

University of the Incarnate Word

**The Athenaeum**

---

Doctor of Nursing Practice

---

12-2020

## Implementation of Comprehensive Foot Exams in Primary Care: A Quality Improvement Project

Dora Elia Trevino

*University of the Incarnate Word, dora20trevino@yahoo.com*

Follow this and additional works at: [https://athenaeum.uiw.edu/uiw\\_dnp](https://athenaeum.uiw.edu/uiw_dnp)



Part of the [Endocrine System Diseases Commons](#), [Family Practice Nursing Commons](#), and the [Nervous System Diseases Commons](#)

---

### Recommended Citation

Trevino, Dora Elia, "Implementation of Comprehensive Foot Exams in Primary Care: A Quality Improvement Project" (2020). *Doctor of Nursing Practice*. 83.  
[https://athenaeum.uiw.edu/uiw\\_dnp/83](https://athenaeum.uiw.edu/uiw_dnp/83)

This Doctoral Project is brought to you for free and open access by The Athenaeum. It has been accepted for inclusion in Doctor of Nursing Practice by an authorized administrator of The Athenaeum. For more information, please contact [athenaeum@uiwtx.edu](mailto:athenaeum@uiwtx.edu).

IMPLEMENTATION OF COMPREHENSIVE FOOT EXAMS IN PRIMARY CARE:  
A QUALITY IMPROVEMENT PROJECT

DORA E. TREVINO BSN, RN

DNP PROJECT ADVISOR

Christina M. Hernández PhD, RN  
Associate Professor, Ila Faye Miller School of Nursing and Health Professions

CLINICAL MENTOR

Nora I. Valdes, M.D.

Presented to the Faculty of the University of the Incarnate Word  
in partial fulfillment of the requirements  
for the degree of

DOCTOR OF NURSING PRACTICE

UNIVERSITY OF THE INCARNATE WORD

December 2020

### ACKNOWLEDGMENTS

First and foremost, I would like to thank God for His blessings and for never leaving my side throughout the last 3 years.

I would like to express my sincerest gratitude to my project advisor Dr. Christina M. Hernandez, who has been of great support throughout the planning and implementation phases of this project. I am grateful for the opportunity to learn from her not just during my undergraduate studies but throughout my graduate studies as well. Her vision, sincerity, and support have motivated and inspired me to be the best doctoral candidate and advanced practice nurse I can be.

I would also like to express gratitude to my clinical mentor Dr. Nora I. Valdes, who welcomed me into her practice with open arms and entrusted me with the care of her patients and her practice. It has been a great privilege and honor to work and study under her guidance.

I am incredibly grateful for my boyfriend Jesus and my sisters Gaby and Anel, who have not only encouraged me to continue my journey towards my DNP but who have accompanied me on long nights and clinical days when there seemed to be no end in sight.

I would like to dedicate this project to my parents Juan Antonio and Dora Elia Trevino, immigrants who worked day and night to support their children and to encourage them to be the very best they could be. Thank you for your love and support, thank you for your prayers and for believing in me when I struggled to believe in myself. Este Proyecto es dedicado a ti, mi Viejo y a ti mi mami, mi mujer virtuosa.

## ACKNOWLEDGMENTS-Continued

Finally, I would also like to dedicate this project to my aunt Angelica Patricia Chavez Mota, who was one of the many lives that COVID-19 claimed. May you rest in peace Tia, you encouraged me to work hard and to learn something new every day. Thank you for your unconditional support and faith in my future practice.

Dora E. Trevino BSN, RN

## TABLE OF CONTENTS

LIST OF TABLES.....	6
ABSTRACT.....	7
STATEMENT OF PROBLEM.....	8
BACKGROUND AND SIGNIFICANCE.....	9
Macrovascular complications .....	10
Microvascular complications .....	10
Diabetic peripheral neuropathy .....	11
ASSESSMENT .....	13
Purpose of practice.....	14
Professionals .....	14
Patients .....	15
Processes .....	15
Patterns.....	17
Need for intervention .....	18
Readiness for change .....	18
PROJECT IDENTIFICATION.....	20
Purpose.....	20
Objectives and anticipated outcomes.....	20
SUMMARY AND STRENGTH OF EVIDENCE .....	21

## TABLE OF CONTENTS—Continued

Standards of care.....	23
METHODS .....	24
Project plan .....	24
Project implementation .....	26
Decision for intervention .....	28
Barriers.....	29
Facilitators .....	31
Ethical considerations .....	31
EVALUATION PLAN .....	31
RESULTS .....	33
DISCUSSION.....	36
Limitations .....	37
Strengths .....	37
Recommendations.....	38
Implications.....	39
CONCLUSION.....	39
REFERENCES .....	41
Appendix A: CFE template.....	46
Appendix B: letter of support .....	48
Appendix C: Human Subjects Research Determination.....	49

## LIST OF TABLES

Table	Page
1. Patient population .....	15
2. ADA Evidence-grading system .....	22
3. ADA Recommendations .....	23
4. Outcome data .....	35

### **Abstract**

The purpose of this quality improvement project was to increase performance and documentation of provider comprehensive foot exams (CFEs) by 50% among patients with Type 2 diabetes (T2DM) in a small clinic in the southwestern United States. The project leader assessed clinic systems including the electronic health record (EHR) to identify means to increase CFE completion and documentation rate for patients with T2DM being seen for a chronic disease management (CDM) appointment. A process was created to incorporate a hardcopy CFE documentation form into the EHR and create a pop-up care reminder notification system. Staff and the provider were educated on the new process, supplies were obtained, and the project leader implemented this project in the spring of 2020. The project leader monitored outcomes through a formative and summative evaluation plan and addressed barriers as they were identified. The COVID-19 pandemic impacted clinic practices in March 2020 and led to modification of project outcomes as the platform for appointments changed from in person to telehealth. The project outcome was achieved as 52% of patients with T2DM who were seen during a CDM appointments received a CFE that was documented completely. The average increase in appointment time was 10 min. Including CFEs in CDM appointments can support the identification of foot ulcers at an early stage and prevent or delay lower extremity amputations. EHR systems should be evaluated for the capacity to support electronic tracking and documentation of these assessments

*Keywords:* Type 2 diabetes mellitus, comprehensive foot exam, electronic health record



### **Implementation of Comprehensive Foot Exams in Primary Care: A Quality Improvement Project**

In 2015, 30.3 million Americans (9.4%) had Type 2 diabetes mellitus (T2DM) (American Diabetes Association [ADA], 2018). Among those 30.3 million Americans, 23.1 million or 76.2% had an actual diagnosis, while 7.2 million or 23.8% remained undiagnosed (ADA, 2018). As recently as 2017, approximately 2,990,000 Texans have been diagnosed with T2DM; this is 14.6% of the adult population in Texas (ADA, 2017a). It is also estimated that about 663,000 of these Texans have diabetes but are not aware of it, placing them at much higher risk for complications from this disease (ADA, 2017a).

According to the American Diabetes Association (ADA, 2017b), in 2017, T2DM cost the U.S. \$237 billion in direct medical care costs making healthcare costs for Americans with T2DM 2.3 times greater than healthcare costs for Americans without T2DM. This amount constitutes a 26% increase in cost to care for persons with T2DM over the previous 5 years (ADA, 2017). Similarly, in 2017, healthcare costs for Texans with T2DM were 2.3 times higher than for Texans who did not have T2DM. (ADA, 2017a).

#### **Statement of the problem**

Currently, foot ulcers or wounds are one of the most common and preventable complications of diabetes mellitus (DM). Approximately 34% of patients with T2DM are at risk for developing a foot ulcer, more than 50% of those ulcers become infected, and around 20% of diabetic foot infections result in some form of a lower extremity amputation (LEA) (Armstrong et al., 2017). Both foot ulcers and amputations are consequences of T2DM and diabetic neuropathy; they are also significant causes of morbidity and mortality (ADA, 2019).

