Implementation of a Comprehensive Diabetic Foot Exam Protocol in rural primary care

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Abstract

Background: Patients with type-2 diabetes mellitus have an increased risk for foot ulcerations and lower extremity amputations. Evidence-based practice guidelines recommend annual foot screening at least yearly for patients with type-2 diabetes. Comprehensive foot exams that include assessments for loss of protective sensation and peripheral artery disease prove beneficial in reducing morbidity and decreasing the incidence of diabetic foot ulcerations. Despite the known benefits of preventive screenings, a limited number of rural providers adhere to well-established treatment guidelines for patients with type-2 diabetes.

Purpose/Aim: The purpose of this quality improvement project was to increase the number of comprehensive foot examinations for adults with type-2 diabetes mellitus in rural primary

care. The overarching aim was that 75% of adult patients with type-2 diabetes would consistently experience a comprehensive foot exam and risk assessment within 15 weeks of project initiation.

Methods: The quality improvement project design involved the introduction of a comprehensive diabetic foot exam protocol in four Rural Health Clinics. Utilizing the Plan-Study-Do-Act quality improvement model, retrospective data was collected from 60 patients to evaluate the percent of patients with type-2 diabetes that received a foot exam in 2017. Educational programs were presented to primary care providers and clinic nurses to introduce the protocol. The project implementation occurred as a 1-week pilot in one Rural Health Clinic then system-wide for 14 weeks.

Results: The retrospective data revealed 42% of patients with type-2 diabetes received a foot exam in 2017. All primary care providers and clinic nurses attended educational sessions on screening guidelines and protocol introduction. Following the 15-week project, 68% of patients with type-2 diabetes experienced a comprehensive foot exam and risk assessment. **Conclusions:** Implementation of a clinically relevant tool in rural primary care resulted in significant improvement in primary care provider adherence to recommended diabetes foot screening guidelines.

Keywords: Type-2 Diabetes, Rural, Adults, Foot Exam, Guidelines

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Diabetic foot ulcers (DFU) are the leading cause of non-traumatic lower extremity amputations in the United States (Centers for Disease Control and Prevention [CDC], 2017) and costs related to the treatment of DFUs are well over a billion dollars annually (Hicks et al., 2016).

Diabetic peripheral neuropathy (DPN) and peripheral artery disease (PAD) are directly related to the development of ulcerations of the foot and lower extremity (Boulton, 2013). With the loss of protective sensation resulting from peripheral neuropathy, patients with diabetes are increasingly susceptible to injuries and trauma of the foot and ankle enhancing the possibility of developing foot ulcerations (American Diabetes Association [ADA], 2017). In over half of patients with DFU, PAD is present further complicating diagnosis and treatment (Brownrigg, Apelqvist, Bakker, Schaper, & Hinchliffe, 2013). Through tertiary prevention in patients diagnosed with type-2 diabetes mellitus (T2DM), assessments for signs of DPN and PAD facilitate identification of patients with loss of protective sensation and impaired perfusion that are at risk for developing long-term complications such as foot ulceration and lower limb amputation (Boulton, 2013; Markakis et al., 2016). Comprehensive foot care that includes screening exams and risk assessments (RA) for patients with diabetes reduces the rate of ulcerations nearly 75% and amputation up to 85% (Hershey, 2017; Pocuis, Man-Hoi Li, Janci, & Thompson, 2017).

In rural health clinics (RHC) located in Franklin and Webster counties of south-central Nebraska, management and treatment of patients with T2DM by primary care providers (PCP) demonstrates significant variability and lack of adherence to well-established evidence-based practice (EBP) screening guideline recommendations for annual foot exams. Specifically, providers inconsistently perform and document annual foot exams for adult patients with T2DM. In RHCs, the compliance rate for yearly diabetic foot exams in 2017 was 42% significantly well below the national rate of 68% (CDC, 2017) and Nebraska rate of 68% (Department of Health and Human Services [DHHS], 2015). Although evidence demonstrates the effectiveness of comprehensive foot examinations (CFE) in reduction and prevention of foot ulcers (ADA, 2017; Oxendine, 2014), PCPs identified barriers to annual foot exam recommendations, similar to those

found in literature review, including lack of adequate knowledge, time constraints, and strongly held negative attitudes and opinions as to the usefulness and practicality of EBP guidelines (Bus & Van Netten, 2016; Furthauer, Flamm, & Sonnichsen, 2013; Vigersky, Fitzner, & Levinson, 2013).

