

Implementing an Evidenced-Based Quality Improvement Project to Standardize Foot Screening  
in Adults with Type 2 Diabetes  
DNP Final Project

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By

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## Abstract

**Introduction:** In the United States, over 37 million adults have type 2 diabetes mellitus (T2DM), with 23% of them unaware of their condition. Diabetes contributes to significant health complications, including over 270,000 deaths, 16 million emergency visits, and 7.8 million hospitalizations annually. Individuals with T2DM are prone to peripheral arterial disease and neuropathy; approximately 25% of people with diabetes will develop a foot ulcer during their lifetime, leading to significant medical expenses, lost productivity, and reduced quality of life. Regular screening and education can prevent up to 85% of diabetes-related amputations. Evidenced- based practice guidelines recommend integrating a process for standardized foot screening in primary care.

**Purpose:** The purpose of this project was to standardize foot screening for patients with T2DM within a comprehensive primary care clinic.

**Methods:** This quality improvement project standardized foot screening using the Inlow's 60-Second Diabetic Foot Screen, a validated, rapid screening tool created for primary care that includes use of the 10-g monofilament test and key risk stratification scoring. Utilizing the Plan-Study-Do-Act model, an educational in-service during the project kick-off provided an opportunity for clinicians and staff to practice using the Inlow's Screen. The healthcare team involved in integrating the standardized screening in practice included four family medicine physicians, two nurse practitioners, one licensed practical nurse, nine medical assistants, the office manager, and several nonclinical office specialists.

**Results:** Pre-implantation data was collected from primary care visits to evaluate the percent of patients with T2DM who received an annual foot exam within the four weeks prior to the project; the data revealed 49.8% of patients with T2DM (n=287) received a foot exam utilizing a monofilament tool. Following project implementation, 55% of adults with T2DM seen in the office (n=209) had a completed comprehensive foot exam. Based on scores from the Inlow's 60-Second Diabetic Foot Screen, three patient referrals were placed for specialist evaluation of their DFU risks.

**Implications for Practice:** Implementation of an evidenced-based, standardized foot screening in primary care can result in an increase of completed foot exams for individuals with T2DM. Leadership buy-in and team collaboration is needed to create an environment that supports practice change.

*Keywords:* Adults, type 2 diabetes mellitus, foot screening [tool], diabetic foot ulcers, primary care office

## **Section 1: Problem Identification & Recommended Best Evidence-Based Practice**

### **Statement of the Problem**

In the United States, more than 37 million Americans have type 2 diabetes mellitus (T2DM), a chronic illness resulting from the body's inability to regulate blood glucose levels (Centers for Disease Control and Prevention [CDC], 2023). Approximately 23% of adults with diabetes are unaware, and another 96 million have prediabetes, elevated glucose levels indicative of developing diabetes, the 7th leading cause of death (CDC, 2023). In one year in the U.S., there are more than 270,000 death certificates with diabetes listed as the underlying or contributing cause of mortality, more than 16 million emergency department (ED) visits with diabetes as a listed diagnosis, and more than 7.8 million hospitalizations for co-morbidities, including major cardiovascular diseases, lower-extremity amputation, and hyperglycemic crisis (CDC, 2017).

In 2022, the total cost of diagnosed diabetes in the U.S. was \$412.9 billion; an estimated 25% of all healthcare dollars is spent on individuals with T2DM (American Diabetes Association [ADA], 2023). Individuals with diabetes have medical expenses on average of more than \$19,000 annually, exacerbated by the cost of insulin, which has tripled over the last decade (ADA, 2023). Management of diabetic foot disease, i.e., diabetic foot ulcers (DFUs) resulting from peripheral neuropathy and/or arterial disease, adds an annual estimated cost of \$9 to \$13 billion (Raghav et al., 2018). For the individual with T2DM who develops a foot ulcer(s), direct and indirect costs can include inpatient and outpatient care, lost productivity, amputation risk, and loss of quality of life for them and their families. Diabetes-related amputations have a high risk of mortality, with survival rates at 5 years estimated at less than 50% (Huang et al., 2018; Singh et al., 2005). DFU (Diabetic Foot Ulcer) is the leading cause of hospitalization,

amputation, reduced mobility, loss of social participation, and lower quality of life in people with diabetes (Zhao et al., 2023).

Individuals with diabetes are prone to peripheral neuropathy, which impairs sensation in the feet, and peripheral arterial disease, reducing blood flow to the extremities and impairs wound healing. Lower extremity disease is twice as common in individuals with T2DM, eventually affecting 50% of adults with diabetes (Hicks & Selvin, 2019; Lazo-Porrás et al., 2016; Singh et al., 2005). Approximately 25% of people with diabetes will develop a foot ulcer during their lifetime (Hicks & Selvin, 2019; Lazo-Porrás et al., 2016). Screening tools to identify early signs of diabetic foot disease have the potential to reduce the incidence of ulceration and amputation. Screening for DFU is imperative, as complications from neuropathy and altered vascular status can develop silently. According to the CDC (2022), providing patient education and completing regular foot exams could prevent up to 85% of diabetes-related amputations.

### **Organizational Assessment of the Problem/Readiness for Change**

OhioHealth is a not-for-profit healthcare system, serving central Ohio since 1891. OhioHealth employs 35,000 associates, physicians, and volunteers. There is a network of 14 hospitals, three joint venture hospitals, one managed-affiliate hospital, 200+ ambulatory sites and other health services spanning across 50 counties. Community health is this organization's driving mission, whose vision includes improving the health of those who are served. The organization's values include: compassion, excellence, inclusion, integrity, and stewardship with a pledge to respect the physical, emotional, and spiritual needs of the patients with the finding that compassion is essential to fostering, healing and wholeness. OhioHealth has more than 1,600 healthcare providers in central Ohio.

One of the 97 OhioHealth ambulatory practices is an outpatient primary care office on the west side of Columbus, Ohio. The healthcare team at the site consists of: four family medicine physicians, two nurse practitioners, one licensed practical nurse, nine medical assistants, one office manager and several nonclinical office specialists. Primary care provided at this clinic includes services for acute illness needs, chronic care management, and preventive health and wellness screenings.

This OhioHealth primary care office utilizes Epic, a comprehensive medical record software system to access, organize, store, and share electronic medical records. In this outpatient setting, there is a health maintenance tab that populates in each patient's chart, which alerts the provider if the foot examination is due to be completed. All six providers utilize a monofilament test/tester to fulfill the requirement of the foot examination annually. The providers are not currently using a standardized screening tool. The main question driving this project: "Is there a gap in care regarding foot screenings that could be addressed through quality improvement?" The team is interested in quality improvement initiatives to improve diabetes management at the primary care office and are eager for evidence-based practice changes to improve their patient's overall well-being and decrease the risk of foot ulcerations for individuals with T2DM.

### **Significance of Screening for Diabetic Foot Disease**

Diligent screening for peripheral neuropathy and peripheral arterial disease is key to reducing the complications and healthcare burden of lower extremity disease in individuals with T2DM. Guidelines established by the American Diabetes Association (ADA) recommend that all patients with diabetes be screened for risk of DFUs and amputation, their feet should be checked at each visit, and a comprehensive foot assessment should be performed at least once a year

(ADA Professional Practice Committee, 2024; ADA, 2023). The ADA has recommended preventive measures to avoid the consequences of diabetes since it began in 1940 and continues to recommend that all patients with diabetes receive detailed foot care guidelines (ADA, 2023; Cooksey, 2020; Hicks & Selvin, 2019; Plummer & Albert, 1995). Their guidelines are consistent with the National Diabetes Education Program, the American College of Physicians, Healthy People 2030 national objectives, and the International Working Group on the Diabetic Foot (ADA Professional Practice Committee, 2024; ADA, 2023; Cooksey, 2020; Schaper et al., 2023; U.S. Department of Health and Human Services, 2023; Zhao et al., 2023), and include recommendations that clinicians should screen all patients with diabetes at diagnosis and annually to identify those at risk for developing DFUs, which includes:

1. Identifying those with an “at-risk foot” which includes loss of sensation.
2. Regularly assessing the feet of people who are at-risk for foot ulceration.
3. Providing education for patients, their families and healthcare professionals.
4. Encouraging routine wearing of appropriate footwear.
5. Treating risk factors for ulceration.