Foot ulcers can be prevented or detected at their earliest stages through comprehensive foot examinations (CFEs) as recommended by the *Standards of Care in Diabetes-2019* for patients with T2DM (ADA, 2019). The American Diabetes Association (2019) recommends that providers perform a CFE with a 10-g monofilament yearly, and conduct foot inspections at every office visit for all patients with evidence of sensory loss or prior ulceration or amputation.

Comprehensive foot exams and foot inspections are vital to early recognition and treatment of patients who are at risk for foot ulcers and amputation. According to the Centers for Disease Control and Prevention (CDC, 2017), only 62.9% of patients with T2DM living in Texas reported receiving a foot exam by a health professional while nationally 71.6% reported they had received the exam. This cost-effective exam requires little equipment, one monofilament per patient, can be time-efficient at approximately 3 min to complete and document the exam, yet can identify a foot ulcer or wound in its earliest stages and prevent or delay a LEA (Ming et al., 2019).

### **Background and Significance**

Type 2 Diabetes Mellitus is a chronic, progressive health condition that affects the body's ability to use insulin to regulate blood sugar and use it as energy (CDC, 2019). Because T2DM is a progressive condition, individuals with this diagnosis are at risk for other long-term complications, including retinopathy, nephropathy, and neuropathy (ADA, 2019). Complications related to T2DM are due to damage of small (micro) and large (macro) blood vessels in the body. These complications are classified into microvascular and macrovascular complications (World Health Organization [WHO], 2020).

**Macrovascular Complications**

Macrovascular complications of T2DM include coronary artery disease (CAD), peripheral vascular disease (PVD), and peripheral artery disease (PAD) (WHO, 2020). These macrovascular complications include cardiovascular diseases that affect not only the vessels in major organs and extremities but also those of the brain and heart. Hyperglycemia, or high blood glucose levels which can accompany T2DM, cause damage to blood vessels in the body by narrowing or occluding the vessels. These occlusions are called atherosclerosis (WHO, 2020). Atherosclerosis leads to decreased blood flow to major organs such as the brain or heart, and to the body's extremities, which may result in myocardial infarction, cerebrovascular accident, or even possible loss of a limb (WHO, 2020).

**Microvascular Complications**

Microvascular complications related to hyperglycemia result from damage to capillary endothelial cells in the retina, neurons, mesangial cells in the renal glomerulus, and Schwann cells in peripheral nerves (Khalil, 2017). Long term exposure to hyperglycemia leads to oxidative stress from superoxide overproduction, in turn causing endothelial damage (Khalil, 2017). Microvascular complications such as retinopathy, which may result in blindness, nephropathy, which may result in kidney failure, and peripheral neuropathy, which may result in diabetic foot ulcers and subsequent LEA, are caused by direct damage to the small vessels in the eyes, kidneys, and nerves retrospectively (WHO, 2020).

Onset and progression of diabetic retinopathy and nephropathy can be decreased through annual eye exams and urine and blood tests (ADA, 2019; WHO, 2020). However, because peripheral neuropathy and diabetic foot disease result from both vessel and nerve damage, it is an

even more common problem than the other microvascular complications related to T2DM (WHO, 2020).

### **Diabetic Peripheral Neuropathy**

Diabetic peripheral neuropathy (DPN) is a microvascular complication of DM and is the leading risk factor for diabetic foot ulcers. It occurs in 13-68% of persons with T2DM (Lung et al., 2020). This microvascular complication is caused by a shift in the balance between nerve fiber damage and nerve fiber repair, where damage supersedes repair (Feldman, 2020). The nerve damage occurs in a fiber-selective pattern, most commonly affects autonomic and distal sensory fibers, and may lead to the progressive loss of sensation, which is characteristic of diabetic neuropathy (Feldman, 2020).

There is an array of factors that cause this shift in balance, such as chronic hyperglycemia, protein kinase activation (causing vasoconstriction), and oxidative stress. Impaired peripheral nerve repair is common with T2DM, and it is hypothesized that this could be due to the loss of neurotrophic peptides that typically mediate nerve repair and regeneration (Feldman, 2020). These peptides include insulin-like growth factors making glycemic control an imperative factor in preventing and slowing down the compromise of nerve repair and viability (Feldman, 2020).

Diabetic peripheral neuropathy is a diagnosis of exclusion, making it difficult to diagnose and treat at an early stage (ADA, 2019). There are many treatment options for DPN; however, up to 50% of these cases are asymptomatic, and if unrecognized, they can lead to injury and disability in a person, including diabetic foot ulcers, infections, and LEAs (ADA, 2019; Lung et al., 2020). Additionally, DPN is the leading cause of disability in patients with T2DM due to ulcers, amputations, fall-related injuries, and gait disturbances (Juster-Switlyk & Smith, 2016).

Distal symmetric polyneuropathy (DSPN) is the most common type of diabetic neuropathy and accounts for 75% of DPNs (Pop-Busui et al., 2017). This type of neuropathy is considered idiopathic in about one-third of its cases, and DM is the second most common cause (Callaghan et al., 2020). Individuals with DSPN often present with tingling, numbness, pain, and/or weakness that starts in the toes and progresses proximally in a "stocking-glove" distribution (Callaghan et al., 2020). Distal symmetric polyneuropathy neuropathy is the leading cause of foot ulcers and is commonly present in at least 10-15% of patients with a new diagnosis of T2DM. This type of neuropathy presents in 50% of persons with T2DM within 10 years after the initial diabetes diagnosis (Pop-Busui et al., 2017).

### **Foot Ulcers and Amputations**

Approximately 25% of persons diagnosed with T2DM are likely to develop a foot ulcer during their lifetime (Hicks & Selvin, 2019). Diabetic peripheral neuropathy accounts for 90% of hospital admissions related to diabetic foot ulcers, and 83% of all major amputations in the U.S. are caused by a complication from DM (Hicks & Selvin, 2019). From 2011-2014, the CDC (2016a) documented a total of 102,835 LEAs in the United States, and 86,800 (84.4%) were attributable to DM. In 2014, the CDC (2016b), reported a total of 11,488 LEAs in the state of Texas; 10,040 or 87.4% of those amputations were attributable to DM. The Texas Department of Health Services reported that Bexar County had the highest number of hospital admissions related to LEAs among all Texas counties (Sunil et al., 2019). According to the San Antonio Metropolitan Health District (2019), the rate of LEA related to DM has consistently been higher in Bexar County than the overall rate in Texas, with Bexar county reporting a rate of 9.7 per 10,000 people and Texas reporting a rate of 6.5 per 10,000.

Because DPN is a progressive and irreversible complication associated with DM, patients who have a history of foot ulcers and poor diabetes management are at high risk for developing ulcers that lead to amputations (Hicks & Selvin, 2019). Raghav et al. (2018) state that the annual expenditure for diabetic foot care or disease is \$8,659 per patient; the medical costs for a lower limb amputation (below the ankle) equates to approximately \$43,800, while the cost for amputations above the ankle increases to, on average, \$66,215. It should be noted that a significant part of the expenditure was not from the surgeries but from rehabilitation and nursing care required after the acute care stay (Raghav et al., 2018). Comprehensive foot exams and patient education about foot care are one evidence-based recommendation that can be conducted inexpensively in the primary care setting and may identify foot ulcers and other diabetic foot complications before amputation becomes the only treatment option (ADA, 2019; Lung, 2020).

### **Assessment**

The project leader completed an assessment of the primary care clinic located in a large metropolitan city in the southwestern United States. This assessment took place over 3 months and largely followed the Dartmouth Institute Microsystem Academy (2005) clinical microsystems format.

The clinic consists of a front desk with a waiting area and a clinical space that includes patient exam rooms and a section where laboratory specimens are collected and processed. The patients check-in and check-out at the front desk, which is staffed by one medical assistant (MA). During a typical visit (without the requirement of social distancing), the waiting room can accommodate seven to eight patients at a time. During the stay home, work safe period requiring social distancing by the local government, the waiting room did not accommodate any patients.

Patients with appointments were expected to call via telephone to check-in and wait in their vehicles until they were called in by office staff.