The purpose of this quality improvement project was to increase the number of CFE for adults with T2DM in rural primary care. The research question for this project was: In rural adult patients, ages 19 years and older, with T2DM, does the use of a Comprehensive Foot Exam Protocol incorporated into existing electronic medical records improve PCP adherence to EBP guideline recommendation for an annual CFE and risk assessment, compared to the non-use of Comprehensive Foot Exam Protocol.

Significance/Literature Review

Diabetes in the United States

National statistics estimate that over 30 million people in the U.S. have diabetes. While 23.1 million (7.2%) have a diagnosis of diabetes the remaining 7.2 million are undiagnosed and unaware of their disease (ADA, 2017). Overall, prevalence of diabetes is higher in minority populations of American Indians/Alaska Natives, non-Hispanic blacks, and people of Hispanic ethnicity (CDC, 2017). However, the percentage of adults of all races with diabetes increases with age reaching 25.2% in those aged 65 and older. Geographical patterns indicate the highest incidence of diabetes in the southern and Appalachian regions, followed by Midwestern states. Rural residents experience a 17% higher rate of T2DM compared to urban residents (Ross et al., 2014; National Rural Health Association, 2015).

Diabetes is a leading cause of morbidity and mortality creating a significant public health and economic burden for patients, healthcare systems, and society (ADA, 2017). Economic

burden associated with diabetes is primarily related to the cost of preventable diabetes complications (Welch et al., 2015). Patients with T2DM that developed neuropathy have up to a 20% lifetime risk of developing foot ulceration (Pocuis et al., 2017). Additionally, the lifetime risk significantly increases to 30-35% with concomitant risk factors such as PAD and foot deformity (Brownrigg et al., 2013). Patients with a DFU have ulcer recurrence rates of 30-40% in the first year after an ulcer episode (Bus & Van Netten, 2016). Care of DFUs is estimated to cost nearly $1.4 billion/year (Hicks et al., 2016) consuming well over a third of total resources allocated for treatment of T2DM and resulting complications. Ulcer prevention, however, represents only a small portion of the total expenditures utilized for diabetic foot care. As the incidence and cost of diabetes continue to rapidly rise, providing high quality evidence-based preventive care is vital to reduce diabetes-associated morbidity and lessen the economic burden.

Burden of Diabetes in Franklin and Webster Counties of Nebraska

According to the CDC (2017), the incidence of diagnosed diabetes in Nebraska is 11.6% notably above the national average of 7.2%. Similar prevalence rates are found in Franklin (10.8%) and Webster (11.1%) counties. High rates of obesity further complicate the burden of diabetes for rural Nebraskans. In the U.S., the rate of obesity for rural residents is nearly 26% appreciably more than the 20% rate in urban populations. Nebraska has experienced a significant increase in obesity rates from 20% to 31% over the past 18 years. In Franklin and Webster counties, obesity rates average 33% exceeding the state and national average (CDC, 2017).

Defining Rural Population and Rural Health Inequities

The concepts of rural and urban are complex, multifaceted, and continue to evolve. The U.S. Census defines rural as "all population, housing, and territory not included within an urbanized area, population $\geq$ 50,000, or urban cluster, population of 2500-49,999" (Ratcliffe, Burd,

& Fields, 2016). Similarly, the U.S. Department of Agriculture defines rural as "areas of open country and settlements with fewer than 2,500 residents" (Cromartie & Parker, 2017; U.S. Department of Agriculture, 2016). The number of people living in rural areas is only 16% of the U.S. population however they reside on 75% of the total land mass. Nebraska is considered a rural state with over 35% of the population residing in areas with less than 2,500 residents. According to the Census Bureau (2016), Franklin County covers 574 square miles with a population average of 5.6 person per square mile and Webster County covers over 577 square miles with a population average 6.6 person per square mile. The RHCs are located in communities within Franklin County including Franklin (pop. 1000), Hildreth (pop. 318), Campbell (pop. 347), and Red Cloud (pop. 1020) in Webster County (US Census, 2016).

