural community (Appendix C). The questionnaire was created using a Qualtrics survey. The provider questionnaires were sent using an encrypted, safe browser at the facility with an opening description of the survey (Appendix G). Total time for providers to complete the anonymous survey questionnaire was between 10-20 minutes. Completion of the survey indicated voluntary participation. Qualtrics data were converted into SPSS (version 28) for analysis.

Quality Assurance and Data Integrity Techniques

Methods employed for assessing completeness and accuracy of data included data management protocol and an audit trail of the data management procedures (Roberts et al., 1997; Wynd & Schmidt, 2003). Other data integrity techniques included developing guides for verification of missing data, coding each subject's data, analyzing for data distribution, and meeting statistical assumptions and any need for transformations prior to quantitative analyses (Keppel & Wickens, 2004). Dr. Wang, biostatistician, was able to guide the quantitative data management procedures and statistical data analysis. All quantitative data was cleaned to identify outliers, data entry errors, or missing values.

Missing data was identified and reported. Rules for managing missing data were discussed with our biostatistician to distinguish types of missing data (Mack et al., 2018; Musil

et al., 2002). Using Qualtrics in the provider survey helped to control ranges and options and to diminish missing data. Data conversion from Qualtrics to SPSS/SAS was conducted for analyses.

Data Analysis

Objective 1

Data analyses were conducted using the SPSS, version 28. Descriptive analysis was conducted on patient's demographic data retrieved from medical record review. A repeated measures ANOVA with a Greenhouse-Geisser correction was used to compare means scores differences of continuous variables (H1C, LDL, systolic BP, and diastolic BP) among baseline, T2 and T3 time points. Once the main within-subject analysis was found, it was compared for statistically significant difference ($p < .05$). Friedman ANOVA, a non-parametric multiple groups comparison was used to analyze categorical or binary variables among baseline, T2 and T3 time points. Post-hoc analysis with Bonferroni correction for multiple time points comparisons was conducted between each pair of time point.

Low-density lipoprotein (LDL) cholesterol was found to have some abnormal values outside of the range very low <40 and/or very high >180 . For such values an LDL calculator called the Martin/Hopkins method was utilized (American College of Cardiology, 2020). This is a personalized approach that is useful for calculating accurate results for numbers that may be elevated or low due to triglycerides changes. This was used in placed of the Friedwald equation and results were updated.

Objective 2

Descriptive statistics were used to summarize the demographic data, CCI, and the proportion of response options for each provider survey question. Content analysis was used to address open-ended questions from anonymous provider survey. Content analysis is commonly

used to uncover opinions important to the study participants (Krippendorff, 2004). This type of analysis can identify the meaning and relationships of words or concepts. An audit trail was maintained throughout the analysis process detailing key decisions undertaken by the researchers (McBrien, 2008). The direct quotes did not contain individual names, and all information is summarized without identifiers. Two members of the research team (DNP student and Faculty of Record [FOR]) conducted data analysis (Miles & Huberman, 1994). Credibility, dependability, and transferability are measures to obtain the trustworthiness of qualitative content analysis (Graneheim & Lundman, 2004). The trustworthiness of this study will be achieved by agreement of study findings through extensive discussion or data saturation (when there is no topic to discuss).

Ethical Considerations

The project was submitted and approved by the institutional review board (IRB) in January 2022, under the exempt category. The study used retrospective data in the medical records. All data reports were de-identified and provider responses were anonymous. All data were de-identified using case ID such as 001, 002, etc. In addition, the survey data was collected anonymously via Qualtrics at the convenience of the participants. The completion of the questionnaire indicated a willingness to participate in the study. No patients or providers were contacted throughout the study, thereby not violating human privacy rights. Data collection and data management was completed by the DNP student and supervised by the FOR and statistician.

Results

Objective 1. For the core quality measures scores (as measured by average hemoglobin A1c; self-management counseling; blood pressure; LDL cholesterol; yearly microalbumin; eye exam, and foot exam) between baseline (2019) and 2 years follow-up (2020 and 2021) scores, the

results will be shared using descriptive statistics for patient demographics and the Charlson Comorbidity Index (CCI).

Patient Demographics

There were 168 chart review completed at baseline. Of 168, 67 (39.9%) were males and 101 (60.1%) were females. The mean age was 60.54 (SD=12.02) years, ranges from 24 to 77 years. Average length of T2DM diagnosis was 5.72 (SD=3.40) years, ranged from 3 to 16 years.

Charlson Comorbidity Index (CCI)

The Charlson Comorbidity Index shows multiple comorbidities that can affect the care of patients with diabetes. Of 168 patients, 68 (40.5%) had only on diagnosis of type 2 diabetes; 59 patients (35.1%) had one comorbidity; 25 patients (14.9%) had 2 comorbidities; 13 patients (7.7%) had 3 comorbidities; 2 patients (1.2%) had 4 comorbidities, and 1 (0.6%) had 5 comorbidities. The most common comorbidities were 1. COPD 33 patients (19.6%); 2. CHF 12 patients (7.1%) and MI 12 patients (7.1%); 3. CVA/TIA 10 patients (6.0%); 4. Mild liver disease 9 patients (5.4%). Over 50% of patients with type 2 diabetes had multiple comorbidities. This concludes the need for patient to have regular examinations and screenings to prevent related comorbidities and provide adequate management of such processes.

Core Quality Measures

A repeated measures ANOVA with a Greenhouse-Geisser correction was used to compare mean scores differences of continuous variables (H1C, LDL, systolic BP, and diastolic BP) among baseline, T2 and T3 time points. The results of ANOVA are shown below. (Table 2)

Table 2*Core Quality Measure (Continuous Variable) Results*

Variables	Mean (SD)			Statistics <i>F</i> (<i>p</i> value)
	Range (Min-max)			
	Baseline (T1)	Yr02 (T2)	Yr03 (T3)	
A1C	7.48 (1.64) 5.00-13.70	7.63 (1.81) 4.50-14.00	7.44 (1.55) 4.70-7.44	NS (<i>F</i> =.92, <i>p</i> =.39)
Systolic BP	128.55 (14.02) 92-164	132.25 (14.33) 100-180	128.87 (12.83) 100-182	*** (<i>F</i> =5.30, <i>p</i> <.01)
Diastolic BP	77.08 (8.75) 58-104	76.37 (8.61) 54-96	75.52 50-102	NS (<i>F</i> =1.07, <i>p</i> =.35)
LDL	90.09 (37.48) 23-234	82.60 (38.62) 12-217	89.52 (40.05) 19-306	NS (<i>F</i> =2.32, <i>p</i> =.12)

Table 2 Results Summary.

- 1) There were no significant differences for *A1C* across Baseline, T2, and T3 (*F* = .92, *p* = .39).
- 2) There were significant differences on *systolic BP* across time points (*F* = 5.30, *p* <.01). Post hoc analysis revealed that systolic BP was significantly increased from baseline to Year 02 (128.55 mmHg to 132.25 mmHg, *F*=8.46, *p* < .01). There was no significant difference between other time points. There were no significant differences for *diastolic BP* across Baseline, T2, and T3 (*F* = 1.07, *p* =.35).
- 3) There were no significant differences for *LDL* across Baseline, T2, and T3 (*F* = 2.32, *p* =.12).