When patients were brought to the clinical area, there was a designated space where vital signs and labs were obtained. There were three patient exam rooms where the provider examined patients and located at the back of the office was the provider's office, a break room, two restrooms (one for staff and one for patients), and a designated area for lab processing, supplies, and medication storage.

### **Purpose of Practice**

The primary clinic did not have a formally stated mission; however, this practice focused on acute care and chronic disease management of families. The provider at this clinic cares for patients across their lifespan by integrating clinical and behavioral sciences.

### **Professionals**

The primary care clinic is composed of one family practice physician, three MAs, and one registered nurse (RN) who only focuses on chronic care management (CCM). Because a large number of patients are Spanish speaking, all staff is bilingual, speaking English and Spanish. The role of the RN was to complete CCM follow-up calls and visits for patients insured by Medicare. The RN contacted patients to ensure that they were taking medications as prescribed, answered questions about medications or vital signs, set up follow-up appointments with the provider, assessed home safety, and ensured and that they had the adequate resources to manage their chronic illnesses. The goal was to prevent patients from needing hospitalization and preclude unnecessary ER visits. As of June 2020, the RN position was vacant.

Each of the MAs took turns working at the front desk, completed office duties, obtained lab specimens, assisted the provider with procedures and basic examinations, and administered

medications such as intramuscular injections. In addition to their daily responsibilities, each MA completed prior authorizations, initiated referrals to specialists, set up patient rooms, or sent out laboratory requisitions as needed or directed by the provider.

### **Patients**

There are a total of 5,328 active patients in the practice, of which 69% are female, and 31% are male. The provider conducts approximately 644 patient visits every month. Fifty-five percent (2,950 patients) of the patients in this practice have been diagnosed with T2DM. A vast majority of the patient population is Spanish-speaking, where 59.2% of patients identify themselves as Hispanic/ Latino. Table 1 contains a breakdown of patient characteristics.

**Table 1**

#### *Patient Population*

Race/Ethnicity	<i>n</i>	%
American Indian or Alaska Native	1	0.02
Asian	28	0.53
Black or African American	145	2.72
Hispanic/ Latino	3,154	59.2
Non-Hispanic White	1,793	33.65
Unspecified	207	3.88

---

*Note.* *N* = 5,328 active patients

### **Processes**

The average patient visit can range from 30 min to 1 hr, depending on how busy the clinic is that day and the needs of the patient. There is only one provider onsite who sees patients



by appointment. The clinic also reserves time slots for same-day appointments. A chronic disease management appointment may last 30 to 45 min, and an appointment for a new patient with chronic diseases can take anywhere from 60 to 90 min depending on the labs required and the extent of the examination. When patients arrive, they sign in at the front desk, and they are given paper forms to update their information as needed and to write down the names of the medications they need to be refilled. Before the patient is taken to the exam room, the MA obtains their vital signs and asks about the reason for their visit and any new medications. Once patients have seen the provider and the required labs have been completed, they are accompanied to the front desk to check out where their copay is collected, and their next follow-up visit is scheduled.

This medical office maintains patient records through an EHR system that is capable of organizing the patient schedule, billing for visits and procedures, sending electronic prescriptions, sending referrals to other providers, and tracking required tests such as mammograms, lipids, hemoglobin A1cs, and immunizations. The office no longer stores any hard-copy records; hard-copy documents such as the forms that patients fill out with their medication refill requests are scanned directly into the EHR and shredded after the appointment. The EHR has many features that the provider uses daily such as the ones described above. However, if the provider would like to add additional features, they would have to pay for these features, which can cost up to \$1,000. The provider has been using this EHR system for the last 5 years, and if there are any difficulties with setup or processes, they can contact the representative of the help desk directly.

**Patterns**

At the time the microsystem assessment was conducted, there was no system in place that reminded the provider to perform CFEs; this played a significant role in these foot exams not being performed at the recommended frequency. Currently, the clinic's EHR has the capability to send pop-up reminders to the provider when a core measure or guideline is due for a patient. For example, there is a system in place to notify the provider when the patient is due for labs or exams like an HgA1c, lipid levels, a colonoscopy, or a mammogram. The system has the capability to track these exams in a spreadsheet where the provider can easily find completion dates and results. CFE's were the only assessment that did not have a notification system in place and that did not appear in the spreadsheet.

Foot inspections were being performed according to ADA guidelines and as a part of the physical assessment. There was in fact, an area to document CFEs in the physical assessment section for each patient visit. However, there was no way to keep track of the completion of CFEs unless the user examined each individual chart or performed a search using current procedural terminology (CPT) codes.

The project leader conducted a report using the EHR that listed the number of CFEs billed for and identified nine (0.3%). This was discussed with the provider, and the provider expressed concern with the results. The provider explained that CFEs were being performed, but the documentation must have not been performed. The EHR does provide a template on the physical assessment section for the foot exams, but it does not populate a report to keep track of their completion.

**Need for Intervention**

During the assessment process, the project leader noted that CFEs were not being performed consistently or regularly for patients with T2DM. The project leader systematically reviewed the clinic's EHR and retrieved documentation for nine patients. The CFEs that were completed followed ADA guidelines in the way that they were performed but were not completed at the recommended frequency. Because the system currently in place has not proven efficient with documentation, tracking, or establishing frequency reminders for CFEs, the project leader consulted with the provider and determined that it would be best to use a hardcopy CFE template and set up a notification system in the EHR.

**Readiness for Change**

After completing the assessment, the project leader met with the provider and staff to discuss the findings. During this meeting, education on *ADA Standards of Medical Care-2019* was presented with an emphasis on the significance of CFEs. The provider and the office staff were open and accepting of the assessment and plan. Throughout the assessment period and during this meeting, the project leader evaluated the team's readiness for change.

The first step in implementing change is to identify and evaluate readiness for change. One must assess the culture of an organization to recognize the barriers and facilitators (Tappen et al., 2017). The project leader previously completed a clinical rotation at the site and had built a rapport with the provider and staff, which served as a facilitator for the initiation of this project. The established rapport was beneficial as it allowed the staff and provider's openness to suggestions and to the possibility of changing the office flow. Another indicator of readiness was the interest that the staff had related to this project. The staff was inquisitive and interested in

learning about the benefits of CFEs and even contributed ideas on how this project could be sustained once the project leader completed the intervention.

Other factors associated with readiness for change were taken into consideration. One factor taken into account was personnel. It was essential to ensure that there would be sufficient personnel; adding tasks to an already stressed and understaffed personnel has the potential to create a hostile environment and could negatively affect the implementation of any project. This clinic had proper staffing and the staff appeared to work well together. Another factor considered was finances and an effect on daily working patterns. It was of great importance to confirm that the site had the financial means to purchase supplies and to support any additions to the daily flow of patient appointments. These factors were discussed with the provider and with the employee in charge of billing to ensure that the implementation of this project would not be cost-prohibitive nor negatively affect the daily workflow during the implementation phase. Neither issue was deemed to be problematic.

The last factor considered was space. The project site was a relatively small office with accommodations for 10 to 11 patients at a time (including the waiting area) pre-pandemic. It was crucial to discuss the use of space for project implementation with both the provider and the staff. The aim was to complete this project without creating disruptions or disarray. The provider and billing specialist agreed that the project could be initiated and sustained in the current office space. Overall, the provider and the office staff were open and accepting of the assessment and plan and demonstrated readiness for change.

A barrier that concerned the project leader was time. Specifically, there was concern that conducting CFEs would increase the length of time a patient spent in the office, the time the provider needed to be with the patient and the time that MA staff spent preparing patients and

processing the CFE documents after patient visits. Patients being seen for a CDM appointment were already spending nearly an hour at the clinic for a regular visit, and the project leader was concerned that a more extended patient visit could result in patient dissatisfaction. Additionally, the project leader was worried that the exams might begin to dissipate if they added too much time to a CDM appointment. This concern was resolved in the planning stages by assisting the provider and staff as much as possible with procuring supplies and developing documents to prevent the prolongation of patient visits.