Quality improvement (QI) measures to meet the guidelines for diabetic foot risk screening should include clinician training on relevant guidelines and evidence-based screening techniques, support for improved cognition and attitude towards foot risk screening, expanding the number of clinicians with these skills, and increasing access to user-friendly screening tools (Zhao et al., 2023). Prevention of DFU is more important than treatment (Zhao et al., 2023). Considering the potential of developing risk of foot disease in people with diabetes, it is recommended that foot screening should be performed by primary care practitioners and specialists to detect foot disease in an early stage (Vatankhah, et al., 2010). Regular comprehensive foot examination, patient

education on foot care like simple hygienic practices, provision of appropriate footwear, and prompt treatment of minor injuries and a multi-disciplinary team approach can decrease ulcer occurrence by 50% and amputations by up to 85% (Vibha, et al., 2018). Prevention of diabetic foot ulceration is critical to reduce the associated high morbidity and mortality rates and the danger of amputation (Vibha, et al., 2018). Every 30 minutes and 30 seconds in the United States, an individual loses a limb from a diabetes-related amputation (ADA, 2023).

### **PICO(t) and Search Strategy**

The literature search was driven by the PICO(t) question: *In adults diagnosed with type 2 diabetes mellitus (P), how does utilizing a foot screening tool (I) compared to current practice (C) affect patient outcomes (O)?* A literature search was completed in CINAHL and PubMed within The Ohio State University's Health Science Library database. The key terms applied during this literature search included *diabetic foot ulcer*, *screening*, and *primary care*. Boolean terms included in the search were AND/OR. The synonym terms used to expand the search were *diabetic foot sore*, *diabetic foot*, *diabetic foot wound*, *screening tool*, *ambulatory care*, *office*, and *clinic*. The search focused on the best evidence for the adult population. In addition, published literature addressing individuals with a diagnosis of pre-diabetes, gestational diabetes or type 1 diabetes were excluded in the literature search for this project.

Upon completing the initial literature search, a PRISMA diagram and checklist were utilized to guide the appraisal process (Appendix A), 178 articles were identified for review within the two databases. There were 116 articles found in CINAHL and 62 articles in PubMed using the identified search terms. There were six references removed from the search summary due to duplicate articles. The remaining 172 articles were screened by the title and abstract for relevance based on search terms; with this review, 149 studies were excluded for not occurring in

a primary care or outpatient care setting, which left 23 studies for full text review. Of the 23 remaining, 11 studies were excluded due to reasons that included: wrong setting, wrong intervention, wrong study design, wrong patient population, or because the study design did not involve screening or the use of a screening tool. Twelve studies were reviewed and appraised for quality and strength and are included in the synthesis tables (See Tables 1 and 2).

### **Levels of Evidence and Outcomes Synthesis**

An established level of evidence hierarchy was used to evaluate the literature in the body of evidence (Melnyk & Fineout-Overholt, 2018). The Helene Fuld Trust National Institute for Evidence-based Practice in Nursing and Healthcare critical appraisal tools were used during the appraisal process. Twelve articles were appraised and synthesized, which lead to the formation of the levels of evidence synthesis table (Table 1). One study was a Level I: Systematic review and one study was a Level II: Randomized controlled trial. Six studies were a Level IV: Cohort study. Another three studies were a Level VI: Evidence-Based Practice (EBP) project and one study was a Level VII: Expert opinion.

Table 1 is a level of evidence synthesis table that was created to synthesize the research studies addressing standardized foot screening as best practice in primary care for people diagnosed with T2DM. The 12 published articles range from a Level 1: Systematic review to a Level VII: Expert opinion. Evidence for standardized foot assessments were published going back to the year of 1995 to year 2023, as DFUs leading to an amputation or even death is a common, ongoing, consequence of diabetes. Studies published as systematic reviews, randomized controlled trials, evidenced-based practice projects, and expert opinion supports the significance of implementing this QI project to promote health and prevent disease and disability related to preventing DFUs within the adult population.



Table 2 is an outcomes synthesis table created to support and identify the interventions and recommendations guided by the evidence from the published literature. The outcomes synthesized focus on the use of a standardized foot screening tool in individuals with T2DM.

### **Critical Appraisal of the Evidence**

Examining the feet of an individual with T2DM is one of the most effective means of preventing significant foot complications including DFU; the strength of this statement is supported by all 12 of the reviewed, published research studies (Alavi et al., 2009; Baker & Kenny, 2016; Cooksey, 2020; Lazo-Porras et al., 2016; Murphy Buschkoetter et al., 2019; Plummer, & Albert, 1995; Singh et al., 2005; Stone, 2017; Vatankhah et al., 2010; Vibha, et al., 2018; Woody, J., 2020; Zhao et al., 2023). Regular inspection at least annually and early treatment are the most effective mechanisms to prevent devastating diabetic foot complications (Alavi et al., 2009). Prevention begins with identifying and screening those at risk.

Utilizing a standardized foot screening tool in patients with T2DM is correlated with improved ability to identify patients at an increased risk of developing a diabetic foot ulcer and reduces the disease burden of diabetes within the targeted population (Alavi et al., 2009; Baker & Kenny, 2016; Cooksey, 2020; Lazo-Porras et al., 2016; Murphy Buschkoetter et al., 2019; Plummer & Albert, 1995; Singh et al., 2005; Stone, 2017; Vatankhah et al., 2010; Vibha, et al., 2018; Woody, 2020; Zhao et al., 2023). Furthermore, there is consensus that using a standardized foot screening tool within primary care increases clinician adherence to current, evidence-based diabetic foot screening policies and guidelines (Alavi et al., 2009; Baker & Kenny, 2016; Cooksey, 2020; Lazo-Porras et al., 2016; Murphy Buschkoetter et al., 2019; Plummer & Albert, 1995; Singh et al., 2005; Stone, 2017; Vatankhah et al., 2010; Vibha, et al., 2018; Woody, 2020; Zhao et al., 2023). Critical analysis of the evidence reveals that using a standardized foot

screening tool increases clinician confidence and awareness of the need to perform the physical foot exam regularly on their patients at risk (Alavi et al., 2009; Baker & Kenny, 2016; Cooksey, 2020; Lazo-Porras et al., 2016; Murphy Buschkoetter et al., 2019; Plummer & Albert, 1995; Singh et al., 2005; Stone, 2017; Vatankhah et al., 2010; Vibha, et al., 2018; Woody, 2020); Zhao et al., 2023). Screening and timely identification of risk factors for DFU is the most cost-effective way to prevent further complications of diabetes (Zhao et al., 2023), and can lead to improved overall control of T2DM (Cooksey et al., 2020).

Of critical importance, a standardized foot screening tool increases the prompt identification of individuals at high risk of amputation (Alavi et al., 2009; Baker & Kenny, 2016; Lazo-Porras et al., 2016; Murphy Buschkoetter et al., 2019; Plummer., & Albert, 1995; Vatankhah et al., 2010; Woody, 2020). It is particularly important to identify individuals at high risk of diabetic foot complications to lower the incidence of preventable DFU and amputations. The prevention of ulcer recurrence is of high significance, as reoccurrence rates range from 28% in 12 months to up to 100% at 40 months (Alavi et al., 2009).

When clinicians prioritize foot screening in individuals with T2DM during office visits, patients are more likely to participate in their own self-care, have improved self-efficacy related to foot care, and engage in effective foot care practices (Alavi et al., 2009; Baker & Kenny, 2016; Lazo-Porras et al., 2016; Plummer & Albert, 1995; Vibha, et al., 2018). To avoid preventable costly complications, evidence-based practice for individuals with T2DM includes ongoing education, foot care, and the use of appropriate footwear (Lazo-Porras et al., 2016).