Next, using the core quality measures benchmark, the mean scores of these continuous variables were grouped into 2 category/dichotomous variables. For example, A1C scores were grouped into Group 1, = <50% and Group 2, = 50% and above; Systolic BP scores were grouped into Group 1 = <140 mmHg and Group 2 = 140 mmHg and above; Diastolic BP scores were groups into Group 1 = <90 mmHg and Group 2 = 90 mmHg and above; LDL scores were grouped into Group 1, LDL = < 100mg/dL and Group 2 = 100mg/dL and above. Friedman Test, a non-parametric multiple groups comparison was used to analyze categorical or binary variables among baseline, T2 and T3 time points. Post-hoc analysis was conducted to detect differences on proportion of benchmark between each pair of time points (See Table 3).

Table 3

Core Quality Measures (Dichotomous) Results

Core Quality Measures	Percentage of Compliance	Baseline (T1)	Yr02 (T2)	Yr03 (T3)	Statistics (χ^2 , p value)
Average A1C <7%	50%	71 (48.3%) N=147	56 (42.1%) N=133	59 (44.7%) N=132	NS $\chi^2 = 1.38$ ($p = .50$)
Blood pressure Systolic BP <140 mmHg	50%	126 (75%) N=167	102 (72.9%) N=140	114 (80.3%) N=142	NS $\chi^2 = 2.80$ ($p = .25$)
Diastolic BP <90 mmHg	50%	150 (89.8%)* N=167	128 (91.4%) N=140	138 (97.2%)* N=142	** $\chi^2 = 7.0$ ($p = .03$)
LDL <100mg/dL	50%	88 (62%) N=142	94 (71.8%) N=131	86 (65.2%) N=132	NS $\chi^2 = 5.15$ ($p = .08$)
DSME	50%	8 (4.8%)* N=168	37 (22%)* N=168	25 (14.9%) N=168	** $\chi^2 = 23.16$, $p < .001$

DSME Appointment	50%	8 (4.8%) N=168	17 (10.1%) N=168	17 (10.1%) N=168	NS $\chi^2 = 5.23, p = .07$
Yearly microalbumin	50%	69 (41.1%)* N=168	81 (48.8%) N=168	102 (61.1%)* N=168	** $\chi^2 = 17.26, p < .001$
Dilated eye exam in the past year	50%	43 (25.6%) N=168	54 (32.1%) N=168	54 (32.1%) N=168	NS $\chi^2 = 2.49, p = .29$
Comprehensive foot exam	85%	41 (24.4%) N=168	62 (36.9%) N=168	47 (28%) N=168	** $\chi^2 = 8.67, p < .05$

*Indicated pair-wise significant differences between time points.

**Indicated overall statistical significance across three time points.

Table 3 Results Summary.

- 1) There were no significant differences for *A1C* across Baseline, T2, and T3 ($\chi^2 = 1.38, p = .50$). The proportion of A1C at baseline, T2, and T3 were lower than the benchmark.
- 2) There were no significant differences for *systolic BP* across time points ($\chi^2 = 2.80, p = .25$). There were significant differences for *diastolic BP* across Baseline, T2, and T3 ($\chi^2 = 7.0, p < .05$). Post hoc analysis revealed that proportion of diastolic BP (<90 mmHg) was significantly higher at T3 as compared to the baseline ($\chi^2 = 2.5, p < .05$). There was no significant difference between other time points.
- 3) There were no significant differences for *LDL* across Baseline, T2, and T3 ($\chi^2 = 5.15, p = .08$). All the proportion across three time points were higher than benchmark.
- 4) Overall, there were significant differences for referral to *DSME* across Baseline, T2, and T3 ($\chi^2 = 23.16, p < .001$). However, there were no significant differences with DSME referrals ($\chi^2 = 2.37, p = .053$) among three time points after Bonferroni correction for multiple tests. The proportion of DSME across three years was lower than the benchmark. There were no significant differences for *DSME scheduled appointments*

across Baseline, T2, and T3 ($\chi^2 = 5.23, p = .07$). Actual DSME appointments were reviewed by the DNP student. The actual number of patients that went to DSME scheduled appointments were less than those referred by medical providers for DSME.

- 5) There were significant differences for *Annual Microalbumin* across Baseline, T2, and T3 ($\chi^2 = 17.26, p < .001$). Post hoc analysis revealed that proportion of *Microalbumin* was significantly higher at T3 as compared to the baseline ($\chi^2 = 2.72, p < .01$), which was above the benchmark. There was no significant difference between other time points. Also, the proportion of Microalbumin at baseline and T2 were lower than the benchmark.
- 6) There were no significant differences for *annual eye exam* across Baseline, T2, and T3 ($\chi^2 = 2.49, p = .29$). The proportion of annual eye exam at baseline, T2, and T3 were lower than the benchmark.
- 7) Overall, there were significant differences for *foot exam* across Baseline, T2, and T3 ($\chi^2 = 8.67, p < .05$). However, there were no significant differences between three time points after Bonferroni correction for multiple tests. The proportion of foot exam at baseline, T2, and T3 were lower than the benchmark.

Objective 2: To explore the perceptions and acceptability of the diabetic education accreditation program (DEAP) team (as measured by Provider Questionnaire), as well as the recommendations from providers to improve the management of T2DM patient care in the facility and rural community, both descriptive statistics with demographics of the participants was collected as well as mixed methods data with Likert scale choices and qualitative responses from open-ended questions.

Provider Demographics

A provider questionnaire was sent to 27 primary care providers to evaluate practice perceptions and acceptability of the DEAP team. Providers were given 2 weeks to complete the questionnaire, which consisted of multiple choice and open-end responses. Of the 27 providers, 10 completed the questionnaire.

Provider Survey Question Results

Demographics. Demographic. Of 10 eligible providers, 10% were physicians (n=1), 70% were nurse practitioners (n=7), and 2 were physician assistants (n=2). The overall mean for providing care for patients with diabetes was 8.80 years (SD=5.90) years, range from 2 to 17 years. Description of responses from providers are as follows: (Appendix C)

Question 1. Of the 10 participants, 80% (n=8) were aware of the type 2 diabetes mellitus protocol, however 20% (n=2), were unaware of the protocol.

Question 2. Based on a 5-point Likert scale, 70% (n=7) were extremely likely to use the protocol, 20% (n=2) were likely to use it, and 10% (n=1) were neither likely or unlikely to use the protocol.

Question 3. An astounding 100% (n=10) participants stated they were aware of the role of the DEAP team in providing diabetic care.

Question 4. All participants highly rated referral to the DEAP team for education and patient management. Using a Likert scale 90% (n=9) reported they were extremely likely and 10% (n=1) reported they were somewhat likely to refer to the DEAP team.

Question 5. There was an abundant response of 100% (n=10) participants that felt COVID-19 had a negative impact on care for patients with diabetes. Using a Likert type scale, of

10 participants, 40% (n=4) stated they somewhat agree and 60% (n=6) strongly agree on the affect COVID-19 had on patient care.