### **Project Identification**

#### **Purpose**

The purpose of this quality improvement (QI) project was to institute an evidence-based practice recommendation from the *ADA Standards of Medical Care-2019* to conduct CFEs for patients with T2DM at a small primary care clinic in the southwestern United States.

#### **Objectives and Anticipated Outcomes**

1. Create and utilize electronic or paper CFE documentation form that would be accepted by the Center for Medicaid and Medicare Services by January 2020 with input from the provider.
  - a. Anticipated outcomes: the provider will approve electronic or paper CFE documentation form.
  - b. The form will be utilized by the provider upon the initiation phase to document all CFEs.
2. Design and implement necessary processes for staff and provider to incorporate CFEs for patients with T2DM during routine CDM appointments by January 2020 and adjust as needed.

- a. Anticipated outcomes: The project leader will direct provider and staff on the incorporation of the CFE process into the daily workflow for appropriate patients.
  - b. Staff and provider will begin implementing the CFE process, and the provider will perform and document exams starting in February 2020.
3. By April 2020, increase to 50% provider performance and documentation of CFEs based on 2019 ADA standards.
  - a. Anticipated outcome: Performance of CFEs will reach at least 50% overall by April 2020, as evidenced by documentation of all portions of the exam (medical history, current history, foot exam, sensory foot exam, risk categorization).
  - b. All CFEs performed will be documented completely based on form.
4. Create and implement formative and summative evaluation processes to assess progress towards 50% completion and documentation of CFEs.
  - a. Anticipated outcome: Weekly flow sheets will demonstrate progress towards a 50% increase; in the event, this goal is not reached weekly second outcome is anticipated.
  - b. Meeting with staff and provider to identify and address barriers to 50% completion and documentation rate with changes made to process as necessary.

### **Summary and Strength of the Evidence**

Each year the ADA publishes the *Standards of Medical Care in Diabetes*. These standards of care are intended to provide tools and recommendations to clinical providers to

assist with the treatment and chronic management of DM. The ADA's professional practice committee performs extensive research and disseminates literature to construct these guidelines with the most updated standards and regulatory changes. Recommendations by the ADA are based on well-designed clinical trials or meta-analyses, and the level of evidence grades them. The levels of evidence range from A to E; a level A grade is given to well-conducted, randomized controlled trials while a level E grade is based on expert opinions or recommendations (ADA, 2019). See table 2 for the full description of each level of evidence used by the ADA. These grades are essential as each evidence-based guideline from the ADA carries the grade that correlates with the level of evidence supporting the recommendation. Specific recommendations from the ADA (2019), which form the basis of this evidence-based project are listed in table 3.

**Table 2**

*ADA Evidence-Grading System*

Level of evidence	Description
A	Well-conducted, randomized controlled trials that include evidence from a well-conducted multicenter trial or a meta-analysis with incorporated ratings.
B	Supportive evidence from well-conducted cohort studies, meta-analyses of cohort studies, or supportive evidence from well-conducted case-control studies.
C	Supportive evidence from poorly controlled or uncontrolled studies; evidence from observational studies with potential for bias; evidence from case series or case reports.
E	Expert consensus, opinions, recommendations, or clinical experience

*Note.* Adapted from "ADA Evidence-grading System for Standards of Medical Care in Diabetes," by American Diabetes Association, 2019, *Diabetes Care*, 42, p. s2

(<http://dx.doi.org/https://doi.org/10.2337/dc19-Sint01>).

**Table 3***Neuropathy and Foot Care Recommendations*

Level of evidence	Recommendation
B	Perform a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations (p. s133).
B	All patients should be assessed for diabetic peripheral neuropathy starting at diagnosis of type 2 diabetes...and at least annually thereafter (p. s131).
C	Patients with evidence of sensory loss or prior ulceration or amputation should have their feet inspected at every visit (p. s131).
B	Assessment for distal symmetric polyneuropathy should include a careful history and assessment of either temperature or pinprick sensation...and vibration... All patients should have annual 10-g monofilament testing to identify feet at risk for ulceration and amputation (p. s131).
C	Patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle-brachial index and further vascular assessment as appropriate (p. s131).

*Note.* Adapted from "Microvascular Complications and Foot Care," by American Diabetes

Association, 2019, *Diabetes Care*, 42, p. s131-s133

(<http://dx.doi.org/https://doi.org/10.2337/dc19-Sint01>).

**Standards of Care**

The ADA (2019), recommends as one of its evidence-based standards that all patients should be assessed for DPN through a CFE as soon as they are diagnosed with T2DM and that these examinations should be conducted at least yearly after that. Patients who, upon exam, present with sensory loss or with a history of ulceration or amputation should have their feet inspected at every visit. According to the ADA (2019) recommendations, the patient's provider should obtain a detailed history regarding any foot abnormalities, previous wounds or ulcers, amputations, or infections (ADA, 2019).



The provider should assess for DPN by testing for loss of sensation using a monofilament to assess small fiber function (ADA, 2019; Lung, 2020). Comprehensive foot examination should include inspection of the skin to look for calluses or ulcers, assessment and identification of foot deformities, a neurological assessment to assess small fiber function and protective sensation using a 10-g monofilament, and a vascular assessment that includes checking pulses in the legs and feet (ADA, 2019). The ADA (2019) adds that if a patient presents with decreased or absent pulses and/or symptoms of claudication, they should be referred for an ankle-brachial index to assess vascular status. If a diagnosis of PAD is established, a referral to a vascular specialist is warranted to evaluate the status and establish revascularization as needed (ADA, 2019).

## **Methods**

### **Project Plan**

The project leader developed a quality improvement project plan designed around the 2019 ADA screening recommendations related to neuropathy and foot care. Specifically, the intervention included a plan to implement CFEs among adult patients with T2DM at the recommended intervals. These are the steps the project leader laid out in the planning phase of this project:

1. Review EHR for CFE documentation capabilities.
  - a. Incorporate a CFE documentation form into existing EHR, or
  - b. Develop a new form for EHR, or
  - c. Develop or identify a hard copy of the CFE form and create a mechanism to incorporate it into EHR.

2. Review EHR for the capacity to create employee/provider notification of the need for CFE based on ADA (2019) recommended intervals.
  - a. If the capacity for notification exists withing EHR, activate this capacity.
  - b. If capacity does not exist, develop a mechanism such as a pop-up notification that informs the provider and staff about T2DM diagnosis and the need for CFE screening.
3. Identify and obtain supplies needed to complete CFE (e.g., 10g monofilament).
4. Once the decision on CFE form and foot exam procedures is made, construct any necessary change in employee workflow and responsibilities.
5. Educate primary care provider and office staff on procedure changes, role changes, and go-live date of February 11, 2020.
6. Indicate to staff location of CFE documentation form (electronic or hard copy) to ensure accessibility when the project leader is unavailable.
7. Educate staff regarding set up of patient exam rooms with the necessary supplies and tools to perform the exams (e.g., 10g monofilament).
8. Provide a folder for staff and explain that they are to place completed CFE templates after they have been scanned into the patient EHR so that the project leader can assess completeness and weekly results.
9. Ensure the availability of a shred box that met criteria outlined by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to shred the collected CFE templates every week.

## **Project Implementation**

The project leader, along with the provider and staff, began implementing CFEs for patients in February 2020. The first step towards initiation started in January 2020 when the project leader focused on education of the primary care provider and the office staff regarding the benefits of performing CFEs in primary care. Because the EHR did not have a CFE documentation form that could be accessed without reviewing each patient's entire record, the project leader explored with the provider the costs and benefits of making changes to the current EHR versus creating or identifying a hard copy CFE documentation template. When discussing the fee to build a new electronic CFE and notification system into the existing EHR, the software management company indicated that initial costs would start at \$1000, and the provider was reluctant to move forward with this expense until the initial quality improvement project demonstrated the feasibility of this project. Therefore, it was decided with the provider's input to begin the project with a hard copy CFE documentation template adapted from the National Diabetes Education Program's (NDEP, n.d.) screening form. See Appendix A for the complete template. The CFE documentation template consisted of four sections: medical history, current history, foot exam, sensory foot exam, and risk categorization (NDEP, n.d.).