### **Recommendation for Standardized Screening Tools**

Critical appraisal of the evidence suggests that standardized foot screening tools for individuals with diabetes is best practice in primary care. Tools to identify early signs of DFU

resulting from peripheral neuropathy or vascular disease have the potential to reduce the incidence of foot ulceration and amputation (Lazo-Porrás et al., 2016). The review of literature and national evidence-based recommendations suggest that using a screening tool annually is a minimum standard for individuals with T2DM who have not already developed a high-risk status for DFU (ADA, 2023; Cooksey, 2020; Schaper et al., 2023; Zhao et al., 2023). Identifying risk early allows for greater opportunity to implement preventive strategies and reduces the morbidity of foot disease for individuals with T2DM. Screening for foot complications should start at the time of diagnosis of diabetes (Vibha et al., 2018).

While there are many screening tests to assess for neuropathy in the feet of individuals with T2DM, testing with 10-g monofilament tester is most commonly used (Baker & Kenny, 2016; Cooksey, 2020; Murphy Buschkoetter et al., 2019; Plummer & Albert, 1995; Singh et al., 2005; Stone, 2017; Vatankhah et al., 2010; Zhao et al., 2023). Screening instruments/tests less commonly used in primary care related to cost and/or ease of use include:

- Ipswich Touch Test (Baker & Kenny, 2016; Zhao et al., 2023)
- Tuning fork (Baker & Kenny, 2016; Cooksey, 2020; Murphy Buschkoetter et al., 2019; Stone, 2017; Vatankhah et al., 2010)
- VibraTip (Baker & Kenny, 2016)
- Reflex hammer (Cooksey, 2020; Murphy Buschkoetter et al., 2019)
- TempStat™ capture of a thermal image of the feet (Lazo-Porrás et al., 2016)
- Michigan Neuropathy Screening Instrument (Murphy Buschkoetter et al., 2019)
- Doppler ultrasound (Singh et al., 2005)

The use of the 10-g monofilament tester developed by Semmes and Weinstein is considered the gold standard for assessing foot ulcer risk (American Diabetes Association

Professional Practice Committee, 2024; Dros et al., 2009; Stone, 2017). Monofilament testers, also called Semmes-Weinstein monofilaments, are calibrated, single-fiber nylon threads that generate a reproducible buckling stress (Dros et al., 2009). More than 15 years ago, systematic review of studies using the 10-g monofilament tester to evaluate peripheral neuropathy found sensitivity ranged from 41% to 93%, and specificity ranged from 68% to 100%; use of the 10-g monofilament tester at 10 sites on each foot was correlated with the highest levels of sensitivity and specificity in detecting neuropathy (Dros et al., 2009).

The Inlow's Simplified 60-Second Diabetic Foot Screen (Appendix B; hereafter referred to as Inlow's Screen) is a validated, standardized, rapid screening tool created for primary care that includes use of the gold standard 10-g monofilament test at 10 sites on the foot and provides key risk stratification scoring that dictate the type and frequency of foot interventions needed (Inlow, 2004; Parasuraman et al., 2017; Singh et al., 2005; Woodbury et al., 2015). Inlow's Screen was developed to maximize time efficiency in routine clinical practice and determine the necessity of referral for patients needing treatment in a timely manner. Inter-rater reliability scores for the Inlow's screen (independently tested on 1266 patients) support use of the tool to facilitate early detection of DFU (Woodbury et al., 2015). Although there are limitations to any specific tool, the effectiveness of the screening questions and the brief physical exam embedded within Inlow's Screen are correlated significantly with identification of risk for foot-related morbidity in individuals with T2DM, which is a benefit in primary care (Inlow, 2004; Parasuraman et al., 2017; Singh et al., 2005; Woodbury et al., 2015).

Because examining the feet of an individual with T2DM is one of the most effective means of preventing significant foot complications including DFU, this QI project included use of the Inlow's Screen in the initiative's efforts to standardize foot screening in primary care.

## **Section 2: Project Planning**

### **Project Purpose Statement**

The purpose of this project was to standardize foot screening for patients with T2DM within a comprehensive primary care clinic.

### **Project Objectives**

1. Integrate a process for standardized foot screening within the primary care clinic.
2. Increase the percentage of foot screenings completed for individuals with T2DM.
3. Assess the rate of referral for individuals with identified or at high risk for DFUs.

### **Framework to Drive Process**

The IHI Model for Improvement was used as a foundation for the QI strategies implemented in this project (Institute for Healthcare Improvement [IHI], 2021). The model guided development of the Plan-Do-Act-Study (PDSA) QI processes and is familiar to the healthcare team at the project site.

### **Population and Setting**

The patient population within this primary care setting has higher risk of chronic disease and of experiencing health disparities based on their socio-economic status, race, ethnicity, and other determinants of health. The focus population at this setting includes patients 18 years and older diagnosed with T2DM. Many of the patients are primarily Spanish speaking, have low income, limited to no insurance coverage, low health literacy, lack of transportation, housing insecurities and substance use disorders.

Determinants of health directly impact the treatment of T2DM, and vulnerability to DFU. For example, follow-up appointments and foot screenings will be delayed if the patient lacks transportation. Furthermore, a filled prescription to improve glucose control may sit at the

pharmacy if the patient does not have the financial funds to pay for medication. These barriers will need to be discussed with the provider and patient to better understand how to overcome limiting social factors, which could decrease diabetes-related morbidity, mortality, and associated healthcare costs. The neighborhoods in which individuals live, work, play, worship, and age directly impact access to food, safety, education, transportation, health behaviors, and stress levels, all factors that influence the vulnerability to poorer outcomes for individuals with diabetes (Chambers et al., 2021; Wadas et al., 2020).

### **Key Stakeholders**

Stakeholders needed to support this project included primary care providers, patients, the office manager, and medical assistants:

- **Primary care providers** were essential to this project, as they were responsible for checking patient records to determine when their last foot screening had been completed, if a screening was needed during the current visit, or if the patient had a scheduled follow up appointment for their foot screening. After a patient's records were reviewed, providers completed a foot screening per guidelines using the standardized foot screening. At the end of each patient visit, primary care providers were responsible for providing patient education, identifying appropriate management including follow-up, and completing any necessary referrals based on the foot screening score and their clinical judgment.
- **Patients** were asked to participate in their care during their office visits during this QI project. Patients had to be willing to take off their shoes and socks, and allow the provider to exam their feet. One of the assumptions of the project was that patients would be less likely to participate in the foot screening if they did not understand the importance of early

identification of foot ulcers. Discussion and education during the patient visits included the benefits of a foot screening for people with T2DM.

- ***The office manager*** was an important member of the project team; her role included ordering medical supplies, such as the monofilament testers, gloves and disposable chux pads. The chux pad was placed on the ground which provided a clean environment for the patients to place their feet during the examination. The providers needed gloves, the 10-g monofilament testers and Inlow's screening tool to perform the standardized evidenced-based foot exam.
- ***Medical assistants*** were crucial to this QI project. To improve time management with completion of the foot examination, medical assistants were important stakeholders who placed the chux on the floor. They also coached and assisted patients with socks and shoes removal prior to the provider entering the room to improve time management.

### **Patient Preferences/Values**

Patient preferences and values were assessed during each primary care office visit. By understanding patient's life circumstances and preferred health care choices, providers supported patient adherence to foot screenings and empowered them to create their own foot care routine. Patients' own attitudes about T2DM and willingness to change were also considered when providing individualized care for best health outcomes. Providing information about the need for daily self-foot inspection was one way to engage individuals in self-care.

### **Clinician/Clinical Expertise**

The project lead was a DNP student collaborating with a mentor who is a DNP-prepared family nurse practitioner employed at the primary care practice and whose leadership was instrumental in getting buy-in from other staff members and trainees. Clinical expertise was

acknowledged and integrated into this project by this mentor, who also is a champion at the primary care office where this QI project was implemented.

Clinicians needed information about this QI project, specifically how to utilize Inlow's Screen. The DNP student led the effort to kick off this QI project, which included education provided to the staff about the Inlow's Screen. The student as project lead remained supportive and available throughout implementation.