Rural residents experience significant healthcare disparities related to greater population risk for poor health, limited access to healthcare providers and systems, and reduced life expectancy when compared to urban residents. Vulnerability of rural populations is accentuated by isolated geographic locations that intersect with low socio-economic status combined with higher number of unhealthy habits, fewer community resources, and limited employment opportunities (National Rural Health Association, 2015). When comparing rural versus urban statistics, rural residents experience high rates of obesity related to sedentary lifestyles and an elevated burden of chronic disease demonstrated by increased incidence of heart and lung disease, diabetes, cancer and stroke (Ross et al., 2014; Vigersky et al., 2013). Abuse and misuse of alcohol, tobacco, and prescription medications are characteristics of rural populations that also contribute to lower overall life expectancy (CDC, 2017).

Diabetic Peripheral Neuropathy Identification

Diabetic peripheral neuropathy (DPN), a microvascular complication resulting from diabetes, affects both small and large sensory fibers and is manifested by paresthesia, dysesthesia, and deficits in normal sensations that profoundly impact patient function and productivity (Alleman et al., 2015; Van Netten et al., 2016). Approximately half of all patients with diabetes will develop neuropathy (Markakis et al., 2016; Pocuis et al., 2017). DPN is directly related to the development of foot ulcers and is a leading cause of amputations in the diabetic population (ADA, 2017; Bus & Van Netten, 2016). Prevalence of DPN is highest in patients with T2DM and often times underreported and undertreated (Schaffer, Sandau, & Diedrick, 2013). Screening patients with T2DM for neuropathy is essential for early treatment, reduction of complications, and decreased morbidity (Bus & Van Netten, 2016).

Key to reducing and preventing foot ulcers and amputations is the identification of those patients at increased risk through a CFE and RA. According to the ADA (2017), all adults with T2DM should undergo a CFE at the onset of diabetes diagnosis and continue annually to identify high-risk conditions. Those patients identified with loss of protective sensation and impaired perfusion are at higher risk and should have a foot exam at each visit. Furthermore, comprehensive foot care programs that include RA based on EBP guidelines demonstrate improvement in diabetes care and patient outcomes (Bus & Van Netten, 2016; Oxendine et al., 2014).

Provider Non-adherence to Established Guidelines

The U.S. Preventive Services Task Force was created in 1984 to promote development of EBP guidelines for preventive service in primary care (Agency for Healthcare Research & Quality [AHRQ], 2015). Over the last 30 years, clinical preventative guidelines were published by universities, interest groups, and organizations based on overwhelming evidence that demonstrates primary, secondary, and tertiary prevention efforts reduce costs, enhance the quality of care, and

improve patient outcomes. In 1989, the ADA established screening and treatment guidelines for patients with diabetes. Highly graded evidence that combines stringent glycemic control, regular preventive screenings, and early detection and treatment of secondary complications demonstrates significant reduction in morbidity and mortality related to diabetes (ADA, 2017; Khoong et al, 2013). Despite the well-established benefit of adhering to screening guidelines, a limited number of rural providers adhere to EBP screening guidelines (Jones, Crabb, Turnbull, & Oxlad, 2014; Ross et al., 2014; Khoong et al., 2013; Vigersky, Fitzner, & Levinson, 2013).

Theoretical Frameworks

This project was guided by the Health Belief Model developed by Hochbaum (1958) and Awareness-to-Adherence Model developed by Pathman et al. (1996). The Health Belief Model (HBM) was developed to integrate stimulus-response theory with cognitive theory in explaining behavior (Hochbaum, 1958). Influenced by Kurt Lewin's (1951) theories that perceptions of reality, rather than objective reality, influence behavior. In HBM, a combination of perceived susceptibility and perceived seriousness of the condition or situation combines into a perceived threat. The perceived threat has a cognitive component that is influenced by weighing the benefits and barriers to the actions. When considering PCP adherence to EBP screening guidelines, provider experience, knowledge, and attitude appear to have greater weight than guidelines based on robust research. Benefits and barriers to adherence are considered before action is taken to follow the recommendations.

To further address guideline adherence, the theoretical framework, Awareness-to-Adherence, developed by Pathman et al. (1996) that focuses on physician non-adherence to national guidelines for childhood immunizations was used. The model describes a progression of steps through awareness, agreement, adoption, and adherence. In 1999, Cabana et al. expanded

the model and added multi-directional flow pathways that described a sequence of behavior change and defined barriers to guideline adherence. Since that time, multiple studies utilized the theoretical model to guide research on adherence to evidence-based guidelines (Khoong et al., 2013; Radwan, Akbari, Rashidian, Anou-Dagga, & Elsous, 2017; Widyahening, Van der Graaf, Soewondo, Glasziou, & Van der Heijden, 2014).

