MULTIDISCIPLINARY APPROACH TO QUALITY IMPROVEMENT
INTERVENTION TO INCREASE PERFORMANCE OF COMPREHENSIVE
DIABETIC FOOT EXAMS FOR AMERICAN INDIANS/NATIVE ALASKANS

by

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DEDICATION

This DNP Project is dedicated to all that have provided a positive influence and encouragement that led to the completion of this project. My grandmother long ago provided a strong role model and imparted in me the determination to pursue excellence. My loving husband and family have sacrificed an enormous amount of time, allowing me to devote my time toward studies and the completion of this DNP Project. And last but not least, a loving and supportive mother who always taught me that I could accomplish anything I set my mind to do.
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ABSTRACT

Background: Low performance rate of comprehensive diabetic foot examinations (CDFEs) causing health care disparity.

Objective: Increasing performance of CDFEs at Phoenix Indian Medical Center, an Indian Health Service (IHS) facility.

Design: Before-after design, convenience sample.

Setting: An IHS adult ambulatory care clinic in urban Phoenix, Arizona.

Target: Four primary care providers (PCPs).

Interventions: Utilizing the PDSA framework, a multidisciplinary group of clinical staff developed a process to increase the performance rate of CDFEs. Brainstorming, use of the Ishikawa diagram, and root cause analysis led to identification of factors contributing to low rates of CDFEs in the clinic. The QI intervention addressed multiple aspects of activities related to the CDFE performance, including pre-visit planning, enhanced communication, making equipment for CDFEs accessible to healthcare providers, and requesting patients to remove shoes and socks.

Measurement: Weekly performance rate of CDFEs.

Results: The results, analyzed with a run chart, showed an upward trend in performance for some providers. The median aggregate performance rates for pre and post intervention were 82.6% and 80.2%, respectively.

Limitations: This study should be replicated over a longer time frame with more participants. Two significant weaknesses were identified in this study. The required provider de-identification prevented provider feedback. The data collection method provided CDFE
performance data based on provider empanelment. This method of data collection reflects composite team care rather than specific provider behaviors.

Conclusions: This multidisciplinary approach to improving the performance rates of CDFEs showed an upward trend for some providers but was not statistically significant. Post intervention CDFE performance rates were not improved.

Significance: This study highlights the role of the doctorally prepared advanced practice nurse (DNP) in designing, facilitating and evaluating a practice change project to address the rate of provider performance of CDFE for their AI/NA patients. An exemplar, this QI intervention can be replicated for quality improvement initiatives targeting improved healthcare outcomes, crucial to the national effort of addressing healthcare disparities.
CHAPTER ONE: INTRODUCTION

Background and Knowledge

American Indians/Native Alaskans (AI/NA) have the highest age-adjusted prevalence of diabetes among all U.S. racial and ethnic groups with a 3-4 fold higher rate of lower extremity amputation (National Limb Loss Information, 2012). The one year mortality rate following a lower extremity amputation among the diabetic population is approximately 30% (Johannesson et al., 2009). The five year mortality rate associated with lower extremity amputations is 43-74% (Amputee Coalitions, 2014; Chow, Lemos & Einarson, 2008; Hinkes, 2009; Moulik, Mtonga, & Gill, 2003). It has been estimated that 46-85% of diabetes related lower extremities could be avoided with performance of an annual comprehensive diabetic foot examination (CDFE) (Boulton et al., 2008; Clayton & Elasy, 2009). The CDFE is a simple, inexpensive, low-tech procedure (O’Brien et al., 2003). However, only 68.2% of adults in Arizona received a CDFE in 2010 (AZDHS, 2010).

Foot-related complications among persons diagnosed with diabetes continue to increase despite numerous evidence-based research efforts and publications documenting the effectiveness of comprehensive diabetes foot exams (CDFEs) in reducing foot related complications (American Diabetes Association [ADA], 2008; Ronnema, Hamalainen, Toikka, & Liukkonen, 1997). Globally, it is estimated that every 30 seconds a lower extremity amputation (LEA) associated with diabetes is performed, representing over 1 million amputations annually (International Diabetes Federation, 2005). In 2011, 17.8% of the Gross Domestic Product (GDP) was spent on healthcare (NIH, 2013). The Centers for Disease Control (CDC) estimated the number of LEAs associated with diabetes to be 67,500 in 2008 (CDC, 2010). Diabetic foot ulcers account for approximately 50% of hospitalizations in the diabetic population. During 2009 the
number of diabetes-related hospital discharges was 5.5 million (CDC, 2010). Statistics for Arizona hospital stays show that the number of hospital discharges in 2009 assigned a code indicating a diagnosis of diabetes was 778,259. Among those hospital discharges, the mean cost was $34,390 with an aggregate cost of $7.2 billion (Arizona Department of Health Services, 2011). The Amputee Coalition Organization (2012) has cited that the number of LEAs could be reduced by half if every patient with type 2 diabetes mellitus (T2DM) received an annual CDFE. A ten year population-based cohort study reported the incidence of amputations in the diabetic population is eight times that of the non-diabetic counterparts (Johannesson et al., 2008). Some sources cite that up to 85% of all lower extremity amputations in individuals with diabetes can be prevented (Bild et al., 1989; NIDDK, 2011). The CDFE is a simple, low tech, relatively quick examination which can and according to national standards (ADA, 2013; Boulton et al., 2008; Hirsch et al., 2006; Indian Health Service, 2013; International Working Group on the Diabetic Foot, 2012; Pinzur, Slovenkai, Trepman, & Shields, 2005) should be performed in the offices of all primary care providers.

Nationally, more than 60% of all non-traumatic lower extremity amputations (NLEAs) are associated with diabetes. While the rate of amputations in the general population has decreased by 65% since 1996, the rate of amputations associated with diabetes is five times that of the general population (CDC, 2012). In one study persons with diabetes experienced an eight-fold higher incidence of LEAs than persons without diabetes (Johannesson et al., 2008). In another study conducted in 2008 the incidence for LEA in persons with diabetes was eight times that of persons without diabetes requiring a non-traumatic amputation (Li, Burrows, Gregg, Albright, & Geiss, 2012). During this same time period one in 190 Americans or 65,700 individuals with diabetes (CDC, 2010; National Diabetes Information Clearinghouse [NDIC],
had undergone a limb amputation. The International Working Group on the Diabetic Foot (2012) cites that 85% of all amputations are heralded by a foot ulcer. Lowering the rate of all amputations associated with diabetes has been a goal of healthcare providers for many years (Boulton et al., 2008). Healthy People 2020 cited the rate of diabetic related LEAs (2005 to 2007) as 3.5 per 1000 persons. Without a change in current practices, the number of limb amputations among persons with diabetes is expected to double by 2050 (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008).

AI/NA have the highest age-adjusted prevalence of diabetes (16.1%) among all U.S. racial and ethnic groups (ADA, 2013) and a 3-4 fold higher rate of LEAs than the general U.S. population (National Limb Loss Information, 2012). In one study American Indians with diabetes suffered a morbidity rate greater than 50% of the rate found in insured non-American Indian adults (O’Connell, Yi, Wilson, Manson, & Acton, 2010). In 2005 American Indians experienced a relative risk ratio for non-traumatic lower extremity amputations (NLEA) when compared to the average U.S. adult relative risk of 14.4% (O’Connell et al., 2010).