### **Outcomes Measures and Data Analysis Plan**

The National Center for Health Statistics (NCHS), the Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) is used by healthcare providers to classify and code all diagnoses, symptoms and procedures recorded in conjunction with medical care and prevention in the United States (CDC, 2023). The ICD-10 codes E.11 (type 2 diabetes mellitus) through E.11.9 (type 2 diabetes mellitus without complications) was part of the data analysis plan for pre- project implementation and project implementation phase data collection. Data was gathered from medical records in Epic at the specific clinical site location with a focus of patients who were age 18 years and older with a diagnosis of T2DM and included ICD- codes E.11-E.11.9.

During this QI project, the medical records of adults with T2DM seen at the primary care office were reviewed for the number of foot screenings completed with the monofilament tester or a missed foot screening opportunity for the annual requirement by clinicians at this primary care office. The number of referrals made for individuals with identified (or at high risk for) DFUs were gathered for data collection as the project implementation data. The project took place over a total of six weeks. The project implementation data was gathered at the completion of this initiative using the same criteria as the pre-implementation data collection and focused on



patients with T2DM seen at the primary care office during the implementation phase of this QI project.

### **Financial Implications**

The cost of supplies that were needed to complete this QI project can be calculated. A 20 pack of monofilament testers cost \$19.08 and a box of 100 gloves cost \$8.99. In addition, a box of 50 disposable chux pads cost \$5.36. There were material costs for paper, ink and lamination supplies to create the copies of Inlow's screening tool that were placed in each of the 12 exam rooms and used as a reference to guide screening during patient visits. Further, there was a nominal cost for the paper, ink and lamination of the exam room "foot care" posters that were placed on the back of the doors in each of the 12 exam rooms.

Much of the cost of this QI project not as easy to calculate. This initiative required clinician time. While using the Inlow's Screen was intended to streamline clinician processes, the time each provider needed to learn how to use and document the standardized foot screening had financial implications. However, the long-term return on investment would be related to improving diabetes management and avoiding costly consequences of DFUs in terms of morbidity and mortality. The value of an individual's overall quality of life is priceless and therefore cannot be calculated in a dollar amount.

### **Resources Utilized**

The Inlow's 60-Second Diabetic Foot Screening Tool (Inlow's Screen) and the monofilament testers were the primary resources needed to complete this project. IT support for dot phrase specific to Inlow's scoring with the recommended screening frequency in Epic's EHR documentation would additionally be optimal for sustainability beyond the QI project timeline of six weeks. However, while a ticket request for the addition of a dot phrase was placed, this took

longer than the project timeline and was not used. Providers were advised to use the current diabetic foot exam dot phrase “.dmfoot” to chart Inlow’s scoring with the recommended screening frequency in the fourth drop down option by left clicking the “\*\*\*\*\*” section of the foot screening for this QI project.

### **Project Approvals**

Approvals were granted to initiate this project by the institutions and organizations involved. The Ohio State University Human Subjects Research Determination Form (Appendix C) was completed, and deemed this project to be QI. The OhioHealth Nursing Scholarly Project Review Committee (NSRP) reviewed the project proposal and granted permission to implement this QI project (Appendix D).

## **Section 3: Implementation Plan**

### **Implementation Framework/Model**

This QI project utilized the IHI Model for Improvement. The project was guided by using the PDSA cycle of the model to implement evidence-based quality improvement and review results to determine if change is needed for future practice.

### **Implementation Strategies**

This QI project was implemented over a six-week timeframe. A project timeline is provided to overview implementation steps:

<b>Project Timeline</b>						
	Dec	Jan	Feb	Mar	April	May
DNP Professional Exam	X					
Complete the Human Subjects Research Determination (HSRD) form	X					
Complete data quality release form	X					
Finalize proposal for QI project based on committee feedback		X				
Seek Feasibility approval at Ohio Health			X			
Develop In-service PowerPoint and foot poster to introduce QI project			X			
Introduce QI project			X			
Kick-off to QI implementation <ul style="list-style-type: none"> <li>- Educational In-service</li> <li>- Foot Poster Signage in exam rooms</li> <li>- Inlow's screen and monofilament testers for all 12 exam rooms</li> </ul>				X		
6 Week Project Implementation				X		
At QI-project completion, collect project implementation data					X	
Analysis of outcomes					X	
DNP Final Project presentation & Defense						X
Disseminate results						X

### ***Education/ Training***

To successfully improve the quality of care in individuals with T2DM, an educational in-service provided to the staff members who were key stakeholders was a necessary evidenced-based step in this project. In the early afternoon on day 1 of kick-off week, a 10-minute educational session was provided to first introduce Inlow's Screen to the primary care providers and staff. This in-service used a sign-in sheet to track the provision of education to all staff as a group in the office. The 10-minute session included review of key content as outlined in the text box:

#### **KICK OFF SESSION – EDUCATIONAL IN-SERVICE**

- **Significance of the Problem**
  - Prevalence of T2DM
  - Cost of T2DM
  - Prevalence and cost of diabetic foot ulcers (DFUs)
- **Objectives of the QI project**
  1. Integrate a process for standardized foot screening.
  2. Increase the percentage of foot screenings completed for individuals with T2DM.
  3. Assess the rate of referral for individuals with identified or at high risk for DFUs.
- **Purpose of this QI project**
  - The purpose of this project is to standardize foot screening for patients with T2DM within a comprehensive primary care clinic.
- **Foot exam guidelines**
  - Copies of Inlow's Screen (see Appendix B) was available during this session
- **Use of the foot poster as a reminder**
  - Foot Poster (see Appendix E) was revealed before they were placed on the back of the door in each of the 12 exam rooms to raise awareness of foot screening.
- **Process for screening and time management in the office**
  - Discussion on how the use of a standardized screening tool can work best in the office for all staff members workflow
  - Scoring of the foot screening (see Appendix B)
  - Use of the monofilament test in step 8 of Inlow's Screen (for sensation)
  - Recommended screening interval (see Appendix B)
  - Discussion on how to document Inlow's Screen score in the EMR under ".dmfoot \*\*\*\*"
  - Referrals for individuals with identified or at high risk for DFUs
  - Contact information for DNP student/Project lead and mentor at clinical site
- **Questions or concerns regarding this project**

### *Communication during step-by-step implementation*

Communication was an essential component of implementing this project from start to finish and was planned throughout the QI project. A foot poster to support the foot screening initiative was placed in exam rooms to promote awareness in patients with T2DM. Specifically for the providers and staff:

- **WEEK ONE:** The “soft launch” was held on day 1 of the 6-week QI project implementation. This kickoff meeting included communication and in-person in-service educational session between the project lead and the key stakeholders, the primary care providers, office manager, and medical assistants at the office. Foot poster signage and a laminated copy of Inlow’s foot screening tool was placed in all 12 exam rooms to act as a reference guide.
- **WEEK TWO:** During week 2’s “formal launch,” the project lead returned to the primary care office to promote open communication, and asked questions such as what is going well and what barriers the staff are experiencing with the screening tool.
- **WEEKS THREE AND FOUR:** Communication included office visits to the staff to encourage screening, and to note when the project was more than halfway completed to cheer on, motivate and support the staff members. Four weeks of pre-implementation data were collected and analyzed.
- **WEEK FIVE:** Included an in-person open communication session between the project lead and staff members, in which barriers were assessed before the completion of this project. Data continued to be collected and analyzed.
- **WEEK SIX:** At the completion of this project, the project lead returned to the office to thank the staff members for their time and discussed future practice changes within the

office. The pre- implementation and project implementation data results were shared with all staff members at this time.

- **AFTER THE QI INITIATIVE:** At the end of week six, all providers, medical assistants and the office manager were thanked for their involvement, and feedback about the project was encouraged. All involved were invited to the DNP Final Project presentation.

## **Section 4: Results**

### **Project Implementation**

In summary, the Inlow's Simplified 60-Second Diabetic Foot Screening Tool was introduced to the staff at the primary care office. An in-person in-service educational session was provided to discuss with key stakeholders best practices for how to integrate a standardized foot screening tool within their current practice to fulfill the required annual diabetic foot exam located within the health maintenance tab of the electronic health record. This QI project took place over six weeks, with four of the weeks being the quality improvement implementation phase. The data were collected, analyzed and shared with all staff members at the clinical site.