Question 6. Provider participants provided responses to the open-ended questions regarding patient concerns during the COVID-19 pandemic. Several participants stated they felt COVID-19 negatively affected T2DM patient care due to loss of patient follow-ups and appointments. One provider stated, *“Patients have missed follow ups or opted for telehealth, often missing out on labs and adjustment of treatment.”* Many participants expressed concerns regarding telehealth visits in place of in-office appointments that *“delayed care.”* One participant particularly mentioned missed opportunities for preventative health screenings such as *“Labs, eye exams, foot exams.”* One participant described the negative impact on patients including: *“Stress, increased sugars, and sedentary lifestyle increase.”*

Question 7. Overall provider participants were aware of the role of the DEAP team. All participants are knowledgeable in providing type 2 diabetes mellitus care, many noted knowing about and using the T2DM protocol. They also highly rated referral to the DEAP team for education and patient management. Several participants expressed concern regarding the care provided in the last 2 years during the COVID-19 pandemic. However, all participants had positive suggestions for improving T2DM patient care at the facility and in the surrounding communities. Notably, almost all participants felt utilization of the DEAP team is vital in the management of T2DM patient care at the facility and in the surrounding community. One participant stated, *“Our facility does a great job with DEAP; Improve community awareness advertise our DEAP,”* while another participant recommended *“Have all T2DM patients have at least one visit with DEAP.”* Many participants felt that the DEAP team should be advertised more to patients at the facility and in the community, as they do an excellent job at improving

T2DM patient care. One participant discussed a deeper dive with the DEAP team and extending care in dietary and exercise education. The participant stated this could be accomplished by *“More access to DEAP at other locations, registered dietician for dietary counseling and even consideration to eventually add someone to assist with fitness prescriptions and an obesity management clinic component.”* Another participant also mentioned the need for increased physical activity by harnessing outdoor recreation; *“Promote outdoor activity now the weather is warmer.”* All suggestions focused on the improved use of the DEAP team to include more dietary and physical activity education to patients.

Discussion

Summary

The evaluation of the care patients with T2DM receive was important to provide insight into systematic quality improvement and improved patient outcomes. This was increasingly imperative for the future guidance of rural healthcare in southern, West Virginia. The purpose of this evaluation was to determine the impact of a standardized diabetes mellitus protocol among patients being treated for diabetes mellitus at a rural, FQHC facility in southern West Virginia.

Interpretation

Objective 1

Hemoglobin A1c Monitoring and Management. There were no statistical differences noted between baseline and T2 and T3. All hemoglobin A1c results fell short of meeting the facility’s benchmark goal of 50% of patients with an A1c of <7%. Despite not meeting the goal, at least 42% of patients had a hemoglobin A1c goal of <7%. Diabetes control has been found to be increasingly difficult during the COVID-19 pandemic. Eberle & Stichling (2021) found that 50% of publications noted deteriorations in glycemic control. Similarly, Forde et al. (2021) found that

39% of diabetes patients suffered from acute hyperglycemia during the pandemic. The “lockdown effect” also contributed to a short-term elevation in hemoglobin A1c levels at 0.3% among 26% of participants (Biancalana et al., 2020). An article by Scott et al. (2020) also noted concerns with overall diabetes management during the COVID-19 pandemic. Telehealth was considered an adequate alternative to in-person visits, as well as continuous glucose monitoring. Both telehealth visits and increased glucose monitoring have been utilized during the pandemic at the facility, however despite these alterations, glucose control has been difficult to manage given the external factors surrounding COVID-19. This may be related to limited internet access in rural Appalachia.

Diabetes Self-Management Education (DSME) Utilization. Overall, there were findings of significant differences for referral to DSME across Baseline, T2, and T3. However, there were no significant differences with DSME referrals among three time points after Bonferroni correction for multiple tests. There were also no significant differences for patients attending DSME appointments across Baseline, T2, and T3. Although the proportion of DSME referrals and patient attended appointments across three years were lower than the benchmark of 50%, there were positive changes with initiation of the DEAP team in 2020. Prior to DEAP initiation at baseline in 2019, only 4.8% of patients received DSME. In T2, this rose to 22%, however dropped to 14.9% in T3. There were more patients referred to DSME in T2, than in T3. This may be due to the initial creation and support for use with advertisement of the DEAP team and facility in 2020. An expected finding was that the actual number of patients that went to DSME scheduled appointments were less than those referred by medical providers for DSME. However, the same number of patients attended DSME appointments at T2 and T3(10.1%). This infers an overall improved compliance to DSME referral and appointment over time. Despite not

achieving the benchmark goal and slightly less referrals in T3 than initially in T2, there is improvement in the number of patients attending DSME. This may be related to increased patient-provider rapport, DEAP feedback and patient reviews, COVID-19 pandemic decline with vaccination availability, community awareness, etc.

Forde et al. (2021) found that COVID-19 had a significant impact on both physical and psychological problems for diabetic patients. The data found that diabetes education and management was extremely or quite severely disrupted during the pandemic. However, with COVID-19 infection rates on the decline, there is hope that DSME appointments will increase with resultant improvement in the care diabetes patients receive. Without the pandemic as a cofactor, DSME is high effective in improving glycemic control, lipids, and BMI, while moderately improving blood pressure management in a study by Mikhalel et al., 2020.

Blood Pressure Monitoring and Management. Despite there being no significant differences for systolic BP across all time points, all time frames exceeded the facility's benchmark goal of 50% of patients achieving a systolic blood pressure of <140mmHg. Around 75% of patients achieved the goal at baseline, and over 80% achieved the goal at T3. This is a great improvement with sustained findings over the time frame of evaluation. There were significant differences for diastolic BP across Baseline, T2, and T3. Post hoc analysis revealed that proportion of diastolic BP (<90 mmHg) was significantly higher at T3 as compared to the baseline. Over 97% of patients met the facility benchmark goal, showing significant control of diastolic blood pressure.

Dyslipidemia Assessment and Control. Like blood pressure analysis, LDL did not show significant differences across Baseline, T2, and T3. However, all data points across three time points were higher than benchmark of 50% of patients meeting an LDL of <100 mg d/L. The

highest number of patients meeting this goal was surprisingly at T2 during the beginning of the of COVID-19 pandemic. However, T2 also had the least number of patients having laboratory evaluations of LDL. A study by Psoma et al. (2020) similarly found no significant difference in LDL levels throughout the pandemic, and surprisingly found a decrease in overall hemoglobin A1c, total cholesterol and BMI levels. This was contributed to more time to attend appointments, exercise, and have healthier diet for people with time consuming work responsibilities pre-pandemic. This could be a direct correlation with the clinic findings in this study.

Urine Microalbumin or Albumin to Creatinine Testing for Diabetic Nephropathy.

There were great improvements noted with annual microalbumin and significant differences across Baseline, T2, and T3. Post hoc analysis revealed that proportion of microalbumin was significantly higher at T3 as compared to the baseline. Baseline and T2 time frames were below the facility benchmark of 50% of patients meeting the measure of having an annual microalbumin. There was a 20% overall increase from baseline to T3, in which T3 was greater than the benchmark goal at 61.1%. This measure may also have been improved by the DEAP team's ability to order testing for provider's if laboratory testing were due.