AI/NA comprises 0.97% of the population in the United States (U.S.) or the fifth largest ethnic group in the U.S. (Arizona Department of Health Services [AZDHS], 2012; Index Mundi, 2013). The percentage of American Indian/Native Alaskan populations in Arizona as reported in the 2010 census was 4%. However, the percentage of American Indian/Native Alaskan populations per Arizona counties ranges from 1.2 to 72.9% (AZDHS, 2012). In 2006, the Arizona Diabetes Strategic Plan 2008-2013, estimated that the prevalence of diabetes in AI/NA would be 9%. In 2010, according to the National Diabetes Surveillance System of the CDC, the age-adjusted percentage of all Arizona residents with self-reported diabetes was 8.1%, with a national percentage average of 9.1% (AZDHS, 2012). The IHS reports that among the 1.9
million AI/NA treated at IHS facilities, 16.1% were diagnosed with diabetes and the southeastern Arizona rates were reported as high as 33% (Arizona BRFSS, 2010).

An in-depth discussion of causes leading to LEAs is beyond the scope of this DNP Project. The body systems primarily associated with LEA among individuals with diabetes are vascular, neurological, and immune system changes (Hinkes, 2009). The triad of neuropathy, deformity and trauma are frequently involved and are often identified as precursors to development of diabetic foot ulcers (DFU), (Boulton et al., 2008). Approximately 15% of all diabetics will develop a diabetic foot ulcer in their lifetime (Bartus & Margolis, 2004). Events leading to the need for a LEA include peripheral neuropathy. The development of neuropathy affects autonomic, sensory and motor functions. A defect in any one or combination of the three categories of diabetic neuropathy results in vulnerability to a diabetic foot ulcer and potential subsequent LEA. Autonomic neuropathy is responsible for dry skin, predisposing the individual to trauma to the skin. Sensory or peripheral neuropathy, the most common neurological manifestation in diabetes, affects the ability to sense touch to the foot. Peripheral neuropathy leads to loss of protective sensation, putting the individual at a high risk of not sensing breaks in skin integrity in the foot. Usually progressive, peripheral neuropathy starts with tingling, eventually leading to pain. Motor dysfunction associated with neuropathy predisposes the individual to trauma (Hinkes, 2009).

Microvascular changes in the individual with T2DM usually result from uncontrolled glucose levels, with resulting vascular insufficiency (Atkins, 2010; Fowler, 2008; Pfeiffer & Schatz, 1995). Vascular insufficiency leaves the individual with less oxygen supply to vital structures in the foot. Deprived of oxygen, tissues break down more easily and are slower to recover from injury. With a dysfunctional vascular system the immune system is less effective in
reaching the diabetic foot ulcer, decreasing the delivery of systemic antibiotics to the site of infection. Oxygen deprivation facilitates tissue break down and delays healing. Vascular dysfunction retards effective resolution of the ulcer through impairment at the cellular level (Hinkes, 2009).

When the musculoskeletal deformities of the foot are not recognized and treated appropriately, the foot is exposed to friction from poorly fitting footwear. Another sequela to uncontrolled glucose levels and vascular insufficiency is Charcot’s foot. This complication requires special footwear, frequent visits to podiatry, and often unloading of the foot. Unloading of the foot refers to redistribution of weight-bearing or reduction of pressure in areas of the foot where up to 85% of diabetic foot ulcers often develop (Sobel & Levitz, 2001). All of the complications discussed are detectable with a CDFE.

Identifying the economic impact of prevention of LEAs has been challenging, (Chow, Lemos, & Einarson, 2008; ADA, 2008). Several factors account for this challenge. The medical literature reports a wide variation in costs of amputation procedure. This variation plus the inconsistency in coding for diagnoses and procedures, results in an inability to obtain precise national data and assessment of cost benefit. With the advent of the electronic health record and computerized data bases, methods for calculating costs have improved. However, some costs are intangible and/or unmeasurable (Li et al., 2012).

Total cost of diabetes care in the U.S. during 2012 was calculated to be approximately $245 billion with $176 billion related to direct care and $660 billion in reduction of productivity (ADA, 2013). After adjusting for age and gender, the data show diabetes rated medical expenditures to be 2.3 times higher than expenditures incurred by the non-diabetic population (ADA, 2013). Stratification of the impact of 17 recommended interventions for diabetes based
on cost-benefit analysis were reported in a meta-analysis (Klonofe & Schwartz, 2000). One of the inclusion criteria was targeting NLEA risk reduction in the diabetic population. The commonly practiced interventions for prevention or reduction of diabetes complications included: 1) eye care, 2) pre-conception care, 3) prevention of nephropathy in both Type 1 and Type 2 Diabetes, 4) self-management, 5) case management, 6) improvement of glycemic control, 7) self-glucose monitoring, 8) medical nutrition therapy, 9) blood pressure control, 10) foot care, 11) smoking cessation, 12) lipid control, 13) tracking HbA1c, 14) exercise, 15) weight loss, 16) influenza, and 17) pneumococcal vaccination. The authors chose an average cost for LEA of $25,000 in 1998 dollar value. Foot care interventions composed of podiatric care, education and specially fitting shoes have been associated with a 50% reduction in LEAs (Bild et al., 1989).

The authors developed a formula to determine the cost effectiveness of an efficient intervention to reduce the rate of LEAs. The formula involves the estimate of incidence of LEAs multiplied by the percent decrease in LEAs multiplied by the estimated direct cost of LEAs. To illustrate this formula, in a population with a 0.08 incidence of LEA, an intervention that resulted in a 50% reduction in LEAs with an estimated direct cost for an LEA of $25,000, the calculation would be 0.08 X 0.5 X $25,000 = $100. So if the cost of providing the intervention was equal to or less than $100/patient, the program could be provided at a cost savings (Klonofe & Schwartz, 2000). The five stratifications of intervention were evaluated for economic impact comparing intervention and non-intervention patients. The authors described the categories of interventions to reduce LEAs as:

1) Clearly cost-saving if the intervention demonstrates eventual savings greater than the cost of the intervention.
2) Cost effective if the intervention showed benefits achieved at no more cost than those interventions typically used for other chronic conditions.

3) Possibly cost effective if the intervention was found to be either ineffective or the report either did not concisely isolate the specific intervention of clearly identified costs though the intervention was clearly thought to be cost effective.

4) Non-cost-effective interventions were more expensive in delivery than those similar interventions for other chronic conditions, using > $25,000 cost for Quality Adjusted Life Years (QUALY) gained.

5) Unclear cost-effective interventions were shown to have less than three exemplar interventions and were not randomized controlled trials (Klonofe & Schwartz, 2000).

Due to the ambiguity found among the studies reporting cost of amputation (some studies cite only the cost component of the procedure) the assessment of cost benefit for performing individualized foot exams was sometimes considered unreliable. An international study evaluated cost-effectiveness of the recommended ADA interventions (Rui, Zhang, Barker, Chowdhury, & Zhang, 2010). Using 2007 dollar value to stratify cost-effectiveness in the U.S. this study stratified interventions as:

1) Very cost-effective (<$25,000 with each life year gained (LYG) of quality adjusted life year (QALY)).

2) Cost-effective at $25,001 to $50,000 per LYG or QALY.