A deviation in the project plan was to have less than all six providers participate in this QI project as three of the providers did not utilize the Inlow's screening tool during the project implementation phase. Another unexpected barrier encountered during this project was gaining access to patient data as a student from outside the organization. This was managed by identifying and contacting proper channels to gain access.

### **Barriers Management Plan**

In an effort to address potential barriers related to time management, clinical staffing, or uncertainty about the QI project, the DNP student lead and the clinical mentor provided ongoing support and discussion regarding the benefits of utilizing a standardized foot-screening tool to

decrease T2DM disease burden with key stakeholders. The level of evidence and outcomes synthesis tables were shared with the primary care providers and clinical support staff informally before the project was implemented just prior to the kickoff. To yield higher compliance rates and sustainably, the project lead asked the medical assistants and clinical staff what worked best in their workflow when implementing this QI project. In addition, open communication and collaboration with providers, medical assistants, clinical staff, the office manager and the project lead significantly helped foster trusting relationships, which allowed all individuals the opportunity to share their ideas.

## **Results**

The health maintenance tab was individually reviewed within 2,115 patient's medical charts via Epic. There were 287 adults with T2DM who met the criteria for pre-implantation data collection and 209 adults with T2DM who were seen during the project implementation phase. The snapshot function was utilized to access if the diabetic foot exam was overdue within the previous 12 months to fulfill the annual requirement or never completed, which was counted as a "missed foot screening" opportunity. The foot exam was counted as a completed screening if the foot screening was completed during the visit that day or if the annual foot exam had been completed within less than 12 months of the previous completed foot screen.

To meet the criteria for data collection, patients had to be 18 years or older with an ICD-10 code E.11 (type 2 diabetes mellitus) through E.11.9 (type 2 diabetes mellitus without complications) and were either seen as an office visit, Medicare wellness, complex/established, new patient, physical, transitional care, pre-admission testing or a well woman visit. Excluded data included patients less than 18 years of age, T1DM, pre-diabetes, unspecified type; hyperglycemia, or was a telehealth, no show/ not seen, Mychart e-visit, procedure (IUD

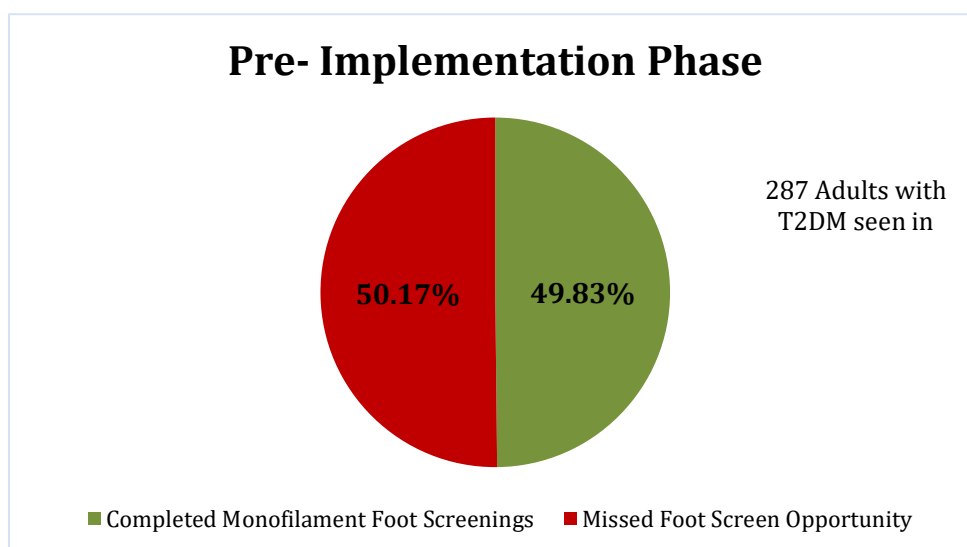
placement or removal), well child or nurse visit. The referral tab was accessed for any referral placed during the project- implementation phase.

Table 3 (below) includes data collected prior to the project, and with the QI implementation. Figures 1 and 2 (below) display the data for pre-implementation and during implementation by percentages.

**Table 3**  
Standardized Foot Screenings for Individuals with T2DM

Adults with T2DM	Pre- Project Implementation	With Project Implementation
Patient visits	287	209
Screenings with monofilament test	143	88
Inlow screen	NA	28
Referrals made for diabetic foot ulcers based on Inlow's screen; identified or risks	NA	3

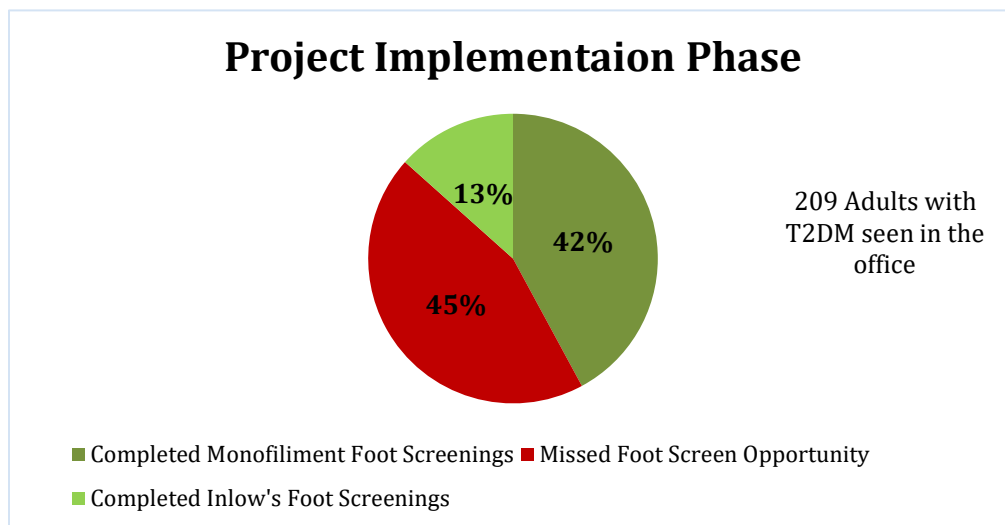
**Figure 1**  
Percentages of patients screened for DFU prior to the project





**Figure 2**

Percentages of patients screened for DFU during the QI project



### Discussion/Implications

The project objectives were met for this QI project to standardize foot screening for patients with T2DM within a comprehensive primary care clinic. Aims included and met:

**1. *Integrate a process for standardized foot screening within the primacy care clinic.***

- This was the first PDSA done with standardized foot screenings at this primary care office. The Inlow's Simplified 60-Second Diabetic Foot Screening Tool was integrated in the process of completing the mandatory annual foot screening for 13% of individuals with T2DM.
- To yield higher compliance rates by providers with utilizing the standardized foot screening tool, a longer implementation timeframe would be optimal for any additional process changes.

**2. *Increase the percentage of foot screenings completed for individuals with T2DM.***

- In the pre-implementation phase, 143 of the 287 adults with T2DM (49.83%) seen in the office had a completed monofilament foot screening for the annual requirement.
- In the project implementation phase, 88 of the 209 adults with T2DM (42%) seen in the office had a completed monofilament foot screening for the annual requirement and 28 of the 209 adults with T2DM (13%) seen in the office had a completed Inlow's foot screening for the annual requirement.
- There was a 5.17 % increase in the number of completed foot screenings during the project implementation phase.

3. *Assess the rate of referral for individuals with identified or at high risk for DFUs.*

- Based on Inlow's screening score for foot ulcers and/or life-threatening complications, there were three referrals placed during the project implementation phase. One patient scored a 23 and therefore the provider placed a referral to podiatry and an ophthalmology. Another patient scored a 12 and a podiatry referral was placed.

### **Sustainability Plan**

Communication between the provider and clinical support staff was provided to gain buy-in and maintain sustainability of this QI project. The DNP-prepared family nurse practitioner employed at the primary care practice where this QI project was implemented and whose leadership was instrumental in getting buy-in from other staff members and trainees created an environment of support and motivation, which was needed to support this practice change in the office.