After this was completed, the project leader identified capacities of the current EHR system and identified a method to link a care reminder pop-up notification to the EHR of patients with the diagnosis of T2DM. This notification was sent to all the staff in the clinic and appeared on their dashboard each morning. The notification informed the staff of which patients had an active T2DM diagnosis and would need a CFE. It should be noted that all previously documented CFEs were completed in 2019, so all T2DM patients were due for a CFE when they came for their next CDM appointment. Every morning after seeing the care reminder

notifications on their dashboard, the front desk MA was responsible for placing the CFE template (see appendix) on the patient information clipboard that was given to the provider before the provider examined each patient. The MA would be able to identify patients needing a CFE because the care reminder pop-up notification generated by the project leader is the only one of its kind.

A second MA, which is usually responsible for taking vital signs and updating information for the appointment would set up the exam room with the monofilament and patient information clipboard. That same MA was responsible for asking or assisting patients in removing their shoes and socks to prepare them for the assessment. After the provider completed a CFE, the form was scanned into the patient's chart by the MA who set up the room. The MA edited the date for the next CFE for the following year on the pop-up care reminder, and this date now actively appeared on the patient's record every time someone accessed it. To establish a new annual schedule and consider the time that a CFE might extend an appointment, CFEs were only performed on patients who were coming into the office for CDM visits, not on patients who came in for an acute illness appointment. The pop-up care reminder for the CFE would remain in place and could only be removed by the creator or the provider once the CFE was completed.

This process worked for the first week of implementation in February 2020, however, it had to be revised after week 2. During week 2, this quality improvement project disrupted the flow of the front desk resulting in a significant decrease in CFE performance. The project leader met with the office staff and the provider to ask for input, and at that time, it was decided that the process would be modified. The original first step that required the front desk MA to place the form in the patient clipboard was modified and that task was delegated to the MA who obtained vital signs and documented visit information. This resulted in a smoother flow of events and did

not disrupt the flow of the front desk MA, who was tasked with answering phones, setting up appointments, and checking the patients in and out.

Due to the COVID-19 pandemic, at week 7, the project leader supervised the project remotely. Every week from week 7 on the project leader would discuss results with the provider via telephone and video conferencing. Records were reviewed and evaluated remotely by the project leader through the use of a clinic laptop. To ensure the continuance of the project, the leader discussed opportunities for improvement and addressed any concerns or challenges incurred during the implementation process.

### **Decision for intervention**

The decision to use a hard copy CFE template for documentation was made with the provider because the number, date, and frequency of CFEs performed were difficult if not impossible to track unless a person reviewed each patient's assessment record to see if a CFE was part of a physical exam. This obstacle became evident after the project leader explored the current EHR and found that there was no way to track individual CFE records as one could track mammograms or certain blood work such as HgA1c. As stated previously, the addition of this feature to the EHR could only be implemented at a minimum cost of \$1000 to the provider, and the consideration to add this feature was dependent on the results of this quality improvement project. At the time of the assessment, the only way to accurately know which patients received a CFE was by searching the current procedural terminology (CPT) code in the system. Moreover, not every patient would have the appropriate CPT code in their medical record unless they had been previously diagnosed with loss of protective sensation (LOPS) (Centers for Medicare & Medicaid Services, 2005). Therefore, it was decided that the project leader would manually set up a pop-up care reminder notification system for CFEs.

**Barriers**

Barriers to this project were not related to staff or provider unwillingness or push back, but rather to daily activities and occurrences that were unavoidable. Time was a barrier that could not be controlled because the flow of the clinic cannot be predicted and there is only one provider to see all the patients and perform the CFEs. Performing CFEs could add up to an additional 10 min to a visit that may have been scheduled initially as a 15 min visit. This could impact overall operations as well as patient wait time and satisfaction. Although these additional 10 min could be perceived as a positive factor for a patient whose visit was 10 min longer, this would not be the case for a patient who did not have that additional time with the provider.

Another barrier to this QI project was the number of available staff. Although there was sufficient staff at the beginning of this project, there were only two MAs that actively participated in project implementation. The absence of one of these staff members could affect the actual performance of CFEs. When the clinic is short an MA, the office manager is required to perform the duties of the absent staff member in addition to their own administrative tasks; this leaves no room for MAs to assist with the performance of CFEs.

The fact that the project leader was forced to work remotely served as a barrier as well. The presence of the project leader throughout the 11-week implementation period could have served as a facilitator by assisting with performance of CFEs, assistance with patients using telehealth technology, and by helping staff when time became a barrier.

***COVID-19***

One barrier that deserves special mention is the COVID-19 global pandemic, which resulted in a city-wide stay at home order during the project implementation period (City of San

Antonio, 2020). The implementation of this quality improvement project continued seamlessly until week 7 (March 25, 2020) when the project leader changed from in-person project supervisor to remote supervisor due to the project leader's possible risk of coronavirus exposure. The provider then assumed in-person responsibility for oversight and completion of CFEs and discussed results with the project leader weekly via telephone and video conferencing. During week 8, due to fear of community exposure to the coronavirus, many patients canceled their CDM appointments, and there was a significant decrease in the number of patients who received services. During that same week, the clinic was also closed for 2 days.

By week 9 of the project (2<sup>nd</sup> week of April), a stay at home/ work safe declaration that was initiated by the mayor and county judge on March 23, 2020, further changed the dynamics of this project (City of San Antonio, 2020). This order, which was in place from March 24, 2020, through June 4, 2020, limited the reasons that a person could leave their home but allowed visits to health care providers. These events led to the provider's decision to offer services via telehealth during weeks 9 and 10.

At that time, the project leader and provider decided to change the outcome criteria for weeks 9 and 10 for patients seen via a telehealth appointment. The outcome criteria for week 9 and week 10 excluded the sensory evaluation and pulse palpation portion of the exam. It was noted that the risk categorization determination might not reflect the full patient risk.

Week 11 was considered a transition week. After seeing that many patients had difficulties with the telehealth technology, the provider decided that both face-to-face and telehealth appointments would be offered.

**Facilitators**

Facilitators for this project included support from the staff and the provider, including a willingness of all staff and the provider to communicate between themselves to incorporate a new process. The provider and the office staff made themselves available to the project leader since the project was proposed, and there was no resistance to change.

**Ethical Considerations**

The project leader submitted the project plan to the university institutional review board (IRB) with a letter of support from the provider (see Appendix B), and the project was deemed non-research by the IRB (see Appendix C). Because this quality improvement project was not a research study, no patient consent was needed; the only ethical consideration was patient privacy. Although identifying hardcopy documentation was created and scanned into the patients' EHR, patient information was disposed of appropriately. As instructed by the U.S. Department of Health & Human Services (n.d.), documents with protected health information were disposed of by a certified shredding company that renders those records as unreadable and unable to be reconstructed.

**Evaluation Plan**

The project leader created a formative and summative evaluation plan. The formative evaluation plan consisted of a review of the clinic processes once the project was implemented, a follow up on the accuracy of CFE documentation, and the gathering of key data weekly. The projected data to be gathered weekly included: the total number of patients with a diagnosis of T2DM seen for a CDM appointment, the number of patients who had a CFE performed, the number of documented CFEs with all aspects of the exam documented, and what, if any elements of documentation were lacking. The project leader planned to use data on the



percentage of completed exams each week to address process, material, personnel, or any unanticipated barriers that prevented at least a 50% completion and full documentation rate. The summative evaluation plan consisted of a compilation of the weekly evaluations summed for a total number and percentage of CFEs completed during the 11-week timeframe among those patients with T2DM seeking care during a CDM appointment.