Foot Screening for Diabetic Nephropathy. Overall, there were significant differences for foot exams across Baseline, T2, and T3. There was noted improvement from 24.4% at baseline to 36.9% at T2 and slightly lower again at 28% at T3. The proportion of foot exams at baseline, T2, and T3 were lower than the benchmark of 85%. The number of patients receiving foot examinations for peripheral neuropathy could have been improved by the DEAP team's sponsoring of foot examinations and ordering of diabetic shoes via partnership with a podiatrist that evaluates patients at the main facility. As mentioned above, the main clinic in houses most of the patient population served by the facilities, thereby providing a large sample population.

This is also one of the more rural locations. Prior to the DEAP program's collaboration with podiatry, the closest specialist was located at least 30 minutes from the main facility. This limited access to care for many elderly, low-income, and underserved patients.

Overall, four of the seven CQM's met facility benchmarks, while two (diastolic blood pressure and microalbumin) had statistically significant results at T3. Improvements are under way for many of the measures that were below facility benchmarks, and future guidance will be made with dissemination of results. The Charlson Comorbidity Index was used to provide a better understanding of the most common comorbidities seen at the facility and evaluate what may be important to focus on in the future. Most patients had at least one other comorbidity with a few of the most common being COPD, MI, CVA, and CHF. For example, over 35% of patients had a diagnosis of end organ damage with T2DM and nearly 20% had COPD. The patients require a high level of care, and some may have been afraid to come into the facility for visits due to COVID-19. It is thereby important for the facility to focus on control of measures such as blood pressure, cholesterol levels, and hemoglobin A1c's to prevent worsening of these diagnoses.

Annual Dilated Eye Exam Screening for Diabetic Retinopathy. The proportion of patients receiving an annual retinal eye exam at baseline, T2, and T3 were lower than the benchmark of 50%. Despite this, there was improvement noted from baseline to T2 and T3, with an increase of nearly 7%. There were no significant differences for annual eye exam across Baseline, T2, and T3 (T2 and T3 both have 32.1%). The low number of patients receiving annual retinal eye examinations may be related to multiple factors. The first includes the lack of available resources of optometrists/ophthalmologists near the facilities during the time frame of analysis. There is only one specialist within 30 minutes of the main facility location, which

houses many of the facility's patients. Certain providers also may not accept the patient's insurance further limiting their access to care. This has since been improved with access to annual screenings at the main facility location, and possibly soon to other facility locations. This allows patients to receive an annual retinal eye examination the same day as their regular follow-up appointment.

Second, data retrieval may also be an issue with evaluation. If a patient's records are not received, the patient may not be counted as having the eye exam for that year. Finally, data input is a major concern for accurate data retrieval and evaluation. Until recently, eye exams were listed under health maintenance as "annual eye exam," by most staff. This, form of wording however did not count toward our number of patients receiving the examination. It instead must be documented as "retinal eye exam," to receive credit. This, however, did not impact this study, as the student ran a manual chart review and utilized all eye exam documentation; "annual eye exam" and "retinal eye exam," as listed in the chart.

Objective 2

All participants were aware of the role of the DEAP team in providing diabetes care. They highly rated referral to the DEAP team for education and patient management. A systematic review by Mikhail et al. (2020) reiterates the success of DSME with improvement noted in all clinic outcomes (hemoglobin A1c, fasting and non-fasting glucose readings, total cholesterol and triglycerides, and BMI) in at least 60% of the studies. All patients reported improved self-management, knowledge, and outcomes as well. Norris et al. (2002), similarly reports improvement in hemoglobin A1c levels at 0.76% at immediate follow-up, 0.26% at 1-3 months, and 0.26% greater than 4 months after DSME. This suggests that engaging stakeholders in the quality improvement from the design to implementation enhance the sustainability of

learned behaviors change over time and may be improved with prolonged or recurrent DSME for maintaining glucose control. A recommendation for future studies would be to further evaluate the effectiveness of DSME over a prolonged period to sustain and improve quality of care over time. This includes implementation of continuous quality improvement projects and evaluation, promotion of leadership with the DEAP team, and making the program visible to all staff members to promote referrals.

Notably, almost all participants felt utilization of the DEAP team is vital in the management of T2DM patient care at the facility and in the surrounding community. Participants were given the opportunity to use an open-ended response for this question to elaborate on T2DM management needs. All participants had positive suggestions for improving T2DM patient care at the facility and in the surrounding communities. Barriers to DSME should be explored to promote awareness and improved utilization to improve outcomes, as it is a universally recommended tool to improved diabetes management. Coningsby et al. (2022) evaluated such barriers to DSME by use of Andersen's Behavioral Model of Health Service Utilization as a framework. After 2 years of data, they found "perceived barriers" to include a lack of knowledge about the program and need for education. They also found "practical barriers" such as transportation issues and other commitments limiting time. The study concluded that barriers need to be assessed on an individual basis to improve access to care and promote awareness. A study by Ndjaboue et al. (2020) analyzed expert patients' knowledge and wisdom to improve diabetes care. The patients similarly felt diabetes management can be improved by individual care plans and group collaboration with open communication by the provider. These suggestions will be provided to the stakeholders during project presentation. Similarly, the clinic had individual barriers (patient level) that include lack of transportation, and

poor access to care including internet. Practical barriers may include provider utilization of the DEAP team due to poor patient adherence, limited access at satellite clinics, and lack of knowledge regarding outcomes associated with use. System level barrier may include poor advertisement, and lack of support to increase providers at satellite clinics and improve access to care.

Limitations

The worldwide COVID-19 pandemic took precedence in 2020. Agency resources were distributed in other more pressing clinical areas, delaying the ability to conduct program evaluation as planned at 12 months. With clinic flow mostly returning to pre-COVID-19 ways, administration has now granted approval for program evaluation to begin. The author, who is a nurse practitioner at the facility and a Doctor of Nursing Practice student at West Virginia University, lead the evaluation. Data collection commenced in February 2022; thus, the evaluation was expanded to include two years of outcomes, rather than the original first year. This evaluation project served as the author's doctoral capstone project and has been approved by facility leadership (Appendix E).

This project brought important program information to the agency, the people they serve, led by, and leveraging the skill set of the doctoral prepared nurse. Program evaluation provided the facility with valuable information in their pursuit to standardize care and reduce the burden of disease. It also assists them in establishing a road map for program expansion or remediation. Doctoral prepared nurses are aptly positioned to conduct program evaluation, given their expertise in management of chronic conditions, program development and evaluation.

Limitations include DEAP team relocation. The DEAP team was relocated to other job positions during the height of pandemic which limited utilization in 2020. This may have

contributed to low DSME utilization as well as other CQM's below benchmark percentages. Another limitation was the small sample size seen on the provider survey. This could be attributed to poor communication for the reason of evaluation (since this is the 1st evaluation), time, or lack of reward for completion. We also recently had changes in the email system d/t outside emails containing viruses, which may have contributed to provider uncertainty with clicking the link for the survey. Measures could also be collected over discrete time frames such as quarterly or monthly to limit changes seen over variable time frames throughout the year.

Conclusion

Diabetes is a challenging health condition that affects many Americans. Standardized protocols and methods have improved T2DM treatment. As health care systems strive to implement best practices in diabetes care, it is also incumbent on them to evaluate their implementation efforts. Much can be learned through the process of evaluation. For the facility, adopting a standardized approach to care has been a comprehensive effort to improve population health. Program evaluation completes the cycle, providing the facility with valuable information to inform their future practices and care of persons with T2DM.