Purpose/Aims

The purpose of the QI project was to increase the number of annual foot exams completed in adults, age 19 and older, with a diagnosis of T2DM in rural primary care. The overarching aim of the project was that 75% of all adult patients with T2DM presenting for primary care in four rural health clinics would consistently experience a CFE and RA within 15 weeks of project initiation.

Methods

A letter of approval was obtained from the University of South Alabama Institutional Review Board prior to implementation of the quality improvement (QI) project. Exemption status was granted (Institutional Review Board IRB00000286, DHHS FWA00001602).

Subjects/Participants

The participants in the project were the PCPs in four RHCs located in Franklin and Webster Counties in south-central Nebraska. The PCPs included one full-time family practice physician, four full-time family nurse practitioners (NP), and one part-time family nurse practitioner. The family practice physician is a medical doctor with over 30 years of experience. All five NPs are masters prepared and vary in advanced practice experience from six months to 23 years. The patient population was adults age 19 years and older with a diagnosis of T2DM.

Setting

Franklin County Memorial Hospital (FCMH) is a critical access hospital (CAH) in Franklin, NE with three provider-based RHCs located in Franklin County and one-independent RHC in neighboring Webster County. The healthcare system serves residents in both counties and surrounding areas including people from north-central Kansas. While some patients travel between 40 to 60 miles to receive care, most patients have access to primary care within a 15-minute drive from their home. The QI project was conducted in the four RHCs.

Tools

The Michigan Neuropathy Screening Instrument (MNSI) is a valid measure of distal peripheral neuropathy in patients with T2DM (Herman et al., 2012; University of Michigan, 2017). The MNSI includes a two-step process: (1) assess neuropathic symptom history from the patient through a 15-item questionnaire, and (2) a physical examination by providers to evaluate appearance and sensation of the feet. Three clinical tests utilizing three different tools are utilized in the neurological EBP screening guidelines recommended (ADA, 2017; University of Michigan, 2017) for a CFE to identify loss of protective sensation (LOPS): (1) Single-use 10-g/5.07 monofilaments, also known as Semmes-Weinstein monofilaments, is placed perpendicular to the skin with pressure applied until the monofilament buckles. It should be held in place for approximately one second and then released at the first, third, and fifth metatarsal heads on the plantar surface and dorsal between base digit one and two (ADA, 2017). The sensitivity of the monofilament test ranged from 0.41 to 0.93, and specificity ranged from 0.68 to 1.00 (Dros, Wewerinke, Bindels, & Van Weert, 2009). (2) 128-Hz tuning forks used to test vibratory sensation. Vibration sensation should be tested by placing the tuning fork over the dorsum of the great toe on the boney prominence of the DIP joint. Evidence of usefulness is documented in clinical cohort studies (ADA, 2017; Schaper et al., 2016). (3) Tendon hammer is used to assess ankle reflexes.

The Achilles tendon should be stretched until the ankle is in a neutral position before striking with tendon hammer. The absence of ankle reflexes is associated with increased risk of foot ulcer (ADA, 2017; Schaper et al., 2016).

Intervention Implementation and Data Collection

The Plan-Do-Study-Act (PDSA) quality improvement model (Langley et al., 2009) was used to guide planning and implementation of the QI project. The model provided a construct for designing, implementing, measuring, and distributing a quality improvement study (Institute for Healthcare Improvement [IHI], 2017). In this QI project, the "Plan" phase involved focused discussions with stakeholders that included retrospective chart data that further defined the problem as lack of adherence to EBP screening guidelines in patients with T2DM. In the "Do" phase, the CFE protocol was developed from EBP guidelines. A template was created in the electronic medical record, and an educational session about the project was developed for providers and staff. In the "Study" phase, the template was introduced and discussed with stakeholders and revisions were made to improve the functionality of the protocol. During the "Act" phase, a one-week trial of the CFE and RA protocol in one RHC was implemented to determine the functionality of the questionnaire and template. No changes were made, and the project was implemented system-wide. The PDSA cycle was repeated during system-wide project implementation.