The criteria for CFE completion included the full performance documentation of a CFE, including the medical history, current history, foot exam, sensory foot exam, and risk categorization as classified on the documentation template. The completion criteria changed for weeks 9 and 10 (during the pandemic), where a completed CFE excluded assessment of pedal pulses and the sensory foot exam because visits were conducted via telehealth. Week 11 was a transition week where visits transitioned from telehealth to in-person visits; therefore, all aspects of CFE were expected to be performed and documented. The actual data gathered weekly from week 1-8 included the total number of patients with a diagnosis of T2DM seen for a CDM appointment, the number of those patients who had a CFE performed, and the number of CFE with all aspects of the exam documented. During weeks 9 and 10, the same data was gathered except the criteria for a complete documented CFE excluded the pedal pulse assessment and sensory foot exam. Table 4 provides a full result of the weekly findings and the final totals.

Records were reviewed weekly by the project leader. Prior to changes in the practice process due to the impact of COVID-19, the project leader was able to gather data directly from the EHR at the clinic. The CFE templates that were collected weekly to assess performance were discarded in a shred box according to HIPAA laws. When the project leader began evaluating the project remotely, the provider allowed the leader to use a laptop from the clinic at home. This password-protected laptop gave the leader access to only weekly visit-related information and

had the clinic's EHR and network security software installed. This allowed the project leader to access data while maintaining HIPAA compliance.

### **Results**

For the 1<sup>st</sup> week of implementation the project leader determined that there was a 60.8% CFE completion and documentation rate, which exceeded expectations, especially for the 1<sup>st</sup> week that the clinic staff had added tasks to their daily workflow. The leader noted that in the 2<sup>nd</sup> week there was a serious decline in CFEs with only a 20% completion rate. During week 2 adjustments were made to the process and this reflected positively on week 3 with a completion and documentation rate of 53.8% CFEs, which represented a 33.8% increase over the previous decline. The adjustments required the change of roles between MAs. Originally, the front desk MA was responsible for placing the CFE template on the patient information clipboard given to the provider before the provider examined each patient. Because this process severely affected the workflow of the front desk, this task was assigned to a second MA who was already responsible for taking vital signs and setting up the exam room with the monofilament and patient information clipboard. This considerably improved the workflow and decreased the workload for the front desk MA.

During the formative evaluation period, the project leader discovered another decline in completed and documented CFEs which occurred during week 6 and week 7. The leader discussed these results with the provider and with the office staff. The decline in performed CFEs was due to the absence of the office manager who was out sick for the duration of those 2 weeks. During the office manager's absence, there was an increased workload on all of the staff including the provider. Therefore, project implementation was not priority as the staff and clinic flow were already being affected.

During week 8 the lowest number of patients were seen as the provider had a family emergency and had to close the clinic for several days; however, there was still 100% completion and documentation. During weeks 9 and 10, the clinic transitioned to a telehealth schedule due to the pandemic and the outcome criteria for CFE performance was modified as noted above. Results for these 2 weeks fluctuated as patients and staff adapted to the new platform for conducting patient visits.

Week 11 was a transition week from telehealth to in-person visits and no patients needing a CFE were seen that week. At the end of the 11 weeks, there were a total of 111 patients seen for a CDM appointment with a diagnosis of T2DM, and 58 of those patients had a completed CFE with documentation in their EMR, yielding a total of 52% CFE completion. Refer to table 4 for the weekly and final outcome.

Finally, the project leader estimated that the performance of CFEs would add approximately 10 min to a patient appointment. While this was not measured specifically, the provider reported that CFE performance added anywhere from 10 to 20 min to a CDM appointment (telehealth or face-to-face). The time increase was dependent on staff preparedness, exam room setup, technical difficulties, and patient punctuality.

Table 4  
Outcome Data

Week	Number of T2DM patients seen for CDM appointment	Number of patients who had a full CFE performed	All aspects of CFE documented from weeks 1-8	Foot inspections documented weeks 9-10	All aspects of foot exam documented on week 11	Percentage of completed and documented CFEs
Week 1	23	14	14			60.8%
Week 2	15	3	3			20%
Week 3	13	7	7			53.8%
Week 4	12	7	7			58.3%
Week 5	18	14	14			77.7%
Week 6	8	3	3			37.5%
Week 7	9	3	3			33%
Week 8	2	2	2			100%
Week 9	6			2		33.3%
Week 10	5			3		60%
Week 11	0				0	-----
Totals	111	53	53	5	0	52%

*Note.* On weeks 9 and 10, patients were only seen via telemedicine, and the criteria for CFE completion and documentation were modified due to the COVID-19 pandemic. The exams began with Week 1 on Tuesday, 02/11/2020, and culminated with Week 11, which began on 04/20/2020. Percentage of completed CFEs = total documentation for CFEs for weeks 1-8 (53) + documentation of weeks 9-10 (5) / total number of patients seen (111).

### Discussion

Pocuis et al., (2017) performed a retrospective record review to assess provider performance of diabetic foot examinations per ADA guidelines. Pocuis et al., (2017) found that 16% of the sample ( $n = 88$ ) had a completed documented annual foot exams according to ADA guidelines. While the Pocuis et al. finding is higher than what the project leader identified prior to initiation of this project (0.3%), Pocuis et al. results indicate that the performance and documentation of annual foot exams needs improvement. Pocuis et al. explain that after inspecting patient records, they discovered that there was not a systematic way of documenting these exams. The documentation found was vague and did not follow a specific template or form. The only documentation that was considered as “complete” in the Pocuis et al. study was documented with the use of a checklist. These findings support the recommendation not only for the use of a template to document these exams but to integrate the CFE into the EHR to increase compliance with ADA guidelines. The findings from Pocuis et al. highlight the importance of using a documentation template like the one used in this project to accurately document an assessment and track its performance.

Wu et al., (2018), conducted a retrospective cohort study and used multiple logistic regression to test for association between the use of a clinical reminder and recommended services by the ADA including HbA1C, retinal exam, and foot exam . The authors concluded that although there was an increase in foot exam performance with the use of a clinical reminder (from 5.7% to 8.6%,  $p = 0.06$ ) it was not statistically significant. Additionally, Wu et al. suggested that practices with solo providers normally operate at a lower profit margin making cost a barrier for the adoption of clinical reminders. Both of these factors have been considered in this quality improvement project. Profit margin must be considered in QI projects such as the

one being presented here, and there is no evidence that the pop-up care reminder system for CFEs is the driving force behind the increased completion rate.

### **Limitations**

One limitation of this quality improvement project was that use of a hard copy CFE template required completion by hand and scanning into the patient record to track CFE performance. This workaround, due to limited EHR capabilities, may decrease the likelihood of project sustainability and may place an extra work burden on staff and the provider. However, it is this type of project that may encourage smaller clinics to invest in a more robust EHR that can sustain greater changes.

Another limitation relates to the COVID-19 global pandemic. Although the project continued during the COVID-19 pandemic and despite the stay home/ work safe orders established by city and county officials, the outcome had to be modified due to the change in visits from in person to telehealth. It is possible that some risk factors were missed when the sensory foot exam portion of the CFE had to be omitted in telehealth visits.

Finally, this quality improvement project may have been impacted because the clinic's EHR did not have a CFE reminder function. This could tremendously affect the sustainability of this project because an accidental deletion of the pop-up care reminder that the leader created could ultimately alter future performance of this screening.

### **Strengths**

A major strength of this project was the implementation of an evidence-based standard into practice. The project leader was able to take the ADA guidelines regarding foot screening for patients with T2DM and after a thorough needs assessment and planning process, implement an 11- week project where CFEs were completed and fully documented at least 50% of the time

instead of sporadically. This project demonstrates that an evidence-based recommendation such as the one pertaining to CFEs can be incorporated into a small primary care practice setting and may increase the number of foot complications that are identified early, thus decreasing the frequency of LEAs.

Additionally, the selection of patients with T2DM with appointments for chronic disease management was performed in a more organized fashion. This process ensured the performance of CFEs during the implementation phase of this project.