Core quality measures were reviewed using continuous and dichotomous variables over T1, T2, and T3 time periods. Hemoglobin A1c, systolic blood pressure, LDL, referral to DSME, patient appointments to DSME, annual neuropathy and retinopathy findings were not statistically significant across the three-time frames evaluated. Diastolic blood pressure and annual microalbumin had statistically significant improvement at T3. Despite limited statistically significant improvement regarding core quality measures, almost all measures showed improvement from T1 to T3. Provider behaviors also correlated with compliance with the utilization of DSME and diabetes protocol driven care. Despite the COVID-19 pandemic, the

facility had noted overall diabetes management and patient care outcome improvement over the evaluation time frames.

The provider questionnaire concluded that most providers were aware of the diabetes protocol and the DEAP team. Majority of the providers were extremely likely to refer to the DEAP team for diabetes patient management. All providers felt that the COVID-19 pandemic negatively affected patient outcomes and provided responses for improving diabetes management including increased access to care via use of DSME. This will serve as a guideline to the facility in future diabetes patient care management and evaluation.

Recommendations

Future recommendations include the evaluation of core quality measures over a time frame after the COVID-19 pandemic effect lessens. The results during the pandemic have provided vital data, however, has also served as an external factor influencing outcomes of the new diabetes protocol and DEAP team creation in providing care. Appointments were limited despite the use of telehealth, due to many issues including cost, transportation, fear of illness, and poor access to care including internet usage. Patients had different eating habits, exercise management, and medication adherence during this time like never before. This could have contributed to limited improvement in core quality measures. Core quality measures could be added to include pneumonia vaccination and medication adherence to angiotensin converting enzyme (ACE) inhibitor, angiotensin II receptor (ARB) blockers, and/or statin use. Finally, core quality measure percentages should be adjusted based on the results of this evaluation to provide attainable, yet challenging benchmarks. Promoting achievements of such goals could also be promoted through use of a reward system for providers and staff.

Implications for Practice

Update Benchmarks. Over half of the measures were found to appraise above the facility benchmarks. Recommendations include increasing benchmark percentages to new, challenging levels, and providing encouraging feedback to providers for areas of practice within the protocol that were successful such as blood pressure, LDL, and urine microalbumin monitoring and management. Also, it would be recommended to consider a reward system for providers and/or by facilities.

Blood pressure, LDL cholesterol, and urine microalbumin screening and management were among the highest percentages of outcome measures noted in the evaluation. Possible rationales for this are described below. Blood pressure has long been a measure of interest of the facility with the use of various interventions, including Target BP. Target BP is a program in which the facility loans machines and logs to patients for home use while changing medications or gaining control. There are also various patient education and posters in the rooms, provider feedback and adherence by the quality improvement team on use of ACE/ARBs, and newly integrated EHR prompts to document control. Blood pressure may also be more easily understood and a concern of patients, as they see it as a ‘real problem.’

LDL cholesterol is often also seen a problem by patients. Most patients are adherent to some form of cholesterol lowering treatment such as diet or medication. Many providers also recommend and verify the benefit in using medications such as statins to prevent comorbidities.

Urine microalbumin is a measure that has recently improved at the facility, as evidenced by the evaluation. All patients with T2DM are recommended to have regular labs every 3 to 6 months, giving providers the ability to discuss the need of urine microalbumin monitoring for the early detection of chronic kidney disease. There is an ease of testing and many providers

have also seen the need to improve facility metrics in this area. Over 35% of patient had findings of target organ damage during the evaluation, creating an initiative for providers to promote regular testing.

Promote Patient Education and Self-Management with an Individualized Care Plan.

There were findings of low DSME/DEAP referral and patient follow-up throughout the evaluation time frames. This could be associated with new utilization of the protocol and creation of the DEAP team. Recommendations include increased education to providers and patients about the utilization of the DEAP team at the facility. This may include regular referral recommendations installed into the EHR as prompts, flyers, Facebook ads, and more. Also, a recommendation would be to expand DEAP providers, if possible, to other satellite clinics to improve transportation concerns with patients.

Patient-Centered Approach to Hemoglobin A1c Control. Hemoglobin A1c control was slightly below the benchmark of 50% at all time frames. This could be improved by use of the DEAP team that includes a a personalized approach to increase education. Creation of a guideline for DSME patient referral (for example new diagnosis, hemoglobin A1c >9%, annual visits, or newly uncontrolled patients) could be beneficial. Use of telehealth visits versus in patient visits would be interesting to evaluate to determine outcomes and patient compliance. Group meetings have also been discussed to provide a support system for patient with T2DM. A patient survey may be beneficial to further understand the best approach. Use of Dexcom trials (continuous glucose monitoring [CGM]) are being utilized now to find trends and improve understanding of each patient's individual control and are integral in improving diabetes control.

Address Barriers to Care. Retinopathy and neuropathy exams were among the lowest measures across the timeframes. Reasoning for this may include rural location with limited

access to care. Retinal eye exams are now available at the main clinic site along with foot exams via podiatry with ordering of diabetic shoes. There is a need to consider expanding such services to satellite clinics to improve adherence, specifically to locations that have limited providers.

Expand Care with Provider and Patient Engagement. Expansion of care to as many patients as possible was found to be a popular response by providers on the survey.

Recommendations for regular use of the DEAP team was also made by majority of providers. A recommendation for future patient engagement includes seeking a more informed understanding of ways to incorporate patient responses and answer questions/concerns for reasoning not to refer to the DEAP team.

Ensure Long-Term Follow-Up. A major key factor in the care of patients with diabetes included the COVID-19 pandemic. All providers felt it caused poor outcomes in patients including lack of visits, missed labs and screenings, and poor diet and exercise. As COVID-19 declines, providers and staff need to reach out to patients that have missed appointments and try to catch up on needed visits/screenings. This is currently being done by nursing, and quality improvement team leaders at the facility.

Doctor of Nursing Practice Essentials

The Doctor of Nursing Practice (DNP) essentials are a vital aspect of the study. The DNP essentials provide clarity and guidance in keeping with the promotion of population health and wellness in the diabetes community. The project includes the eight core essentials and are discussed below (American Association of Colleges of Nursing, 2006).

I - A scientific background of the current facility's T2DM protocol utilizing the ADA 2018 and AACE 2015 recommendations

II - Organizational leadership via the creation of an evaluation tool for diabetes management

III - Integration of evidence-based practices utilizing established evaluation practices (CDC Program Evaluation Tool)

IV - Technology utilization of the AZARA data analyzation, Excel spreadsheets, teams email system

V - Avocation and institution of systems level policy change for annual evaluation of the current diabetes protocol

VI - Interprofessional collaboration among all members of the healthcare team via the Chronic Care Model

VII - Health promotion and disease prevention by creation of an evaluation tool for an underserved, rural population of T2DM patients

VIII - Advancement of nursing practice by leveraging the skill set of the doctoral prepared nurse in chronic disease management, program evaluation, change leadership, and dissemination of findings through scholarly publications and presentations. DNP-led diabetic evaluation of current guidelines and future recommendations to improve clinician knowledge and holistic patient outcomes

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[6th-highest-poverty-rate-in-the-country-even-before-covid-hardship-more-relief-needed/](https://wvpolicy.org/data-released-today-shows-west-virginia-had-6th-highest-poverty-rate-in-the-country-even-before-covid-hardship-more-relief-needed/)

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Appendix A

Facility Diabetes Care Protocol

Clinical Goal: To reduce unnecessary death and disability from diabetes

Description: In an effort to reduce unnecessary morbidity and mortality from diabetes and its complications, the clinic utilizes the current American Diabetes Association Standards of Medical Care in Diabetes for the prevention, diagnosis and treatment of diabetes and its related complications.