3) Marginally cost-effective at $50,000 to $100,000.

4) Not cost-effective at > $100,000 per LYG or QALY.
The results of this analysis suggested comprehensive foot care compared with conventional care to be cost-effective. In conclusion the authors recommended that policy makers give these preventive interventions higher priority than is currently reflected in funding.

The use of cost-effectiveness as a means to determine adoption of an intervention is only one perspective to be considered. Other issues such as distribution of costs or financing; the willingness of society vs. individuals to pay, ethical aspects, and societal and legal perspectives must be considered (Rui et al., 2010). Data analyzed by the Centers for Disease Control and Prevention (2007), suggest that comprehensive diabetic foot programs can reduce the incidence of lower extremity amputations by 45 to 85%.

The need for appropriate CDFEs is a major national budgetary concern in the context of healthcare expenditures. In 2010 17.6% of the Gross National Product (GNP) went to healthcare costs, representing $2.6 trillion (The World Bank, 2013). Also supporting the need for improved healthcare outcomes is the reduction in costs when amputations can be avoided. The direct care costs of diabetes is $116 billion (Healthy Arizona: Community Dashboard: Adults with Diabetes, 2013) with this covering the costs of 8.3% of our national population. CDC (2011) reports 65,700 amputations related to diabetes were performed in 2006. The direct cost of an amputation-associated with diabetes has been estimated to be $30,000 to $60,000 (Hinkes, 2009). A mortality rate post amputation has been cited to be at 40% (Hinkes, 2009). More striking is the five-year mortality rate post amputation that has been cited to be anywhere between 43-74% (Hinkes, 2009; Robins et al., 2009). Deaths among individuals having had LEA are most commonly due to cardiovascular/cerebrovascular events or the complications of pneumonia (Moulik, Mtonga, & Gill, 2003).
Quality of life is an important consideration for patients who have had an amputation. While dollar amounts can catch the attention of legislators and are necessary to gain support for new programs, we cannot ignore the issue of quality of life for patients with diabetes who have had an amputation. Studies consistently show a decreased quality of life for individuals having undergone an amputation compared to the perception of quality of life in the general population (Crosby & Miller, 2005; del Godoy, Braile, Buzzato, Longe, & Fontesm, 2010; Hart, Redekop, Henk, Meyboom-de Jong, & Berg, 2007; Pell, Donnan, Fowkes, & Ruckley, 1993; Senha, Wim, Perlanayam, 2011; Solli, Stavem, & Kristiansen, 2011). Among most health related quality of life scales the primary factor associated with a significantly decreased perception of quality of life was impaired mobility. After amputation individuals often have difficulty with reintegration into previous social groups and returning to a “normal” life (Crosby & Miller, 2005). Compared to non-amputees, those having had amputations note a decreased quality of life due to changes in physical capacity and physical, emotional and social aspects of life (del Godoy et al. 2012).

Local Problem

Standards of diabetes care routinely include an annual CDFE (ADA, 2013; Boulton et al., 2008; Indian Health Service, 2009). The ADA, AACE (American Association of Clinical Endocrinologists), IWGFC (International Working Group on Foot Care) and APMA (American Podiatric Medical Association) advocate for individuals to receive an annual CDFE. Depending on the history of the patient or the examination findings, referral to a podiatrist may be indicated (Bild et al., 1989; National Diabetes Education Program, 2011). Examinations are critical to the early detection of diabetic ulcers or finding of risk factors that predispose patients to the development of foot ulcers. Importantly, one must remember with the increased incidence of obesity associated with T2DM, some of these patients cannot perform a full foot inspection.
According to recommendations of the ADA (2013), the CDFE should encompass inspection, assessment of bilateral pulses and neurological assessment including protective sensation evaluation and either vibratory sensation testing, pinprick sensation, or an Achilles reflex examination. Associated with the clinical examination is a focused history to discern any past history of foot ulceration, amputation, vascular or neuropathic symptoms, smoking, ability to visualize the entire foot and current foot care practices. Lack of ability to see the entire foot coupled with decreased sensation associated with diabetic neuropathy poses a great risk for foot ulcers to go undetected if healthcare providers are not performing foot exams. Singh, Armstrong, and Lipsky (2005) conducted a meta-analysis of research studies examining the efficacy of methods to decrease the rate of foot ulcers in a diabetic population. Substantial evidence supported the screening of all patients to identify those at higher risk for diabetic foot ulcers. The target for persons receiving diabetic foot exams at least annually by 2020 is 74.8% (Healthy People 2020). Statewide statistics in Arizona show than 68.2% of adults diagnosed with diabetes received a CDFE in 2010 (CDC, 2013). The IHS Diabetes Audit is a computer program, which runs from the Resources and Patient Management System (RPMS). The RPMS is a computerized system designed for IHS-wide system use. This program is constructed to make available detailed and comprehensive information of clinical and administrative nature. The information can be available for use at all levels of the Indian health system in order to allow them to better manage the health care delivery system. The Diabetes Audit provides the means to examine the care received by diabetic individuals using agreed upon standards of care. It supports health professionals in making sure their patients receive the best possible care. Government Performance Reporting Act (GPRA) is a clinical reporting system focusing on several specific measures associated with primary or secondary prevention and early intervention. The premise
of the IHS is GPRA links process measures to outcomes (IHS, 2013). The GPRA measures the performance of several guideline driven preventive measures but does not report the performance of CDFEs. According to information from the Diabetes Audit, the average rate of CDFEs for patients seen in 2012 at IHS facilities who received CDFEs was 68%. The average rate of CDFEs for patients seen in 2011 at the Primary Care Medicine Clinic at Phoenix Indian Medical Center who received care was 68.5%.

In summary, the burden of lower extremity complications of diabetes has been examined globally, nationally and locally. While diabetes self-management education is vital to decreasing the incidence of LEAs, clinical practice must incorporate the standard of care recommendations aimed at prevention or earlier diagnosis of foot complications. Around the world, an amputation occurs every 30 seconds. Some studies have shown individuals with diabetes suffer eight times the rate of amputations than those without diabetes. With optimization of diabetic foot exams, the incidence of amputations could be reduced by 40 to 85%. In the U.S., the rate of non-diabetic amputations has experienced a decline while the counterparts with diabetes are increasing (Li et al., 2012). The American Indian/Native Alaskan population represents 0.97% of the U.S. population; however this same group represents 9.1% of individuals diagnosed with diabetes. Various studies show a cost savings in practice improvements implementing increased performance of diabetic foot exams. Studies also highlight the concept that costs of lower extremity amputations cannot be captured by dollars alone. A multidisciplinary intervention successful in improving the rate of comprehensive diabetic foot exams should improve healthcare process and therefore, patient outcomes.
Literature Review

This literature review addresses methods to select and implement quality improvement projects. The focus is specific to research that assesses best practices for improving diabetes care delivery methods in outpatient settings. Not all research regarding best practices is applicable to all settings and populations. Successful implementation of change or different practice requires systematic planning with consideration of available resources, the target and environment, alignment with the organizational goals, and backing by administration.