### **Recommendations**

It would be of great benefit to repeat this quality improvement project at another time after the resolution of this pandemic and possibly for a longer time frame. Implementing this project at another time could improve the quality of results and serve as beneficial to other primary care practices with the same area for improvement. Also, implementing this project over a longer period of time could improve results where a large decline was witnessed due to these patients being seen every 3 months for follow-up. Unfortunately, because the COVID-19 pandemic has not entirely resolved at this time and continues to evolve, other recommendations are necessitated for an increase in completion rates.

Expanding the role of the chronic care management RN may influence the sustainability of this project in the long run. When the position for RN is filled, it would be of great value for the RN to assist with tracking and performing CFEs at home with the supervision of the provider since they will already be contacting these patients for follow-up.

Another recommendation would be for the provider to invest in a more robust EHR that allows the creation of documentation, tracking, and reminder features. The capability of the

EHR system to add the CFE to the patients' records may improve completion rates and ultimately, patient outcomes.

### **Implications**

Because T2DM is a chronic illness that requires frequent follow-up and chronic management, it would be prudent to suggest that the performance and documentation of CFEs become a healthcare effectiveness data and information set (HEDIS) measure. HEDIS is a performance improvement tool that measures performance in healthcare areas where improvements can be made (National Committee for Quality Assurance, n.d.). The addition of CFE as a HEDIS measure can improve the effectiveness of prevention and screening tools such as the CFE and, in the long run, improve patient outcomes in the primary care setting.

The DNP-prepared nurse practitioner focuses on a continuum of care and understands how to measure outcomes of new models of care (Beeber et al., 2019). The DNP also has the skills and the groundwork for bridging the gap between new models of care and superior patient outcomes. This factor is vital because foot ulcers are one of the most common and preventable complications of T2DM, and 20% of them result in amputations (Armstrong et al., 2017).

### **Conclusion**

Because foot ulcers are one of the most common and preventable complications of T2DM and 20% of them result in amputations, primary care providers must be up to date with the most current standards of care (Armstrong et al., 2017) and be willing to put evidence-based guidelines into practice. Being up to date with the most current standards of care and having the resources in one's practice set to track outcomes can make a significant difference in the quality of a patient's life. Foot ulcers and amputation are major causes of morbidity and mortality in



patients with DM. Therefore, the completion of CFEs in 52% of patients in the practice, may be a big step towards an increase in life expectancy (ADA, 2019).

### References

- American Diabetes Association. (2017a). *The burden of diabetes in Texas*.  
<http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/texas.pdf>
- American Diabetes Association. (2017b). *The cost of diabetes*.  
[https://www.diabetes.org/resources/statistics/cost-diabetes?language\\_content\\_entity=en](https://www.diabetes.org/resources/statistics/cost-diabetes?language_content_entity=en)
- American Diabetes Association. (2018). *Statistics about diabetes*.  
<https://www.diabetes.org/resources/statistics/statistics-about-diabetes>
- American Diabetes Association. (2019). Standards of medical care in diabetes-2019. *Diabetes Care*, 42. <http://dx.doi.org/https://doi.org/10.2337/dc19-Sint01>
- Armstrong, D. G., Boulton, A. J., & Bus, S. A. (2017). Diabetic foot ulcers and their recurrence. *New England Journal of Medicine*, 376(24), 2367-2375.  
<http://dx.doi.org/10.1056/NEJMr1615439>
- Beeber, A. S., Palmer, C., Waldrop, J., Lynn, M. R., Jones, C. B. (2019). The role of Doctor of Nursing Practice-prepared nurses in practice settings. *Nursing Outlook*, 67(4), 354-363.  
<https://doi.org/10.1016/j.outlook.2019.02.006>
- Callaghan, B. C., Price, R. S., & Feldman, E. L. (2020). Distal symmetric polyneuropathy in 2020. *JAMA Neurology*, 324(1), 90–91. <https://doi.org/10.1001/jama.2020.0700>
- Centers for Disease Control and Prevention. (2016a.). *Hospitalizations for lower extremity amputations in adults with diabetes, United States*.  
<https://nccd.cdc.gov/Toolkit/DiabetesBurden/Hospitalization/Lea>
- Centers for Disease Control and Prevention. (2016b). *Hospitalizations for lower extremity amputations in adults with diabetes, Texas, 2014*.  
<https://nccd.cdc.gov/Toolkit/DiabetesBurden/Hospitalization/Lea>

Centers for Disease Control and Prevention. (2017). *Diabetes 2017 report card*.

<https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf>

Centers for Disease Control and Prevention. (2019). *Diabetes*.

<https://www.cdc.gov/diabetes/basics/diabetes.html>

Centers for Disease Control and Prevention. (2020). *Initial public health response and interim clinical guidance for the 2019 novel coronavirus outbreak- United States, December 31, 2019-February 4, 2020*.

[https://www.cdc.gov/mmwr/volumes/69/wr/mm6905e1.htm?s\\_cid=mm6905e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6905e1.htm?s_cid=mm6905e1_w)

Centers for Medicare & Medicaid Services (2005). *Billing of the diagnosis and treatment of peripheral neuropathy with loss of protective sensation in people with diabetes*.

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r498cp.pdf)

[Guidance/Guidance/Transmittals/downloads/r498cp.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r498cp.pdf)

City of San Antonio. (2020). *City of San Antonio and Bexar County announce stay home, work safe orders*.

<https://www.sanantonio.gov/gpa/News/ArtMID/24373/ArticleID/18649/City-of-San-Antonio-and-Bexar-County-announce-Stay-Home-Work-Safe-Orders>

Feldman, E. L. (2020). *Pathogenesis and prevention of diabetic polyneuropathy*. UpToDate.

[https://www.uptodate.com/contents/pathogenesis-and-prevention-of-diabetic-polyneuropathy?search=diabetic%20neuropathy&source=search\\_result&selectedTitle=5~150&usage\\_type=default&display\\_rank=5#H13](https://www.uptodate.com/contents/pathogenesis-and-prevention-of-diabetic-polyneuropathy?search=diabetic%20neuropathy&source=search_result&selectedTitle=5~150&usage_type=default&display_rank=5#H13)

Hicks, C. W., & Selvin, E. (2019). Epidemiology of peripheral neuropathy and lower extremity disease in diabetes. *Current Diabetes Report*, 19(10). <http://dx.doi.org/10.1007/s11892-019-1212-8>

- Juster-Switlyk, K., & Smith, A. G. (2016). Updates in diabetic peripheral neuropathy. *F1000 Research*, 5(738), 3-7. <http://dx.doi.org/10.12688/f1000research.7898.1>
- Khalil, H. (2017). Diabetes microvascular complications—A clinical update. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, 11(1), s133–s139. <https://doi.org/10.1016/j.dsx.2016.12.022>
- Lung, C., Wu, F., Liao, F., Pu, F., Fan, Y., & Jan, Y. (2020). Emerging technologies for the prevention and management of diabetic foot ulcers. *Journal of Tissue Viability*, 29(2), 61-68. <https://doi.org/10.1016/j.jtv.2020.03.003>
- Ming, A., Walter, I., Alhajjar, A., Leuckert, M., & Mertens, P. R. (2019). Study protocol for a randomized controlled trial to test for preventive effects of diabetic foot ulceration by telemedicine that includes sensor-equipped insoles combined with photo documentation. *Trials*, 20(521), 2-10. <https://doi.org/10.1186/s13063-019-3623-x>
- National Committee for Quality Assurance. (n.d.). *HEDIS measures and technical resources*. <https://www.ncqa.org/hedis/measures/>
- National Diabetes Education Program. (n.d.). *Comprehensive diabetes foot examination form*. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/ndep/index.html>
- Pocuis, J., Li, S. M., Janci, M. M., & Thompson, H. J. (2017). Exploring diabetic foot exam performance in a specialty clinic. *Clinical Nursing Research*, 26(1), 82-92. <http://dx.doi.org/10.1177/1054773815596699>
- Pop-Busui, R., Boulton, A. J., Feldman, E. L., Bril, V., Freeman, R., Malik, R. A., Sosenko, J. M., & Ziegler, D. (2017). Diabetic neuropathy: A position statement by the American

Diabetes Association. *Diabetes Care*, 40(1), 136-154.