Methods:

1. Diagnosis:

A. Diabetes

I. Criteria for the diagnosis for non-pregnant patients in stable state (not acutely ill)

1. Fasting plasma glucose (FPG) \geq 126 mg/dl
2. Random plasma glucose \geq 200 mg/dl with symptoms of hyperglycemia
3. Plasma glucose $>$ 200 mg/dl 2 hours after 75-gram oral glucose tolerance test (OGTT)
4. Hemoglobin A1c \geq 6.5%

II. For FPG and OGTT, patients ingest no calories for at least 8 hours prior to testing, and should have adequate carbohydrate intake for several days prior to test

III. Diagnosis of diabetes should be confirmed on a different day

B. Pre-diabetes

I. Impaired Fasting Glucose (IFG) defined as FPG 100 to 125 mg/dl

II. Impaired Glucose Tolerance (IGT) defined as plasma glucose 140-199 mg/dl 2 hours after OGTT

III. Category of increased risk for diabetes

1. HBA1c 5.7 to 6.4%

C. Screening

I. All adults ≥ 45 years of age

II. All adults with BMI ≥ 25 kg/m² with additional risk factors for diabetes

III. The American Academy of Pediatrics and ADA recommend screening all obese children with additional risk factors for T2DM (i.e. positive family history, non-white race, acanthosis nigricans, etc.) on physical examination

2. Newly diagnosed people with diabetes

A. A complete physical exam should be performed along with lab work-up to include a urinalysis, urine microalbumin, complete metabolic profile (CMP), fasting lipid panel, hemoglobin A1c, and EKG if over 40 years of age

B. Dietary and lifestyle education, including self-management goals, should be given and documented

C. Blood Pressure (reference Hypertension Protocol)

I. Blood pressure should be measured at every routine clinical visit.

II. Patients found to have elevated blood pressure ($\geq 140/90$) mmHg should have blood pressure confirmed using multiple readings, including measurements on a separate day, to diagnose hypertension

1. All hypertensive patients with diabetes should be encouraged to monitor their blood pressure at home

2. For patients with blood pressure $> 120/80$ mmHg, lifestyle intervention consisting of weight loss if overweight or obese; a Dietary Approaches to Stop Hypertension (DASH)–style dietary pattern including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity should be encouraged

D. Lipid Management (reference Lipid Management protocol)

1. Lifestyle modification focusing on weight loss (if indicated); the reduction of saturated fat, *trans* fat, and cholesterol intake; increase of

dietary n-3 fatty acids, viscous fiber, and plant stanols/sterols intake; and increased physical activity should be recommended to improve the lipid profile in patients with diabetes

2. All patients with diabetes and atherosclerotic cardiovascular disease, high-intensity statin therapy should be added to lifestyle therapy

3. For patients with diabetes aged <40 years with additional atherosclerotic cardiovascular disease risk factors, the patient and provider should consider using moderate-intensity statin in addition to lifestyle therapy

4. For patients with diabetes aged 40-75 years and >75 years without atherosclerotic cardiovascular disease, use moderate-intensity statin in addition to lifestyle therapy

II. Type 2 diabetes (see algorithm for treatment of type 2 diabetes; Standards of Medical Care in Diabetes page S76)

1. Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacologic agent for the treatment of type 2 diabetes

2. A patient-centered approach should be used to guide the choice of pharmacologic agent. Considerations include efficacy, hypoglycemia risk, history of atherosclerotic cardiovascular disease, impact on weight, potential side effects, renal effects, delivery method (oral vs subcutaneous), cost and patient preferences

3. Consider initiating insulin therapy (with or without additional agents) in patients with newly diagnosed type 2 diabetes who are symptomatic and/or have A1C \geq 10% and/or blood glucose levels \geq 300 mg/dl

4. Consider initiating dual therapy in patients with newly diagnosed type 2 diabetes who have A1C \geq 9%

5. A patient-centered approach should be used to guide the choice of pharmacologic agent. Considerations include efficacy, hypoglycemia risk, history of atherosclerotic cardiovascular disease, impact on weight, potential side effects, renal effects, delivery method (oral vs subcutaneous), cost and patient preferences

F. Consideration for referral to a Diabetes Educator (CDE) for Diabetes Self-Management training (DSMT), Registered Dietician (RD), or Certified Nutrition Specialist (BCNS) should be encouraged.

G. Referral for a diabetic eye exam

H. A prescription for testing of blood glucose levels at home should be provided.

Prescription for testing equipment should include: blood glucose meter, blood glucose testing strips, lancing device, lancets, and control solution

I. Target goal for A1C should be less than 7% in most patients and consider less than 6.5% in those healthy patients with low risk of complications. Individualized A1C 8% or greater may be considered for frail patients

J. Follow-ups should be at least at 3-month intervals until glucose is stable, and should include A1C if not done in past 3 months

3. Established people with diabetes

A. Office visits every three months with a review of home blood glucose logs. More frequent visits may be warranted if patient is symptomatic, or abnormalities exist in lab tests

B. Reinforce exercise and diet education, including self-management goals, at least annually

C. Document foot exam and education for patient to do daily foot exam every routine visit

D. Diabetes pharmacologic treatment evaluation

I. In patients without atherosclerotic cardiovascular disease, if monotherapy or dual therapy does not achieve or maintain the A1C goal over 3 months, add an additional antihyperglycemic agent based on drug-specific and patient factors

II. A patient-centered approach should be used to guide the choice of pharmacologic agent. Considerations include efficacy, hypoglycemia risk, history of atherosclerotic cardiovascular disease, impact on weight, potential side effects, renal effects, delivery method (oral vs subcutaneous), cost and patient preferences

III. In patients with type 2 diabetes and established atherosclerotic cardiovascular disease, antihyperglycemic therapy should begin with lifestyle management and metformin and subsequently incorporate an agent proven to reduce major adverse cardiovascular events and cardiovascular mortality (currently empagliflozin and

liraglutide, but other agents currently being studied), after considering drug-specific and patient factors

IV. In patients with type 2 diabetes and established atherosclerotic cardiovascular disease, after lifestyle management and metformin, the antihyperglycemic agent canagliflozin may be considered to reduce major adverse cardiovascular events, based on drug-specific and patient factors

V. Continuous reevaluation of the medication regimen and adjustment as needed to incorporate patient factors and regimen complexity is recommended

VI. For patients with type 2 diabetes who are not achieving glycemic goals, drug intensification, including consideration of insulin therapy, should not be delayed

VII. Metformin should be continued when used in combination with other agents, including insulin, if not contraindicated and if tolerated

E. Diabetes and hypertension (see page s90 of Standards of Medical Care in Diabetes-2018 for chart)

I. Most patients with diabetes and hypertension should be treated to a systolic pressure goal of <140 mmHg and a diastolic blood pressure goal of <90 mmHg