Kenny, Smith, Goldchmid, Newman, and Herman (1993) analyzed survey data with the purpose of assessing physician adherence to guideline recommendations for preventive laboratory and clinical services. These surveys were assessed for completeness, and only those respondents who also completed the clinical section of the survey (n=1434) were analyzed (Kenny et al., 1993). The study evaluated guideline recommendation adherence based on physician specialty, type of diabetes being followed, and age of the physician. The sample consisted of 31% family practitioners, 29% internists, 18% generalists, and 22% pediatricians. Composite adherence rates for pediatricians treating T1DM were higher than for those who treated T2DM. This study confirmed other studies showing guideline adherence is strong with eye exams, blood pressure monitoring, neurological and circulatory examination. Guideline adherence was poor with teeth, gums, and foot examinations. The group showing the highest rate of performance of diabetic foot exams was internists younger than age 39 (80% for DM Type 1 and 62% for DM Type 2).

In a study of resident physicians at a medical facility, baseline data regarding physician adherence to guideline recommendations for diabetic foot examinations were gathered, followed with two lectures and the announcement of an upcoming Quality Assurance audit. Along with
the educational intervention and announcement of pending chart audits, the staff had the patients remove shoes and socks after the patient was in the examination room. An increase in performance of CDFEs rose from a baseline rate of 14 to 58% at three months, and 62.1% at six months (O’Brien et al., 2003). The baseline data were obtained from a retrospective chart review, and the data for months three and six were obtained with a prospective method.

In another meta-analysis (Peek, Cargill, & Huang, 2007), multiple electronic data bases were searched and a survey of select journals was conducted to evaluate intervention studies conducted from 1985-2006 that were designed to improve diabetes care for adult minority patients diagnosed with T2DM. Studies were excluded if the focus was on diabetes prevention, children, or were not based in healthcare settings. The systematic review yielded a total of 573 studies, 43 studies met the inclusion criteria. Two studies included randomized controlled trials (n=22), controlled trials (n=7), pre/post studies (13), and one observational study. The purpose of this systematic review was to analyze the efficacy of QI programs and disease management in ethnic or minority populations. The primary outcome measures of all studies were post intervention HbA1c, blood pressure and cholesterol. The provider based approaches in these studies included practice guidelines, CME, computer based decision support systems, in-person feedback and case study learning. Sustained improvements were noted out to three years with the use of practice guidelines and CME. Provider feedback and reminders were also shown to be associated with improved quality of care. A limitation of this study was the lack of comparable research containing both process and outcome measurements. This research again showed the power of encouraging the use of evidence based, guideline driven care, continuing medical education, and performance feedback.
In summary, a review of the literature regarding practice improvement to improve quality of healthcare outcomes for adults diagnosed with T2DM through evidence based strategies supports provider based approaches. Models that are multidisciplinary, utilize information technology, and reminder prompts have been shown to significantly increase the performance rate of CDFEs (Shojania, Ranji, & McDonald, 2006). The provider based approaches most frequently shown to improve quality of care were CME offerings focused on evidence based recommendations and guidelines, feedback to providers, and reminder systems.

The medical literature repeatedly documents that multidisciplinary teams are effective in addressing the treatment and prevention of diabetic lower extremity complications (Fitzgerald, Mills, Joseph, & Armstrong, 2009; Hinkes, 2009). The importance of team efforts in quality improvement or sustainment efforts has been recognized by experts in the field of improvement efforts. Interestingly, the success of multidisciplinary efforts in bringing about improvement has been known for at least 70 years but only gained notoriety from large organizations in the last 20 years. Multidisciplinary teams are effective because members come from different foci, providing different perspectives. A multidisciplinary team approach can be used to eliminate the fragmentation of care. Within the team it is vital to have a champion or leader, collegial sharing of ideas, a shared vision, and a common desire for innovation (Grol et al., 2013). Successful quality improvement efforts in health care depend on a team to analyze problem areas and to develop solutions, followed by testing the solution for effectiveness. Analysis of problem area requires the involvement of those employees involved on the frontline. These individuals experience the problem and are often able to define the factors associated with the processes in need of change for remediation in the context of the situation. When staff is empowered to have meaningful participation in problem identification and solving, an opportunity presents to allow
the team to positively contribute to the organization, leading to a greater commitment to the organization.

While this practice inquiry is a quality improvement initiative, similarities exist in those approaches found effective for translational research. Both QI and Translational Research involve the implementation of evidence based findings. Using Rodger’s (Rodgers, 2009) Diffusion of Innovations, the AHRQ Translation Research Model places emphasis on the nature of the intervention being implemented, the communication or dissemination plan, and the social system or target audience (AHRQ, 2014). The nature of the intervention covers characteristics such as relevance and effectiveness. For ease of adoption, the intervention should not conflict with values and perceived needs of the end user. The EBP changes should be perceived as relatively simple. The inclusion of clinical information systems, staff training, and needed equipment to carry out the intervention are key to successful implementation and integration of change (AHRQ, 2014).

The proposed practice improvement is an increase in the performance rates of CDFEs conducted by providers in the Primary Care Medical Clinic of Phoenix Indian Medical Center for the American Indian/Native Alaskan patient population diagnosed with diabetes. To be acceptable, change should positively impact patient outcomes and institutional administration (IOM, 2001). Implementation of this proposed practice improvement will address the six areas of acceptable care as proposed by the Institute of Medicine (IOM, 2001). The Institute of Medicine issued a consensus report calling for change in healthcare delivery (IOM, 2001). The changes need to address the six target areas of safety, effectiveness, patient centered, timely, efficient and equitable delivery of care. Increasing rates of effective and efficient CDFEs will improve safety
of care delivery through EBP by providing culturally sensitive and professional CDFEs to the selected population at this practice site.

The Plan, Do, Study, Act (PDSA) model provides a well-defined, democratic framework for population/setting specific implementation of changes such as practice improvement. Small tests of change such as the PDSA cycle allow for rapid identification and testing of needed change. Because the PDSA cycle starts with a small target, it allows faster implementation. This method also allows for ease in adaptation of the intervention when data or experiences warrant adaptation. Organizations are often more comfortable with this framework as it allows for less investment, therefore less risk, than that involved in a full scale implementation of change throughout the organization. The cycle should include the perpetual evaluation of efficacy of the given intervention. Important to the design of a program for implementing practice improvement is the incorporation of methods to assess impacts of practice improvement and the sustainability of that change (Titler, 2008). The impact of the practice improvement may be evidenced by change in healthcare outcome, change in the healthcare delivery system, change in system supports, and an effect on practice patterns (Melnyck, & Fineout-Overholt, 2003).

Inherent in the PDSA model are three well-defined questions which lead to a focused intervention with specific measureable goals (Langley et al., 2009). The three questions are:

1. What are we trying to accomplish?
2. How will we know that the change is an improvement?
3. What changes can we make that bring about improvement?

Consistent with providing and sustaining a culture of quality and safety in healthcare delivery, the PDSA cycle depends on continuous learning which stems from introducing needed change and reflection on the impact of the change, following with adjustments as indicated by measured
outcomes. Multiple PDSA cycles are necessary for insuring continual provision of healthcare delivery which meets the needs of the target population. Each cycle reflects a small test of change, thus requiring incremental adjustments which are effective in the given population, setting and resource availability (Langley et al., 2009).