<http://dx.doi.org/https://doi.org/10.2337/dc16-2042>

Raghav, A., Khan, Z. A., Labala, R. K., Ahmad, J., Noor, S., & Mishra, B. K. (2018). Financial burden of diabetic foot ulcers to the world: A progressive topic to discuss always.

*Therapeutic Advances in Endocrinology and Metabolism*, 9(1), 29-31.

<http://dx.doi.org/https://doi.org/10.1177/2042018817744513>

San Antonio Metropolitan Health District. (2019). *Diabetes in Bexar County- 2017/2018 report*.

<https://www.sanantonio.gov/Portals/0/Files/health/News/Reports/Diabetes/DiabetesReport2017-2018.pdf>

Sunil, T., Limon, A., & Ochoa, L. (2019). Lower extremity amputation among diabetic patients in San Antonio, Texas. *Hispanic Health Care International*, 17(2), 73-78.

<http://dx.doi.org/10.1177/1540415319828267>

Tappen, R. M., Wolf, D. G., Rahemi, Z., Engstrom, G., Rojido, C., Shutes, J. M., & Ouslander, J.

G. (2017). Barriers and facilitators to implementing a change initiative in long-term care utilizing the INTERACT quality improvement program. *The Health Care Manager*,

36(3), 219-230. <http://dx.doi.org/10.1097/HCM.0000000000000168>

The Dartmouth Institute Microsystem Academy. (2005). *Clinical microsystems: Assessing, diagnosing and treating your outpatient primary care practice*.

<https://clinicalmicrosystem.org/knowledge-center/workbooks/>

U.S. Department of Health & Human Services. (n.d.). *What do the HIPAA privacy and security rules require of covered entities when they dispose of protected health information?*

<https://www.hhs.gov/hipaa/for-professionals/faq/575/what-does-hipaa-require-of-covered-entities-when-they-dispose-information/index.html>

World Health Organization. (2020). *About diabetes*.

[https://www.who.int/diabetes/action\\_online/basics/en/index3.html](https://www.who.int/diabetes/action_online/basics/en/index3.html)

Wu, S. S., Chan, K. S., Bae, J., & Ford, E. W. (2018, September 12). Electronic clinical reminder and quality of primary diabetes care. *Primary Care Diabetes*, 13(2), 150-157.

<http://dx.doi.org/https://doi.org/10.1016/j.pcd.2018.08.007>

## Appendix A

## CFE Documentation Template

## Comprehensive Diabetes Foot Examination Form

Adapted from the National Diabetes Education Program's Foot Screening Form

Name:

Date:

Age:

Age at Onset:

Diabetes Type ☐ 1 ☐ 2Current Treatment: ☐ Diet ☐ Oral ☐ Insulin**I. Medical History**

(Check all that apply.)

- ☐ Peripheral Neuropathy
- ☐ Cardiovascular Disease
- ☐ Nephropathy
- ☐ Retinopathy
- ☐ Peripheral Vascular Disease

**II. Current History**

1. Any change in the foot or feet since the last evaluation?

☐ Yes ☐ No

2. Current ulcer or history of a foot ulcer?

☐ Yes ☐ No

3. Is there pain in the calf muscles when walking that is relieved by rest?

☐ Yes ☐ No**III. Foot Exam**

1. Are the nails thick, too long, ingrown or infected with fungal disease?

☐ Yes ☐ No

2. Note foot deformities.

- ☐ Toe deformities ☐ Bunions ☐ Charcot foot ☐ Foot drop
- ☐ Prominent metatarsal heads
- ☐ Amputation (Specify date, side and level.)

## 3. Pedal Pulses

(Fill in the blanks with a "P" or an "A" to indicate present or absent.) Posterior tibial:

Left

Right

Dorsalis pedis:

Left

Right

4. Skin Condition (Measure, draw in and label the patient's skin condition using the key and foot diagram to the right.)

C = Callus R = Redness W = Warmth

F = Fissure S = Swelling U = Ulcer

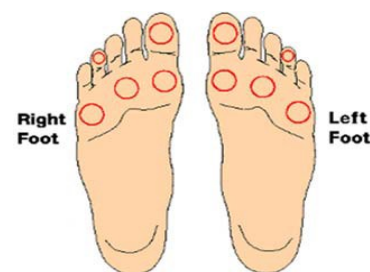
M = Maceration PU = Pre-ulcerative lesion D = Dryness

**IV. Sensory Foot Exam**

Label sensory level with a "+" in the five circled areas of the foot if the patient can feel the 5.07 Semmes-Weinstein (10-gram) nylon filament and "-" if the patient cannot feel the filament.

NOTES

NOTES



**V. Risk Categorization** (Check appropriate item.)

Low-Risk Patient

All of the following:

- ☐ Intact protective sensation   ☐ No severe deformity  
☐ No prior foot ulcer   ☐ Pedal pulses present  
☐ No severe deformity   ☐ No amputation

High-Risk Patient

One or more of the following:

- ☐ Loss of protective sensation  
☐ Absent pedal pulses  
☐ Severe foot deformity  
☐ History of foot ulcer

**VI. Footwear Assessment**

1. Does the patient wear appropriate shoes?

☐ Yes ☐ No

2. Does the patient need inserts/orthotics?

☐ Yes ☐ No**VII. Education**

1. Has the patient had prior foot care education?

☐ Yes ☐ No

2. Can the patient demonstrate appropriate self-care?

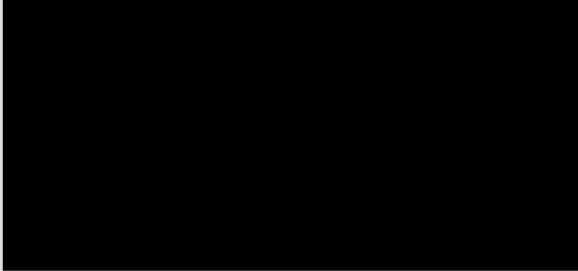
☐ Yes ☐ No**VII. Management Plan** (Check all that apply.)

- ☐ Provide patient education for preventive foot care.   ☐ Refer to an APMA member podiatrist or an appropriate physician.

Date: \_\_\_\_\_ Provider Signature: \_\_\_\_\_



**Appendix B**  
**Letter of Support**



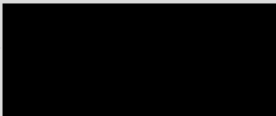
November 25, 2019

Institutional Review Board  
University of the Incarnate Word  
4301 Broadway Street  
San Antonio, Texas 78209

To Whom It May Concern:

I, [REDACTED] MD, am aware of the Doctor of Nursing Practice project that will be conducted by Ms. Dora E. Trevino BSN, RN [REDACTED]. I am aware the quality improvement project *Implementation of comprehensive foot exams in family practice* will be conducted over the year 2020 at this clinic, and it will be overseen by Ms. Trevino. I approve and fully support the implementation of this quality improvement project.

Sincerely,



## Appendix C

### Human Subjects Research Determination



12/2/2019

Project Lead: Dora Trevino

Project title: Implementation of comprehensive foot exams in family practice

Dora:

Your project titled Implementation of comprehensive foot exams in family practice was deemed to be **Not Regulated Research**.

Your proposed project was reviewed and found to not meet federal regulatory requirements for human subject research and does not require approval via the IRB process. Please use the IRB number **NRR [19-060]** when inquiring about or referencing this determination.

No further review of the project as proposed is required. Should you determine at any point you wish to add additional elements to the project, please contact us before initiating those components, as this may impact the determination.

For information regarding the IRB or the review process, please contact me at (210) 805-5885.

Sincerely,

Ana Hagendorf, PhD, CPRA

Ana Hagendorf, PhD, CPRA  
Director, Office of Research and Sponsored Projects Operations  
Office of Research and Graduate Studies  
University of the Incarnate Word  
4301 Broadway, CPO 1216  
San Antonio, Texas 78209  
(210) 805-3036  
[wandless@uiwtx.edu](mailto:wandless@uiwtx.edu)