II. Lower systolic and diastolic blood pressure targets, such as 130/80 mmHg, may be appropriate for individuals at high risk of cardiovascular disease, if they can be achieved without undue treatment burden

III. Lifestyle modification should be evaluated and reinforced

IV. Patients with confirmed office-based blood pressure >160/100 mmHg should, in addition to lifestyle therapy, have prompt initiation and timely titration of two

drugs or a single-pill combination of drugs demonstrated to reduce cardiovascular events in patients with diabetes

V. Treatment for hypertension should include drug classes demonstrated to reduce cardiovascular events in patients with diabetes (ACE inhibitors, angiotensin receptor blockers, thiazide-like diuretics, or dihydropyridine calcium channel blockers)

VI. Multiple-drug therapy is generally required to achieve blood pressure targets. However, combinations of ACE inhibitors and angiotensin receptor blockers and combinations of ACE inhibitors or angiotensin receptor blockers with direct renin inhibitors should not be used

VII. An ACE inhibitor or angiotensin receptor blocker, at the maximally tolerated dose indicated for blood pressure treatment, is the recommended first-line treatment for hypertension in patients with diabetes and urinary albumin-to-creatinine ratio ≥ 300 mg/g creatinine or considered in those with values 30–299 mg/g creatinine.

VIII. If one class is not tolerated, the other should be substituted

IX. For patients treated with an ACE inhibitor, angiotensin receptor blocker, or diuretic, serum creatinine/estimated glomerular filtration rate and serum potassium levels should be monitored at least annually

F. Yearly funduscopic exams

G. Yearly microalbumin urine, repeat in 3 months if abnormal. Any patient with persistently abnormal urine microalbumin will be referred to nephrology for further evaluation. If possible, stop any diuretic after first abnormal microalbumin

H. HBA1C done every 3 to 6 months depending upon how well diabetes is controlled

I. Lipid management

- i. Reinforce lifestyle modification
- ii. Intensify lifestyle therapy and optimize glycemic control for patients with elevated triglyceride levels (≥ 150 mg/dl and/or low HDL cholesterol (< 40 mg/dl for men, < 50 mg/dl for women))
- iii. Provider may need to consider adjusting intensity of statin therapy based on individual patient response to medication (e.g. side effects, tolerability, LDL cholesterol levels, or percent LDL reduction on statin therapy). For patients who do not tolerate the intended intensity of statin, the maximally tolerated statin dose should be used
- iv. For patients with diabetes and atherosclerotic cardiovascular disease, if LDL cholesterol is ≥ 70 mg/dl on maximally tolerated statin dose, consider adding additional LDL-lowering therapy (such as ezetimibe or PCSK9 inhibitor) after evaluating the potential for further atherosclerotic cardiovascular disease risk reduction, drug-specific adverse effects, and patient preferences.

J. Antiplatelet agents

- I. Consider aspirin therapy (75-162 mg/day) as a secondary prevention strategy in those with diabetes and a history of atherosclerotic cardiovascular disease
- II. Aspirin therapy (75-162 mg/day) may be considered as a primary prevention strategy in those with type 1 or type 2 diabetes who are at increased cardiovascular risk. This includes most men and women with diabetes aged ≥ 50 years who have at least one additional major risk factor (family history of

premature atherosclerotic cardiovascular disease, hypertension, dyslipidemia, smoking, or albuminuria) and are not at increased risk of bleeding.

III. Clopidogrel may be used in documented aspirin allergy

K. Non-compliant patients or those on multiple medications with no substantial change in A1C, should be considered for referral to endocrinology.

How Often to Audit: annually

How Many Charts to Audit: 10 per FTE

Identify Charts: Random screen from Electronic Health Record (EHR) of people with diabetes who are active users

Acceptable Levels of Compliance:

Average HgbA1C <7%: 50%

Documented self-management counselling within the last year: 50%

BP Controlled <140/90: 50%

LDL less than 100 mg/dL: 50%

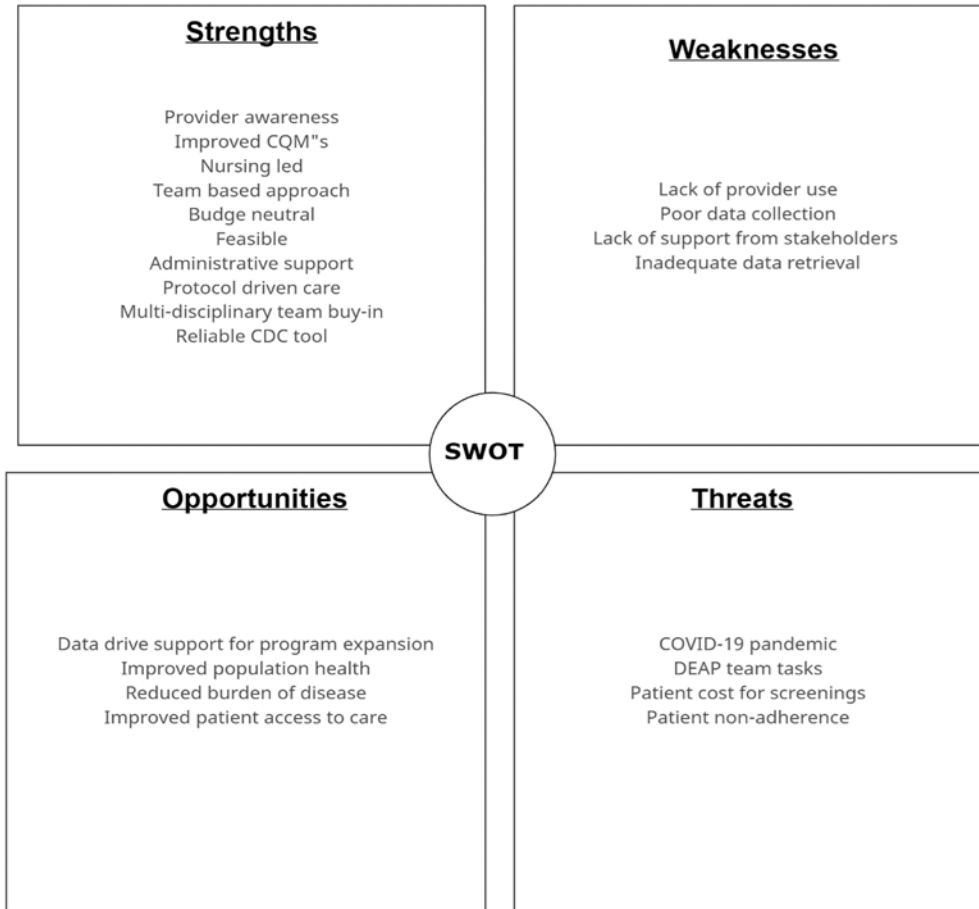
Yearly microalbumin: 50%

Dilated eye exam in past year: 50%

Comprehensive foot exam documented at all routine follow-up appointments: 85%

Appendix B

SWOT Analysis



Appendix C

Provider Questionnaire : Perceptions and Recommendations

- a. Please identify your role: (1) physician (2) nurse practitioner (3) physician assistant (4)
Other, please specify _____
- b. How long have you been providing diabetic care and treatment: _____ years.