A potentially successful quality improvement initiative requires leadership which can facilitate the PDSA committee in succinctly formulating specific, clearly articulated goals. Not all changes result in improvement, thus the importance of the second question as referenced above. The determination of improvement requires the delineation of what parameters should be measured to determine if the change resulted in improved outcomes. While improved healthcare outcomes should be the ultimate goal, process changes are requisite to healthcare outcome improvement. Important to planning is the selection of outcome measures, when and how those data will be collected, and what statistical tests will be used to test for improvement. Finally, the third question, addressing what changes can be made, requires strong leadership that is knowledgeable and willing to challenge the status quo.

**Project Purpose**

The purpose of this DNP project is to develop and implement a quality improvement project at Phoenix Indian Medical Center, Primary Care Medical Clinic, and a division of IHS that will improve the performance of CDFE among AI/NA patients diagnosed with diabetes. The quality improvement project will involve providers, nurses and other members of the interprofessional care team in improving CDFE performance per IHS guidelines. CDFE facilitates earlier detection and earlier intervention of abnormal findings in the AI/NA population resulting in a potential decreased rate of amputations. The project has three specific aims:
1) Conduct a quality improvement project with providers and staff of an IHS clinic to increase the performance of CDFEs with AI/AI patients.

2) Apply the PDSA model to develop and implement the QI project with providers and staff of an IHS clinic. Evaluate the impact of provider and clinical staff participation in the quality improvement project on rates of performance of CDFE within four weeks post intervention. Assess if involvement of providers and clinical staff in the quality improvement project, in particular identification of barriers to performing CDFE and resolution of low CDFE rates (68%), leads to an increase (10%) in the rate of performance of CDFEs within one month post-intervention.

3) Develop a quality improvement process that the clinic staff may replicate for future quality improvement initiatives.

**Intended Improvement: Implementation of Practice Quality Improvement**

The Institute for Healthcare Improvement (IHI) has compiled the steps recommended for leading an effective QI project and which have been disseminated in the IHI Leadership Guide to Patient Safety White Paper (Botwinick, Bisognano, & Haraden, 2006). The IHI steps have been compiled by a group of senior leaders advising quality of care and patient safety be addressed as a strategic initiative within an organization. The steps for leading an effective QI project reflect the importance of awareness, systems-level thinking, strong communication skills, and utilization of a systematic approach. The steps suggested are as follows:

1) Address strategic priorities, culture, and infrastructure.

2) Involve key stakeholders.

3) Communicate and stimulate awareness of the specified focus needing improvement.

4) Create, supervise, and communicate system level aims.
5) Track and evaluate or measure performance over a period of time to strengthen the data to be analyzed in determining effectiveness of the intervention.

6) Support staff and patients/families affected by the changes.

7) Align the activities involving other systems. Consider incentives.

8) Redesign the system and improve reliability.

An abundance of evidence based research has been published supporting the efficacy of CDFE in decreasing the rate of non-traumatic lower extremity amputation. The research has been evaluated and considered sufficient to support the recommendation of annual CDFEs (ADA, 2013; Bild et al., 1989; Healthy People, 2020).

This quality improvement project involves the implementation of evidence based practice (EBP) with the use of published best evidence that has been associated with successful increased performance of guideline driven chronic care. Evidence based practice (EBP) is defined as the conscientious and judicious employment of current best evidence with the consideration of the values of the patient and guided by clinical expertise (Titler, 2008). Best evidence is comprised of empirical evidence gathered from randomized controlled trials and other quantitative and descriptive qualitative research (Titler, 2008). The information supporting best evidence may be derived from case reports, scientific principles and expert opinions. Basic to all successful efforts of EBP implementation is the consideration of critical analysis and synthesis of the literature, with evaluation of potential impact on patient care and provider performance. In reviewing best practices, it is vital to consider the context and setting (Titler, 2008) as some interventions are not adaptable in certain settings. The adoption of CDFE has been studied in a variety of settings, with various populations, and by various provider types. These varied study characteristics lend
to the ability to generalize these study findings to the Primary Care Medicine Clinic at Phoenix Indian Medical Center.
CHAPTER TWO: METHODS

Ethical Considerations

The American Indian/Native Alaskan population has not only suffered disproportionate losses in the recent and remote past, they have been erroneously portrayed in a negative fashion by different sectors of the media. Additionally, this population is affected by the healthcare disparities experienced by a variety of minority groups in America. The goal of this Quality Improvement Process is to develop an initiative to increase CDFEs in the American Indian/Native Alaskan population receiving care at Phoenix Indian Medical Center with previously proven safe and effective interventions (HHS, 1979). Beneficence in the context of ethical research refers to the prescriptive directive of protection from harm and safeguarding well-being. The directive of beneficence in research activities involving human subjects is an obligatory component of design. The overarching quality of beneficence encompasses securing well-being of the population, the idiom of “do no harm,” with consideration of maximizing benefit while minimizing harm (U.S. Department of Health and Human Services [HHS], 1979). Specific to this Quality Improvement project, beneficence is observed through the implementation of interventions, which have been shown to improve healthcare outcomes among diabetic populations. The targeted group for this improvement intervention is the clinical provider group on the coral team, with AI/NA being recipients of potentially improved clinical practice and enhanced healthcare outcomes.

The aspect of justice is multifocal in research. The principle of justice is applied in different areas of the research design. Components of the design must congruently weigh the concepts of benefit versus burden. Prior to the publication of the Belmont report, many research efforts were unjust. Justice is addressed when selecting a research focus; delineating inclusion
and exclusion criteria; as in the concept of respect, considering the ability of research subjects to comprehend the risk, benefits and alternatives of the undertaking, and always allowing the freedom to refuse or withdraw from the study without consequence (HHS, 2009).

Privacy and anonymity can be protected through the design of the study and with the method used to report findings. These elements are related to the concepts of respect and autonomy. This Quality Improvement did not report the names of providers or staff who participated in the project. No personally identifying information was used in this study. The research participants in this study were primary care providers and clinical staff at Primary Care Medicine Clinic. Instead of using the name of the primary care provider, each provider was assigned a number unknown to the primary investigator. The study refers to Provider 1, 2, 3, or 4. The data specialist will carry out this method of blinding.

Vital to the concept of beneficence is a clear delineation of risks and benefits inherent in study participation. Benefit refers to any associated relationship between participation in the study and a positive effect on health or welfare of the research participant. Risk is considered potential harm such as emotional, physical, social, spiritual, economic, or legal negative outcomes which might be associated with research participation. Both risk and benefit are considered as probabilities, not as possibilities when the risk/benefit analysis is measured. A benefit can extend beyond the effect on the research subject. The knowledge gained from a study is also considered a benefit (HHS, 2009). The participant consent form will reflect these concepts.

This study is an evidence based intervention designed to enhance healthcare outcomes of the diabetic patients at Phoenix Indian Medical Center. According to the Belmont Report, because this study introduces evidence based standards of care, evaluating how best to facilitate
provider and staff adoption of practice improvement, it need not be considered research for the purposes of an Institutional Research Board (IRB). Specific to the IHS IRB, review of Quality Improvement (QI) Projects conducted by entities outside the IHS, also require an initial review by the IHS IRB chairperson. The co-chairpersons of the IHS IRB reviewed the QI protocol. The co-chairpersons met with the author to discuss the QI proposal. A few editorial suggestions were offered in the provider consent form. The suggestions related to language, which ensures the participant of no risk to issues related to employment based on participation/lack of participation and performance in the QI intervention. With the letter of support for the QI project (See Appendix A) and specific details of the DNP project protocol (See Appendix B), the IHS IRB granted a letter of approval for this DNP project.