IT support for dot phrase specific to Inlow's scoring with the recommended screening frequency in Epic's EHR documentation modification would additionally be optimal for sustainability to support organizational changes. Further training in Epic's SlicerDicer self-service reporting tool to offer the providers intuitive and customizable data exploration abilities would be optimal to improve additional time management skills and foot screening data accuracy. Providing feedback was a key evidence-based implementation strategy as barriers to missed screening opportunities to increase annual foot screening requirements were discussed.

## **Section 5: Dissemination**

### **Internal Dissemination**

The results of this QI project were shared with the organization's Nursing Research Project Manager to review the benefits of utilizing a standardized foot-screening tool when caring for patients diagnosed with T2DM. Internal dissemination will also occur with a public, final project presentation as required by the Ohio State University School of Graduate Studies; all key stakeholders and the DNP student's mentor will be invited to attend the presentation by web conferencing. Once all approvals of the final project dissemination are in place, and *Implementing an Evidenced-Based Quality Improvement Project to Standardize Foot Screening in Adults with Type 2 Diabetes* is complete, it will be submitted to Knowledge Bank, The Ohio State University's institutional repository. Additional dissemination opportunities include submitting a blog to the American Diabetes Association or a poster presentation at The Ohio State University Wexner Medical Center's annual Nursing Excellence Fair.

### **External Dissemination**

Submission to peer-reviewed journals such as *Diabetes & Primary Care*, *Journal of Diabetes* and/or *Health Promotion Practice* would reach an audience focused on decreasing

disease burden by utilizing a foot screening tool in a primary care office. A summary of this project may also be submitted to the *Journal of Clinical Diabetes* to be featured as a clinical QI success story as part of the external dissemination plan.

### **Reflection of AACN DNP Essentials**

The American Association of Colleges of Nursing (AACN) list core competencies for Professional Nursing Education (AACN, 2021). While working through completion of this project, ten of the ten essentials were met during this DNP QI project.

#### ***Domain 1: Knowledge for Nursing Practice***

The DNP student increased knowledge for practice by critically appraising and utilizing the best evidence-based practice screening tools to decrease T2DM complications related to foot ulcers, which ultimately improved quality and longevity of patients' lives.

#### ***Domain 2: Person-Centered Care***

The DNP student provided compassionate nursing care that is individualized, and family oriented by fostering caring relationships with providers, staff, and patients to promote an environment for health and well-being. In addition, the DNP student demonstrated advanced communication skills to model best care practices towards all team members by implementing an evidenced-based practice intervention, utilizing a foot screening tool for early identification and treatment of a DFU.

#### ***Domain 3: Population Health***

The DNP student improved population health at the primary care office by targeting a specific population of adults diagnosed with T2DM by utilizing an evidenced-based screening tool in addition to providing patient education of diabetic foot care.

#### ***Domain 4: Scholarship for the Nursing Discipline***

This QI project utilized the IHI Model for Improvement to evaluate patient and provider outcomes. The Plan, Do, Study, Act (PDSA) cycle framework guided the impact of new practices or change in current practice based on project outcomes.

***Domain 5: Quality and Safety***

The DNP student analyzed missed screening opportunities that could impact patient safety with a focus on adults diagnosed with T2DM within the primary care office. Minimizing risks of harm to patients and clinicians while enhancing quality by utilizing evidenced-based practice was the focus of this project.

***Domain 6: Interprofessional Partnerships***

This clinical site allowed opportunity to work towards strengthening patient outcomes by fostering an environment that promoted continuous learning. The DNP student promoted an environment that advanced learning by utilizing Inlow's evidence-based screening tool, which provided a learning opportunity while working with all care team members within the primary care clinical site.

***Domain 7: Systems- Based Practice***

Participating in organizational strategic planning during this project helped develop a quality improvement practice change that enhanced value, access, quality, and cost-effectiveness care. System improvement strategies was based on performance data and metrics over the timeframe of this project.

***Domain 8: Informatics and Healthcare Technologies***

Identifying the impact of information and communication technologies of Inlow's scoring in the EHR documentation workflow process was evaluated to discover the impact and use of technology in the outpatient primary care setting.

***Domain 9: Professionalism***

This project allowed the DNP student to work towards strengthening patient outcomes by facilitating communication and fostering opportunities for intentional presence in practice. The DNP student critiqued her own personal and professional practices in the context of nursing's core values to sustain professional identity.

***Domain 10: Personal, Professional, and Leadership Development***

Communication and leadership skills was utilized to implement this project in a setting that promoted self-care, personal health, and well-being of all individuals. This was an opportunity for the DNP student to explore intentional change guided by leadership principles and theories in managing change within a primary care environment.

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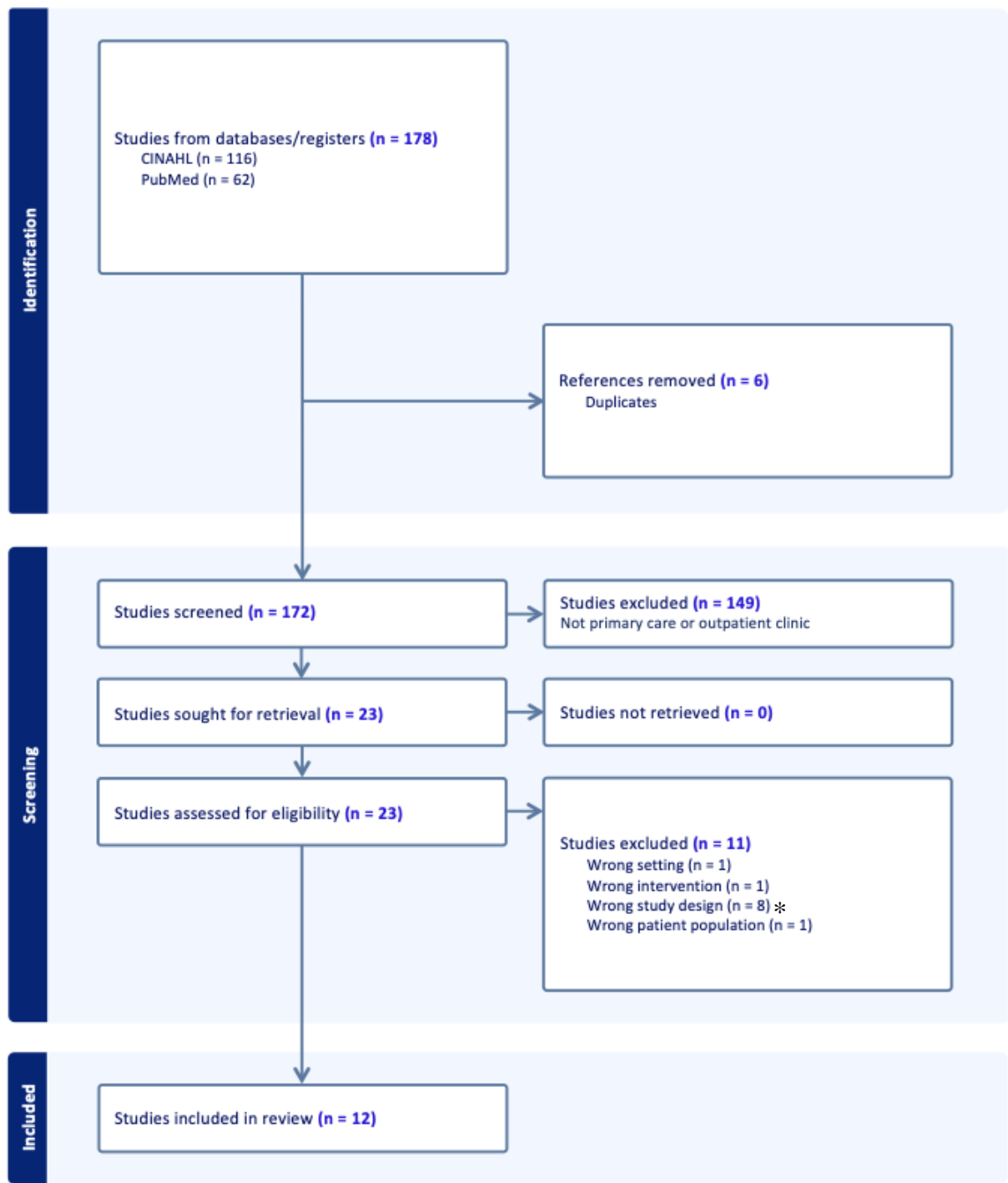
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### Appendix A PRISMA Diagram