Retrospective chart review was completed by randomly selecting a sample total of 60 adult patients with T2DM from the electronic diabetes registry utilizing T2DM ICD10 codes E11-E11.9. The retrospective chart review included demographic data collection and data extraction from dictation, clinic notes, and assessment data to determine if a foot exam was completed and documented over the previous 12 months. Process measures included the percentage of adult

patients, age 19 years and older, with a diagnosis of T2DM receiving a foot exam within the previous 12 months.

Prior to implementation of the project, educational training sessions were conducted for all PCPs and clinic nursing staff on screening guideline recommendation for annual foot exam, demonstration of CFE with RA, and the introduction of the foot exam protocol in the electronic medical record. Trial implementation of the foot exam protocol was conducted over a one-week period to evaluate usability and time involvement with no changes recommended. The project was implemented system-wide in four rural health clinics and data collected from all adult patients, age 19 years and older, with T2DM that presented for primary care during the 15-week study period.

Analysis/Evaluation

Data analysis was completed utilizing SPSS program (Cronk, 2014). Baseline process data was collected from 60 random retrospective chart reviews of 2017 data. All PCPs and office nursing staff attended the educational session on screening guideline recommendations for patients with T2DM, foot exam and risk assessment demonstration, and introduction of the foot exam protocol in the electronic medical record. Data was collected from all adult patients with T2DM presenting to the rural health clinic during the 15-week project and analyzed for the percentage of CFE and RA completed. Further analysis was completed for each of the four clinic sites and each of the six PCPs identified as either medical doctor or nurse practitioner. The five nurse practitioners were assigned NP1through NP5 in order of their employment hire dates.

Results

Sixty patients were randomly identified in the electronic medical record from ICD-10 codes E11-E11.9 indicating diagnosis of T2DM. Demographic data was collect ensuring that all patients selected were 19 years and older with a diagnosis of T2DM. Included in the 60 patients, 35%

(n=21) were female ranging from 52-92 years of age, with a mean age of 72, and 65% (n=39) were male, ranging from 38-85 years of age, with a mean age of 62. Table 1 shows retrospective data collected from the convenience sample. Charts reviewed for 60 patients with T2DM revealed 42% (n=25/60) had received a foot exam in the previous year (2017). The clinic site percentages varied greatly from 52% (n=12/23) at Main Street Clinic, 40% (n=11/29) at Pool Medical Clinic, 29% (n=2/7) at Hildreth Clinic, to none completed at Campbell Clinic. Data for each PCP was analyzed and reported as percent of patients seen with T2DM receiving a foot exam. Percentages varied from NP1 42% (n=14/25), MD 35% (n=7/20), NP2 29% (n=2/7), NP 5 33% (n=1/3), NP 3 20% (n=1/5), to NP4 none completed.

Table 1

Percentage of adult patients with T2DM receiving a foot exam in 2017

Clinic Site	n = number charts reviewed	% of total charts reviewed	n= number of foot exams completed	% of patients receiving foot exam
Pool Medical Clinic	29	48%	11	40%
Hildreth Clinic	7	12%	2	29%
Campbell Clinic	1	2%	0	0%
Main Street Clinic	23	38%	12	52%
Total	60		25	42%
Provider				
PCP 1 (MD)	20	33%	7	35%
PCP 2 (NP1)	25	42%	14	56%
PCP 3 (NP2)	7	12%	2	29%
PCP 4 (NP3)	5	8%	1	20%
PCP 5 (NP4)	0	0	0	0
PCP 6 (NP5)	3	5%	1	33%
Total	60		25	42%

Data collection for 2018 was completed 15 weeks post project implementation. Eighty adults patients, age 19 years and older, with T2DM presented for primary care. Demographic data revealed 52.5% (n=42) were female ranging in age from 26-89 with a mean age of 67 and 47.5% (n=38) were male ranging in age from 47-84 with a mean age of 66. Table 2 shows data collected

from 80 patients with T2DM presenting for primary care during the 15-week intervention. The percentage of patients receiving a CFE and RA was 63% (50/80). Clinic site percentages varied from 88% (n=29/33) at Main Street clinic, 75% (n=3/4) at the Hildreth Clinic, 43% (n=18/42) at Pool Medical Clinic, to no completions at the Campbell Clinic (n=0/1). Data for each PCP revealed percentage of patients seen with T2DM receiving a CFE and RA. Percentages ranged from 88% (n=29/33) for NP1, 71% (n=5/7) NP2, 60% (n=3/5) NP3, 38% (n=11/29) MD, and 34% (n=2/6) NP5, to none completed by NP4.