Setting

The setting for this DNP project is an ambulatory care outpatient clinic in Phoenix, Arizona, serving urban AI/NA. The clinic is associated with Phoenix Indian Medical Center, an entity of the Indian Health Services (IHS). Primary Care Medicine Clinic is an ambulatory care center, which houses providers and staff providing healthcare for all federally recognized AI/NA tribes. It is a goal to empanel each patient to an individual provider. The provider staff includes both Family Practice and Internal Medicine clinicians. Among the staff of MDs and DOs are one nurse practitioner and one physician assistant. Each clinician has a panel of patients, providing acute, chronic, and preventive care for these individuals. Many individuals have multiple chronic conditions including Diabetes Mellitus. The panels range in size from 780 to 1100 patients. Most patient appointment slots are designed to allow 30 minutes with the provider.

Also involved in the care of patients in the Primary Care Medical Center are a multidisciplinary group of registered nurses, licensed practical nurses, medical assistants, clerical
staff, nutritionists, and pharmacists. Four of the registered nurses are Certified Diabetes Educators (CDE), with one being co-located among providers and staff in the section of the clinic implementing the Patient Centered Medical Home. The co-location of the CDE combined with pre-planning for care, facilitates the delivery of patient centered diabetes self-management education. Phoenix Indian Medical Center also provides services of ophthalmology, podiatry, dental, surgery, oncology, obstetrics and gynecology, behavioral health, radiology, some laboratory services, and pediatrics. These services are available for consultation or referral.

The mission of Phoenix Indian Medical Center is to offer quality healthcare that is uniquely suited to American Indians and Alaska Natives. In line with the mission is the vision statement to be the primary choice of American Indians and Alaska Native people seeking to achieve the highest level of physical, mental, social, and spiritual wellbeing (Phoenix Indian Medical Center, n.d.). Following the mission and vision statement, the Primary Care Medical Clinic is in the process of implementing the Patient Centered Medical Home. This quality improvement intervention is also consistent with the mission, vision, and concept of patient centered care.

The primary care providers at the Primary Care Medicine Clinic are divided into four teams. This QI initiative will be conducted with the Coral team because this team is currently utilizing pre-visit planning and a one-to-one provider/nurse or CMA ratio, facilitating quality improvement efforts. If a patient is not able to obtain an appointment with the specified primary care provider, every attempt is made to appoint the patient with a provider co-located on the Coral Team. Studies have supported this method of scheduling based on an empaneled team approach for improved health care delivery and outcomes in the ambulatory care setting (NDEP, 2014; Reid et al., 2009). Each primary care provider is paired with a nurse or certified medical
assistant (CMA), consistent with a collaborative team concept for health care delivery. This method allows coordination of care efforts including pre-visit planning for each individual patient. This setting of collaborative health care delivery provides the opportunity to focus on the needs of patients specific to their individual backgrounds and health care needs. The administration of this IHS facility encourages and recognizes the effectiveness of collaboration and strong communication strategies between all members of the health care team.

The administrative team at Phoenix Indian Medical Center has focused on implementing the patient centered medical home over the past two years. In supporting this implementation, processes have been put in place to allow needed changes in healthcare delivery methods in the facility. Some of the process changes have included added focus on information technology, addition of staff to lead and monitor changes focused on improvements in patient care and healthcare outcome, physical changes in various areas of operation at Phoenix Indian Medical Center, and inclusion of frontline staff with planning and implementing many of the changes. A great emphasis has been placed on improvement of quality and safety of healthcare services. Many changes in this facility have been brought about through the Plan Do Study Act (PDSA) quality improvement framework. The PDSA framework encourages involvement of stakeholders who happen to be in the frontline of care, placing an emphasis on data collection to support or refute new ideas.

**Planning the Intervention**

Planning a QI initiative entails attention and knowledge of a multiplicity of factors. Batalden (2014) refers to the importance of the work before the work. Essential in this phase is the identification of various goals for the initiative. Among the potential goals, it is possible that some goals may be conflicting. Consider people to involve in the initiative, also consider to
whom this project matters. Aim for involvement of people with some shared goals. During this phase, a clear scope of the problem should be articulated. Planning also involves assuring needed resources are gathered. Equally important is possession of knowledge of previous efforts for change in the facility. The knowledge of how the system responded to change is helpful in planning appropriate strategies to move in a positive direction, cohesively and with shared commitment. A timeline for this project was developed and utilized (Appendix C).

Successful implementation of a quality improvement (QI) project to facilitate meaningful change involves an organized, systematic approach preceded by careful planning (Amputation Coalition, 2012; Grol & Wensing, 2013; NDEP, 2011). A QI project is the implementation of change (Langley et al., 2009). The steps necessary to achieve and increase the rate of CDFEs involve a comprehensive assessment of the many factors, which either facilitate or impede a transition in practice. Conducting a Quality Improvement (QI) project requires a focus on organizational and behavioral processes which are not effective in providing the desired healthcare outcome (Titler, 2004). The literature (Eccles & Davis, 2013; Grol & Wensing, 2013) strongly emphasizes the importance of administrative support and strong, credible clinical leadership, which supports quality improvement efforts. Relevance to the target audience with a focus on healthcare outcome improvement is integral to successful adoption of new interventions. The recommended intervention should be supported by evidence based research. To be considered evidence-based the intervention must have sufficient, scientifically based research suggestive of efficacy (Spring, Ferguson, Pender, & Starven, n.d.).

The first step in planning the intervention is selecting an area of interest that has the potential to make a positive impact when addressed with the knowledge and skills attained in the clinically focused doctorate of nursing practice program. Low performance rate of CDFEs
(<90%) performed by providers with American Indian/Native Alaskan patients who have diabetes mellitus is an issue at the Primary Care Medical Clinic. Improving the rate of CDFE at this facility was approached through an evidence based intervention consistent with current guidelines related to care of individuals with diabetes mellitus. This section will discuss the steps in planning the intervention. The plans for the study of the intervention will be discussed in the next section.

The process outcome of the planned intervention was to increase by 10% the rate of CDFEs performed by providers at Primary Care Medicine Clinic with their AI/NA patients diagnosed with diabetes. The distal healthcare outcome of the Quality Improvement initiative was the decreased rate of non-traumatic lower extremity amputations (NLEAs). The plan was discussed with the director of Ambulatory Care, the chiefs of Family Practice and Internal Medicine, representing the formal leadership of Primary Care Medicine Clinic. With the support of the formal leadership of Primary Care Medicine Clinic, the chance of successful implementation of change is strengthened (Langley et al., 2009). Nursing and clerical staff are under the immediate supervision of the Clinical Nurse Supervisor. Plans for implementation of a quality improvement initiative aimed at increasing the performance rate of CDFEs were also discussed with the Clinical Nurse Supervisor, outlining the expectations for nursing and clinical staff associated with this quality improvement intervention. Feedback regarding planning was also solicited from the Clinical Nurse Supervisor, drawing from her experience and clinical expertise. The Clinical Nurse Supervisor is a key stakeholder in this process to improve healthcare outcomes of patients served by this clinic.