\* = Study design did not involve screening or the use of a screening tool

Table 1

## Levels of Evidence Synthesis Table

	1	2	3	4	5	6	7	8	9	10	11	12
<b>Level I: Systematic review or meta-analysis</b>							<b>X (165)</b>					
<b>Level II: Randomized controlled trial</b>				<b>X</b>								
<b>Level III: Controlled trial without randomization</b>												
<b>Level IV: Case-control or cohort study</b>	<b>X</b>	<b>X</b>				<b>X</b>			<b>X</b>	<b>X</b>		<b>X</b>
<b>Level V: Systematic review of qualitative or descriptive studies</b>												
<b>Level VI: Qualitative or descriptive study, CPG, Lit Review, QI or EBP project</b>			<b>X</b>		<b>X</b>			<b>X</b>				
<b>Level VII: Expert opinion</b>											<b>X</b>	

**LEGEND**

1. Alavi et al., 2009; 2. Baker, N., & Kenny, C., 2016; 3. Cooksey, C., 2020; 4. Lazo-Porras et al., 2016; 5. Murphy Buschkoetter et al., 2019; 6. Plummer, E. S., & Albert, S.G., 1995; 7. Singh et al., 2005; 8. Stone, E., 2017; 9. Vatankhah et al., 2010; 10. Vibha, et al., 2018; 11. Woody, J., 2020; 12. Zhao et al., 2023.

Table 2

## Outcomes Synthesis Table

	1	2	3	4	5	6	7	8	9	10	11	12
Identification of DFU risk	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Identification of amputation risk	↑	↑		↑	↑	↑			↑		↑	
Adherence to DM screening guidelines	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Clinician confidence, awareness	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Patient self-care, health behaviors	↑	↑		↑		↑				↑		
Diabetes control				↑								
Disease burden (Financial cost, Mortality and Morbidity)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓

**SYMBOL KEY**

↑ = Increased, ↓ = Decreased

Green = Positive change, Red=Negative change

**LEGEND**

1. Alavi et al., 2009; 2. Baker, N., & Kenny, C., 2016; 3. Cooksey, C., 2020; 4. Lazo-Porras et al., 2016; 5. Murphy Buschkoetter et al., 2019; 6. Plummer, E. S., & Albert, S.G., 1995; 7. Singh et al., 2005; 8. Stone, E., 2017; 9. Vatankhah et al., 2010; 10. Vibha, et al., 2018; 11.

Woody, J., 2020; 12. Zhao et al., 2023.

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## Appendix B

### Inlow's 60-Second Diabetic Foot Screening Tool

**INLOW'S**  
**60-second Diabetic Foot Screen**  
**SCREENING TOOL**

Canadian Association  
of Wound Care  Association canadienne  
du soin des plaies  
www.cawc.net

Patient Name:

Clinician Signature:

Date:

Look – 20 seconds	Score		Care Recommendations
	Left Foot	Right Foot	
<b>1. Skin</b> 0 = intact and healthy 1 = dry with fungus or light callus 2 = heavy callus build up 3 = open ulceration or history of previous ulcer			
<b>2. Nails</b> 0 = well-kept 1 = unkempt and ragged 2 = thick, damaged, or infected			
<b>3. Deformity</b> 0 = no deformity 1 = mild deformity 2 = major deformity			
<b>4. Footwear</b> 0 = appropriate 1 = inappropriate 2 = causing trauma			
Touch – 10 seconds	Left Foot	Right Foot	Care Recommendations
<b>5. Temperature – Cold</b> 0 = foot warm 1 = foot is cold			
<b>6. Temperature – Hot</b> 0 = foot is warm 1 = foot is hot			
<b>7. Range of Motion</b> 0 = full range to hallux 1 = hallux limitus 2 = hallux rigidus 3 = hallux amputation			
Assess – 30 seconds	Left Foot	Right Foot	Care Recommendations
<b>8. Sensation – Monofilament Testing</b> 0 = 10 sites detected 2 = 7 to 9 sites detected 4 = 0 to 6 sites detected			
<b>9. Sensation – Ask Four Questions:</b> i. Are your feet ever numb? ii. Do they ever tingle? iii. Do they ever burn? iv. Do they ever feel like insects are crawling on them? 0 = no to all questions 2 = yes to any of the questions			
<b>10. Pedal Pulses</b> 0 = present 1 = absent			
<b>11. Dependent Rubor</b> 0 = no 1 = yes			
<b>12. Erythema</b> 0 = no 1 = yes			
<b>Score Totals =</b>			

Screening intervals for foot ulcers and/or limb-threatening complications. Use the highest score from left or right foot. Screening intervals may vary based on clinical judgement and individual patient factors.

Score = 0 to 5 → recommend screening yearly

Score = 6 to 11 → recommend screening every 6 months

Score = 12 to 17 → recommend screening every 3 months

Score = 18 to 23 → recommend screening every 1 to 3 months

Inlow's 60-second diabetic foot screen has been shown to have content validity, determined in community care and Complex Continuing Care (CCC), and intrarater and interrater reliability in LTC, CCC, and acute care (dialysis). 2010.

Adapted from Inlow S. A 60 second foot exam for people with diabetes. *Wound Care Canada*. 2004;2(2):10-11. © CAWC 2010 - P1419E

## Instructions for Use

**General Guidelines:** This tool is designed to assist in screening persons with diabetes to prevent or treat diabetes-related foot ulcers and/or limb-threatening complications. The screen should be completed on admission of any patient with diabetes and then repeated as directed. Both feet need to be screened; use the highest score to determine recommended screening intervals.

**Specific Instructions:** Review each of the parameters listed in the Diabetic Foot Screen and select the appropriate score based on patient's status. Once the diabetic foot screen is completed determine care recommendations based on patient need.

### 1. Skin:

Check the skin on the foot including between the toes.

- 0 = skin is intact and has no signs of trauma. No signs of fungus or callus formation
- 1 = skin is dry, fungus such as a moccasin foot or interdigital yeast may be present. Some callus build-up may be noted
- 2 = heavy callus build-up
- 3 = open skin ulceration present

### 2. Nails:

- 0 = nails well-kept
- 1 = nails unkempt and ragged
- 2 = nails thick, damaged or infected

### 3. Deformity

- 0 = no deformity detected
- 1 = may have some mild deformities such as dropped metatarsal heads (MTHs) (the bones under the fat pads on the ball of the foot). Each MTH corresponds to the toe distal to it, so there is a 1st MTH at the base of the first toe etc. Bunions may also be considered a deformity as well as deformities related to trauma.
- 2 = Charcot or amputation are each considered a major deformity that misshapes the foot significantly and often prevents wearing of off-the-shelf footwear

### 4. Footwear

Look at the shoes that the patient normally wears and discuss what he or she wears in the house

- 0 = shoes provide protection, support and fit the foot. On removal of the footwear there are no reddened areas on the foot
- 1 = shoes are inappropriate and do not provide protection or support for the foot.
- 2 = shoes are causing trauma to the foot either through a poor fit or a poor style i.e. cowboy boots. Foot is red over bony areas when shoe is removed

### 5. Temperature – Cold

Does the foot feel colder than the other foot or is it colder than it should be considering the environment?

- 0 = foot is of "normal" temperature for environment.
- 1 = foot is cold – compared to other foot or compared to the environment

### 6. Temperature – Hot

Does the foot feel hotter than the other foot or is it hotter than it should be considering the environment?