Please select the best answer.

1. Are you aware of the facility's type 2 diabetes mellitus (T2DM) protocol?
 - a. Yes
 - b. No
2. How likely are you to utilize the T2DM protocol in practice?
 - a. Extremely likely
 - b. Likely
 - c. Neutral
 - d. Not likely
 - e. Never
3. Are you aware of the role of the diabetic education accreditation program (DEAP) team?
 - a. Yes
 - b. No
 - 3.1 If answer No, please explain why not?
4. How likely are you to refer to the DEAP team for patient education/management?
 - a. Extremely likely
 - b. Likely

- c. Neutral
 - d. Not likely
 - e. Never
5. Do you think the COVID-19 pandemic has negatively affected T2DM patient care in the past 2 years?
 - a. Yes
 - b. No
- 5.1. If you answered yes, how strongly has it affected T2DM care?
 - Strongly agree
 - Agree
 - Neutral
 - Disagree
 - Strongly disagree
6. Please describe briefly how the COVID-19 pandemic has negatively affected T2DM patient care (Open-ended, short response): _____
7. How can we improve the management of T2DM patient care in our facility and rural community? (Open-ended, short response) _____

Appendix D

Budget

Budget Categories	Personal Funds	Organizational Contributions
ADMINISTRATIVE COSTS	\$0	~\$4,280
<p>Cost of evaluation study for staff is covered under current salary. It was estimated that the team leader at the facility collected the data at an average rate of (\$50 per hour). There were around 40 hours spent on data collection and provider survey distribution. The cost for 40 hours of time spent by the team champion nurse practitioner on completing the data collection is estimated to be \$2,000. The team leader nurse practitioner average rate of (\$50 per hour), 2 pharmacists – 2 DEAP team members (\$65 per hour), 1 registered nurse – DEAP member (\$30 per hour), and 1 receptionist – DEAP member (\$18 per hour) was utilized for time spent for meetings. The average time spent for meetings of staff members was estimated at 10 hours; the team champion nurse practitioner (~\$50/hour) , and 4 DEAP members (x2 ~\$65, x1 ~\$30, x1~\$18) to equal about \$2,280.</p>		
MARKETING	\$0	\$0
No funds necessary.		
EDUCATIONAL MATERIALS/ INCENTIVES	\$15	\$0
Cost of Zoom meeting upgrade for DNP defense.		
Budget Categories	Personal Funds	Organizational Contributions

PROJECT SUPPLIES (office supplies, postage, printing, etc.)	\$0	\$50
\$50 estimated to print reports from Qualtrics.		
OTHER	\$0	\$0
Other: No other costs associated.		
TOTALS	\$15	~\$4,330

Appendix E

Project Approval

176 Medical Center Drive • Rainelle, WV 25962
Phone 304-438-6188 • Fax 304-438-6819

January 14, 2021

RE: Hannah Hellems / Comprehensive Type II Diabetes Guidelines and Prescribing Practices Project

To Whom It May Concern:

Rainelle Medical Center, Inc. fully supports and approves Hannah Hellems completion of her project for the Doctor of Nursing Practice project involving diabetes protocol evaluation. We are very pleased when our employees take the initiative to better themselves and further their education through projects such as this.

Thank you for your time.

Sincerely,

Kristi Atha-Rader, MBA, CEO
Rainelle Medical Center, Inc.

Appendix F

Medical Record Review Template

De-identified Medical Review

Demographic:

Sex ___ Male ___ Female

Age ___ years

Length of diabetes mellitus diagnosis ___ years

Core Quality Measures	Baseline (T1)	T2	T3
Average hemoglobin A1C <7%	Value	value	Value
Documented self-management counseling within the last year	Value	value	Value
BP controlled <140/90	Value	value	Value
LDL <100mg/Dl	Value	value	Value
Yearly microalbumin	Value	value	Value
Dilated eye exam in the past year	Value	value	Value
Comprehensive foot exam documented at all routine follow-up appointments	Value	value	Value

Note: These include type 2 diabetes mellitus diagnosis codes (ICD-10). Diabetes diagnosis, retinopathy, nephropathy, and neuropathy exams will be reported by a positive or negative finding in the chart for the specified periods.

Charlson Comorbidity Checklist: Does patient have the following diagnosis in the medical records? If yes, check X

<input type="checkbox"/> Diabetes Mellitus (must check)	<input type="checkbox"/> Hemiplegia
<input type="checkbox"/> Myocardial infarction	<input type="checkbox"/> Ulcer disease
<input type="checkbox"/> Peripheral vascular disease	<input type="checkbox"/> Mild liver disease
<input type="checkbox"/> Cerebrovascular disease or TIA	<input type="checkbox"/> Moderate/severe liver disease
<input type="checkbox"/> Dementia (Exclusion Criteria)	<input type="checkbox"/> Any malignancy
<input type="checkbox"/> Congestive Heart failure	<input type="checkbox"/> Metastatic solid malignancy
<input type="checkbox"/> Diabetes with end organ damage	<input type="checkbox"/> Leukemia
<input type="checkbox"/> Chronic pulmonary disease	<input type="checkbox"/> Malignant Lymphoma
<input type="checkbox"/> Connective tissue disease	<input type="checkbox"/> AIDS
<input type="checkbox"/> Moderate/severe renal disease	

Appendix G

Cover Letter

Dear Prospective Participant,

This letter is a request for you to participate in a research project **Evaluation of a Comprehensive Diabetes Mellitus Protocol at a Rural, Federally Qualified Health Center in Southern West Virginia**. This project is being conducted by Hannah Davis, MSN, APRN, FNP-C in the School of Nursing at WVU under the supervision of Dr. Ubolrat Piamjariyakul, PhD, RN, an Associate Dean of Research and Scholarship at WVU in the School of Nursing, to fulfill requirements for the degree of Doctor of Nursing Practice.

If you decide to participate, you will be asked to complete an anonymous, online survey. Your participation in this project will take approximately 10-15 minutes. All participants must be primary care providers at the clinic being evaluated. You must be 18 years of age or older to participate. You will not receive any direct benefits or incentives for your participation in the study.

Your participation in this project will be kept as confidential as legally possible. Your involvement is anonymous. All data will be reported in the aggregate. You will not be asked any questions that could lead back to your identity as a participant. Your participation is entirely voluntary. You may skip any question that you do not wish to answer, and you may stop participating at any time. Your employment status will not be affected if you decide not to participate or withdraw. West Virginia University Institutional Review Board's approval of this project is on file with the WVU Office of Human Research Protections.

If you have any questions about this research project, please feel free to contact me at 304-438-6188 (ext. 1064) or by email at hdhellems@mix.wvu.edu or Ubolrat Piamjariyakul (ubolrat.piamjariyakul@hsc.wvu.edu), supervising faculty. Additionally, you can contact the WVU Office of Human Research Protections at 304-293-7073.

I hope that you will participate in this research project, as it could help us better understand the impact of a standardized diabetes mellitus protocol, the providers' perceptions and acceptability of the diabetic education accreditation program (DEAP) team, and recommendations to improve the management of diabetes patient care in the facility and rural community. Thank you for your time and consideration.

Sincerely,

Hannah Davis, FNP-C