Consideration of essential concepts related to successful quality improvement interventions is fundamental to planning an effective strategy. Over the past century, several QI
concepts have evolved. In a summary by Agins (2011) for the Health Resources and Studies Administration (HRSA), four core principles were cited: 1) A focus on the customer results in improvement activities that culminate in improved patient health outcomes; 2) Measurement is integral to having data that evaluate whether an intervention results in improvement; 3) To improve health care activities, the systems of care must be evaluated and honed to link to improved outcomes; and, 4) Membership of QI team members should be composed of those individuals involved in the implementation of the process being examined. The team members must be committed and have an active voice in discussion and planning. To summarize, the essential concepts include a focus on customer and improved health care outcome; a valid and reliable method of measurement; examination of systems linked to outcome; and democratic involvement of those individuals involved in the process being improved.

Components of the Intervention

Organizing Framework

The Plan Do Study Act (PDSA) Model (Langley et al., 2009) provided the organizing framework for this QI project. The project was introduced to one pod of providers and clinical staff (coral pod) in the Primary Care Medical Clinic, Phoenix Indian Medical Center facility. The Clinical Team (coral team) chosen consisted of four providers, two registered nurses, one a Certified Diabetes Educator (CDE), one licensed vocational nurse, three certified medical assistants, and two medical support assistants. The selection of this pod was based on the previous accomplishments of this team through collaboration, coordination, and willingness to make changes to promote improved quality of care. This group has been involved in implementing the Patient Centered Medical Home Model of care delivery. The methods
proposed to increase the rate of CDFEs performed at Primary Care Medicine Clinic are congruent with the methods used to improve clinical care by this group.

Studies have shown that programs developed for improvement in chronic health condition outcomes have failed when providers do not cooperate with the intervention (Feifer et al., 2006). This lack of cooperation among providers, in the absence of support for standardized implementation resulted in idiosyncratic care delivery with no measurable outcome improvement. Some programs were unsuccessful when providers refused and were not required to adopt the intervention (IHI, 2010).

Methods exist to explore and overcome lack of cooperation among providers or other members of the healthcare team. IHI presented an audio-cast moderated by Madge Kaplan (citation) with the panel of three experts in the field of healthcare teams and communication on managing conflict in healthcare teams. The methods discussed highlighted how conflicts with skilled leadership of discussion can produce creativity and identification of common ground and interests. Key to the conversion of conflict to creativity is a basic understanding of group dynamics, the dynamics of change, dynamics of human behavior, and excellent communication skills. Humans are “hard-wired” to jump to assumptions. Assumptions are often incorrect. Assumptions can result in behaviors of withdrawal, silence, and attempts to turn the focus on who is right and who is wrong. An effective group leader can often turn this scenario of conflict into a situation where members identify common concerns regarding the focus needing improvement. Moving forward from the common concerns and focusing on the issue, rather than the opposing positions, can allow the group to move to a more creative and relaxed level leading to solutions (Kaplan, 2014).
When conflict occurs it is helpful to listen unconditionally to the person who is obstructing the group process, noting the tone of voice, pace of speech. The leader, remaining calm, allows that person to verbalize his/her concerns. Do not jump in and do not provide a counter-attack. Guide the conversation to common goals. Conflict resolution, when successful in the group setting can be a springboard to creative problem solving through identification of common goals, improved trust, and promote bonding (Kaplan, 2014).

The multidisciplinary approach, using the PDSA framework, is strengthened by combining the perceptions of past experience of the group with frontline knowledge of job details, thus moving the project toward an upward trajectory (McDavid & Hawthorn, 2006). Productive PDSA endeavors require preplanning and utilization of strategic, broad invitations to solicit input surrounding the issue being explored. Discussions allowed full exploration of the phenomena of diabetic foot examination performance as the individuals in the group have experienced them. The PDSA team for this QI intervention was composed of frontline staff involved in the processes related to delivery of patient care at the Primary Care Medicine Clinic.

The PDSA team moved through the stages of improving the safety and quality of care delivered at the Primary Care Medicine Clinic. The first stage, planning, resulted in identification of barriers to the performance of CDFEs. The PDSA team reviewed the current processes surrounding the performance of CDFEs (see Appendix E), identified the barriers to the performance of CDFEs. Once barriers were identified, utilizing root cause analysis, the PDSA team moved forward to develop an approach to mitigate the barriers (Zegers et al., 2013). The plan was developed including feedback from the multidisciplinary input contributed by the PDSA team members. IHS has developed clinical guidelines regarding the performance of CDFEs in diabetic patients. This guideline specifies at least an annual CDFE performance in all
patients with diabetes. While the guidelines are clear, flexibility exists in order for each IHS site to determine how to best implement the guidelines. The work of the QI initiative was to identify what issues were barriers to implementation, develop and test changes proposed to facilitate the use of the guidelines related to CDFEs.

One useful method of generating ideas for improvement is brainstorming (Wensing, Bosch & Grol, 2013). Brainstorming can be done individually or in groups. The group method offers an ability to draw from the diverse and rich experiences of the group to gain insight to the possible causes of the problem. The causes or factors identified should each have an effect. That effect either causes or contributes to the cause of the problem situation. Group brainstorming also encourages the feeling of “buy in” and bonding. The group was encouraged to move through this process with open minds and a nonjudgmental attitude. Again judgmental attitudes are often tied to assumptions, which often lead to conflict. In order to allow team members to have a voice, the group was composed of five members. As in all methods or tools for change, planning is imperative. Some items considered for preparation were environment, ability to document what transpired during the meeting, and needed resources. Environment included room temperature, lighting, space, and consideration of the group’s wishes for a table to facilitate writing. A group member was requested to keep notes of the meeting. A white board was used to facilitate discussion of contributing causes and effects (IHI, 2014).

Quality improvement interventions involve measurement of indicators to determine if the intervention achieved the desired results. There are three classifications of indicators recognized in quality improvement work; structure, process, and outcome (AHRQ, 2014;Braspenning et al., 2013). Outcome, as in healthcare outcomes, should be the long-term goal. For this DNP project, process measures demonstrating the rate of CDFEs were examined. If the quality improvement
intervention is successful in increasing the performance rate, eventually outcome measures would be essential to determine if the intervention improved healthcare outcomes.

The process measure was the performance rate of annual CDFEs among patients presenting for appointments and due for a CDFE. Because the CDFE is performed annually, not all diabetic patients seen during the time frame of this project will require a CDFE. The goal of this quality improvement initiative is to increase CDFE performance rates by 10% to be achieved within four weeks of implementation of the changes. The data regarding performance rates of CDFE was collected through a method already utilized for the IHS diabetes audit. The patients’ personal identification was not shared with the author.

The PDSA team determined the processes designed to improve the rate of CDFE. The electronic health record (EHR) was the tool for data collection. This method offered a rapid gathering of patient data and was utilized by the data specialist to provide pre- and post-intervention analysis on the performance rate of CDFEs. The EHR also has reminder prompts alerting the user when certain testing or examinations are due. The CDFE is documented into a user-friendly template in the EHR by the clinician performing the examination. While some mechanisms for facilitating performance of CDFEs are present, the low rate reflects a need for further identification of factors contributing to the sub-optimal performance rates of CDFEs. The PDSA team consensus regarding facilitating factors and barriers lead to a prediction of changes needed in the current care delivered to patients with diabetes mellitus. The proposed intervention must be safe, effective (evidence based), patient-centered, timely, efficient and equitable (IOM, 2001). The first PDSA cycle was implemented utilizing suggested adaptations to the current process of planning for and providing care for patients with diabetes.
Recruitment

The recruitment process is necessary to assemble the appropriate staff to compose the PDSA team. The coral team was already aware that the author planned to lead an initiative to improve the performance rate of CDFEs at the Primary Care Medicine Clinic. The author is a practicing APRN and coral team member. A recruitment poster was designed, with the intent to engage the interest of staff members regarding participation in the quality improvement initiative (Appendix E). The recruitment posters were displayed in areas visible to the health care providers and clinical staff.