- 0 = foot is of "normal" temperature for environment
- 1 = foot is hot – compared to other foot or compared to the environment

### 7. Range of Motion

Move the first toe back and forth – plantar flex and dorsiflex.

- 0 = first toe (hallux) is easily moved
- 1 = hallux has some restricted movement
- 2 = hallux is rigid and cannot be moved
- 3 = hallux amputation

### 8. Sensation – Monofilament Testing

Using the 5.07 monofilament, test the sites listed.

Do not test over heavy callus.

- digits: 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup>
- metatarsal heads: 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup>
- midfoot: medial, lateral
- heel
- top (dorsum) of foot

And then score out of 10:

- 0 = 10 out of 10 sites detected
- 2 = 7 to 9 out of 10 sites detected
- 4 = 0 to 6 out of 10 sites detected

### 9. Sensation – Ask Four Questions

Ask the following four questions:

- i. Are your feet ever numb?
  - ii. Do they ever tingle?
  - iii. Do they ever burn?
  - iv. Do they ever feel like insects are crawling on them?
- 0 = answered No to all four questions
  - 2 = answered Yes to one or more

### 10. Pedal Pulses

Palpate (feel) the dorsalis pedis pulse located on the top of the foot.

- 0 = pulse present
- 1 = pulse absent

### 11. Dependent Rubor

Pronounced redness of the feet when the feet are down and pallor when the feet are elevated.

- 0 = no dependent rubor
- 1 = dependent rubor present

### 12. Erythema

Look for redness of the skin.

- 0 = no redness of the skin
- 1 = redness noted

**Remember:** Strategies for the prevention and management of diabetes related foot ulcers need to consider more than just the results from a foot assessment. For more information on a **holistic assessment** and classifying patients based on risk refer to the **Best Practice Recommendations for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers: Update 2010** at [www.cawc.net](http://www.cawc.net).



## Appendix C

Page 1

### Human Subject Research Determination Form

It is important to ensure the protection of human subjects in research and quality projects. Please complete the survey below.

Thank you!

Response was added on 12/12/2023 11:23am.

#### Instructions:

1. Please complete the requested project information, as this form may be used for documentation that neither IRB review nor an exemption is required.

2. Please select the appropriate answers to each question in order as they appear. If all of the questions are answered without receiving an error message, the form must be printed AND signed as certification that the project is "not human subjects research," and does not require IRB review or exemption.

If you are unsure how to answer any of the questions, please contact ORRP for additional guidance at ORRPDeterminations@osu.edu.

#### PROJECT INFORMATION

Name of PI, advisor, or mentor	Alice M Teall
Advisor Email	teall.3@osu.edu
Student Name:	Allison Seiter
Project Title	Implementing an Evidence-Based Quality Improvement Project to Standardize Foot Screening in Adults with Type II Diabetes
Brief Description of Project/Goals:	The purpose of this project is to standardize foot screening for patients with type II diabetes mellitus within a comprehensive primary care clinic. (This information is important and provides the necessary information to determine if the project requires IRB review.)

#### QUESTIONS

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

Yes

No

(This question determines if additional federal regulations, like FDA regulations, apply to the project. This information is based on the Common Rule (45 CFR 46.102(d)) that states "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." If the answer to this question is 'YES' - IRB review is likely required.)

---

2. Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?

- Yes  
 No

(This question is to determine if the project received funding to be conducted as a research study, quality improvement, or program evaluation. If the funding source requires a specific level of IRB review and oversight or considers the project to constitute human subjects research, you may be required to submit an IRB application.)

---

3. In addition to any other purposes, is the project intended to develop or contribute to generalizable knowledge (e.g. testing a hypothesis) AND/OR has the project been designed in such a way that the findings will be generalizable (e.g. randomization of subjects; comparison of case vs. control)?

- Yes  
 No

(This question is to evaluate project intent and design. The project design plays a key role in determining intent. If the project uses standardized research methods like testing a hypothesis or randomization to determine results, then it is research. If the intended outcome is simply to report on what happened at the institution/program, even if another site does something similar and sees benefit, this does not indicate research design or intent.)

---

4. Will the results of the project be published, presented or disseminated outside of the institution conducting it?

- Yes  
 No

(The purpose of this question is to determine if and how project results will be disseminated. Note that program evaluation and QI projects can be published or presented without being considered research projects; not all information that is published or presented represents generalizable knowledge. Lack of intent to disseminate the information is generally a strong indicator that a project does not constitute research.)

---

5. Will the project occur exactly as proposed regardless of whether individuals conducting it may benefit professionally from it?

- Yes  
 No

(This question is not focusing solely on whether an individual will professionally benefit, but rather whether they would conduct the project (or conduct it in the exact same way) regardless of the potential for professional benefit (e.g. adding it to a CV or getting funding based on the results).)

---

6. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

- Yes  
 No

(If the intention upon designing and conducting the project is not to improve or evaluate a specific practice/program, then the answer should be "No" indicating research intent and IRB review is likely required. If the project is intended to create knowledge or draw conclusions applicable beyond the particular institution or specific program, then the project is likely research as defined by the federal regulations and IRB review or exemption is required.)

---

If no message appears above indicating the certification is not valid, IRB Review is not required because, in accordance with federal regulations, the project does not constitute human subjects research as defined under 45 CFR 46.102(d).

Student: Sign this form below attesting to the accuracy. Download and save a copy of the completed form, print or email the form to your advisor for signature. This serves as record that IRB review is not required for this project.

---

Are you using data collected or procured from the institution your project is being implemented?  Yes  
 No

---

Has written approval been received by authorized personnel from the institution?  Yes  
 No

---

Student: I certify that the information provided is accurate.

*Allison Seiter*

---

Student Signature date: 12-12-2023

---

The following information is to be completed by the student's advisor once the student has completed and submitted the form.

Please note -

\* If the student and advisor are completing the form together, the advisor can digitally sign the document

\* If the student and advisor are not completing the form together:

1. Student adds their signature and then clicks on the Save and Return Later button (Not Submit).
2. The student then records the ID# of the form that pops up when clicking the Save and Return Later button and provides this ID# to the advisor. The student exits out of the form.
3. The advisor then accesses the link and clicks on the "returning" link in the top right-hand corner.
4. The advisor will be prompted to enter the ID# and this will bring up the student form.
5. The advisor reviews the questions/answers selected, enters the student email for the confirmation, and signs the form.
6. The advisor submits the form.
7. The student will get the email confirmation with the PDF of the completed/signed form and retains it to include in the appendix of the final project document.

A copy of the final fully executed form (both student and advisor signatures visible) should be retained for addition to the final project.

---

Advisor: I have reviewed the student project and agree to the information provided.

*Alice M Teall*

(Please note - this field is for Advisor completion)

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Advisor Signature date: 12-12-2023

## Appendix D



Allison K. Seiter, MSN, BSN, RN-BC  
The Ohio State University

March 6, 2024

**RE: Implementing an Evidenced-Based Quality Improvement Project to Standardize Foot Screening in Adults with Type 2 Diabetes**

Dear Ms. Seiter:

The Nursing Scholarly Project Review Committee (NSPR) has reviewed the proposal referenced above. Clear evidence was submitted to justify both the need for the practice change and that evidence supports the proposed plan. You have adequately addressed all concerns from the pre-review and the revisions are accepted.

The NSPR has determined that the project proposal you submitted does not meet the Federal definition of research as cited in CFR 45-46:102. According to the Federal Code, research is defined as:

(1) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

You have permission to implement the evidenced-based practice change as written proving that the unit manager at the intended intervention site agrees. Upon completion of the project and before dissemination (poster or manuscript), you must submit the results so that the OhioHealth can review the presentation to ensure Health Insurance Portability and Accountability Act (HIPAA) compliance.

Congratulations on your progress towards this worthy endeavor.

A handwritten signature in blue ink that reads "Teresa Wood PhD, RN, NEA-BC".

Teresa Wood PhD, RN NEA-BC  
Program Manager, Nursing Research

Appendix E

Foot Poster

# Diabetic Foot Exam

**Amputation Prevention**

Save your Foot, Save your Life

Ask your Provider Today!