Table 2

Percentage of adult patients with T2DM receiving a foot exam and risk assessment in 2018

Clinic Site	n = number of patients with T2DM presenting during 15-week project	n=number of foot exams completed	% of patients receiving a foot exam	n= number of risk assessments completed	% of patients receiving a risk assessment
Pool Medical Clinic	42	18	43%	18	43%
Hildreth Clinic	4	3	75%	3	75%
Campbell Clinic	1	0	0%	0	0%
Main Street Clinic	33	29	88%	29	88%
Total	80	50	63%	50	63%
Provider					
PCP 1 (MD)	29	11	40%	11	38%
PCP 2 (NP1)	33	29	88%	29	88%
PCP 3 (NP2)	7	5	71%	5	71%
PCP 4 (NP3)	5	3	60%	3	60%
PCP5 (NP4)	0	0	0%	0	0%
PCP 6 (NP5)	6	2	34%	2	33%
Total	80	50	63%	50	63%

Outcome measure results: (1) the goal to increase PCP and office nursing staff knowledge of EBP guideline recommendations for CFE in patients with T2DM was met. One hundred percent participation by PCPs and office nursing staff in educational sessions with demonstration of CFE and RA with an opportunity for return demonstration; (2) CFE were performed and documented on 63% (50/80) of adult patients with T2DM that presented for primary care within the 15-week

project below 75% completion goal; and (3) RA were performed and documented in 63% (50/80) of adult patients with T2DM within the 15-week project surpassing the 50% goal.

Discussion/Summary

This QI project showed overall improvement of documented CFEs for patients with T2DM from 42% pre-implementation to 63% post-implementation. Three of the four RHCs showed improved percentage of completion of CFE. Percentages varied from Hildreth Clinic (29%/75%), Main Street Clinic (52%/88%), Pool Medical Clinic (40%/43%) to the Campbell Clinic (0%/0%) that was unchanged. Five of six PCPs percentage of completion of foot exam improved. Percentages varied from NP1 (52%/88%), NP2 (29%/60%), NP3 (20%/40%), MD (35%/38%), NP 5 (33%/34%) to NP4 (0%/0%) who resigned from the practice prior to project completion.

Improving the quality of care for rural adult patients with T2DM is essential to reducing and preventing long-term complications such as foot ulcerations. This QI project demonstrates the effective use of PDSA QI Model in implementing EBP guideline recommendations into rural clinical practice through the use of comprehensive diabetic foot exam protocol. The findings from this QI project support local efforts to improve adherence to EBP screening guidelines with the use of a clinically relevant tool incorporated into the existing EMR. Through input from PCPs in the planning and implementation of the project, the CFE protocol was customized for local provider usability. Significant improvement in adherence to EBP screening guideline recommendation for an annual foot exam reveals successful planning and implementation of the QI project. The simple streamlined process of this QI project provides ease in duplicating a similar project in other rural health clinics.

Limitations

The QI project has several limitations including convenience sample, small sample size, and retrospective data collected by reviewing dictated notes in the EMR subject to individual interpretation. The administration of the RHCs was very supportive of the QI project and the strong support may have overly influenced the change process.

Conclusion

Chronic health conditions such as T2DM provide complex management challenges for rural PCPs. The American Diabetes Association along with other national organizations and educational institutions provide screening and treatment guidelines for patients with T2DM. Evidence demonstrates use of evidence based practice screening guidelines improves clinical outcomes and significantly reduces the risk of preventable diabetes complications. However, multiple studies have shown that a limited number of rural PCPs utilize EBP screening guidelines in clinical practice. Improving rural provider adherence to well-established guidelines is essential to improving the care of rural residents with T2DM. Through QI initiatives in rural primary care, clinically relevant tools such as the CFE protocol incorporated into existing electronic medical record resulted in significant improvement in PCP adherence to evidence based practice screening guideline recommendation for an annual foot exam enhancing patient care and improving patient outcomes.

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