PDSA Team Processes

The PDSA team, composed of recruited volunteers from the Coral Team, consisted of one medical support assistant, one registered nurse, one CMA, one Family Practice MD, and was facilitated by the author. The author is an Advanced Practice Registered Nurse (APRN). Recruitment flyers (Appendix E) were posted in the work areas of the coral team for the purpose of recruiting volunteers for the PDSA team. This team was comprised of a group of five PDSA team members, which allowed input from all aspects of direct care delivery.

There are four phases of the Quality Improvement project: Plan, Do, Study, and Act. The procedures associated with each phase are described:

1. Plan [P]: During the PLAN phase, the PDSA team members met weekly for five weeks. The PDSA team collaboratively planned, conducted, and analyzed the method to improve the performance rate of CDFEs. During the planning phase, all team members contributed to the identification and prioritization of issues posing barriers to the performance of CDFEs. The PDSA team agreed on the problem of low performance rates for CDFEs at the Primary Care Medicine Clinic. A brief review of
statistics supporting the association between CDFEs and the reduction of diabetic foot complication was provided by the author. This was followed with a brief review of the literature comparing the efficacy of various methods of improving compliance with standards of care.

The problem was defined as the low performance rate of CDFEs in the Primary Care Medicine Clinic for American Indian/Native Alaskan patients diagnosed with diabetes. The clinic-wide performance rate of CDFEs was 68.5% in 2013. The Team reviewed the data to reflect a change in the performance rate of CDFEs. Based on the analysis of the data collected, the PDSA Team made a recommendation regarding future utilization of the quality improvement method. Data reflecting the performance rate of CDFEs for each of the previous four weeks for each of the four providers on the Coral team exceeded that of the composite performance rate of CDFEs performed at the Primary Care Medicine Clinic. The PDSA team agreed on the need for improvement of the performance rate of CDFEs. The target for performance rate of the annual CDFE was defined as 90%. The team defined the objective of meeting a 10% increase in the performance rate of CDFEs by each coral team primary care provider within four weeks. The author introduced the PDSA team to the concept of the fishbone diagram to conceptualize the factors associated with performing the CDFE.

The first PDSA team meeting applied the method of brain storming to identify the barriers to performance of CDFEs. A cause and effect fish bone diagram was used for identification and analysis of contributing factors to the low performance rate of CDFEs.

The PDSA team worked collaboratively to map the processes involved in achieving the performance of a CDFE. The processes identified started with the initial scheduling of an appointment for the patient visit, following through to the actual CDFE (Appendix D).
The problem statement (Low Performance Rates of CDFEs) was written on the center right side of the board. After drawing a box around the statement, a line ending with an arrow pointing to the box was drawn starting from the center left. Branches were drawn from the straight line. These branches contained the main categories or components identified as relating to the performance of CDFEs. The branches drawn in a diagonal fashion, appeared above and below the straight line, thus the appearance of fishbones. In guiding the group in brainstorming to develop the list of potential components of the problem the question “why does this happen?” was repeatedly posed. For example, the problem of low performance rate of CDFEs is a result of CDFEs not being performed. “Why does this happen?” The categories listed in the diagram include methods, providers, patients, resources, measurement, and environment. As the group members shared views on why the problem existed, the responses were noted under the proper category on a line drawn parallel to the center line. If “not enough time” is a response, time would be listed under the category of resources. A category can have several or no items. A cause can also fall under more than one category. As an example, when CDFEs are performed but not documented could fall under method, measurement, and provider. Probe further with each response, “why does this happen?” Answers to this question are defined as sub-causes. As the team delved deeper into the causes of each example, the facilitator added to the fishbone diagram with lines that are horizontal and parallel with the listed category (Figure 1)
FIGURE 1. Ishikawa or Fishbone Diagram

When the team exhausted responses, the focus moved to areas of the diagram with fewer ideas and probing was resumed (American Society for Quality [ASQ], 2014). Once the team agreed the diagram reflected their collective ideas, the fishbone diagram was inspected for any causes that appear to be related. Finally the group voted on the category that was seen as a barrier to the desired level of performance. The cause selected as most probable was a factor that the group has power to bring about change (Georgia Leadership Institute for School Improvement [GLISI], 2009).
The process of root cause analysis facilitated the PDSA team in shaping an approach to improve the performance rate of CDFEs (GLISI, 2009). Using the information gathered from the root cause analysis the PDSA team identified barriers to the performance of CDFEs and generated a clear hypothesis suggesting why the CDFE was not being performed as recommended by IHS guidelines. After drilling down, deeply examining the different barriers to the performance rate of CDFEs, the PDSA team members came to a consensus that ineffective utilization of pre-visit planning, inconsistent availability of equipment for CDFEs, lack of team approach between the nurse/certified medical assistant and the provider, the omission of having the patients remove shoes and socks, all were barriers which the team had the power to improve. The category of process was identified as a barrier which the group had the power and skills to change and improve. The PDSA team decided to make five changes in the current processes of care leading up to the time the provider was ready to visit with the patient:

1) **Barrier**: The pre-visit screening process was not being used as the point in which patients were identified for a CDFE.

   **Solution**: The nurse/CMA would identify which patients were due for the CDFE during the pre-visit planning.

2) **Barrier**: Primary care providers often either felt not enough time was available for a CDFE or the provider felt the examination should be performed by a podiatrist. (The provider perception that the CDFE was not the responsibility of the primary care provider would not be addressed by this project.)

   **Solution**: The nurse/Certified Medical Assistant would inform the provider that the CDFE was due so the provider could prioritize and better utilize the time spent with the patient.
3) Barrier: The primary care providers have expressed concern that extra time was required to explain the need for the foot exam and wait for the patient to remove shoes and socks.

Solution: Once the patient was situated in the exam room, the patient would be asked to remove shoes and socks and a “chux” pad would be placed under the feet as a protective barrier.

4) Barrier: Exam rooms were not consistently equipped with a monofilament needed for the examination. The absence of needed equipment results in either the provider losing time obtaining the equipment or re-enforced the setting for low performance rates of CDFEs.

Solution: Each nurse/CMA would check the examination room, replenishing needed equipment and placing the monofilament in a visible area for the provider.

5) Barrier: Patients were not aware the CDFE were due to be performed at that visit:

Solution: As the nurse/Certified Medical Assistant prepares the patient for the visit (weight measuring and obtaining vital signs), the patient would be informed of the need for the CDFE. A diabetic foot care poster is situated in each room on the back of the exam room door. When the door is shut, patients often read the material on the poster.

The identification of barriers allowed generation of potential solutions for each barrier. Approaches to standardize processes were developed by this multidisciplinary PDSA team. Utilizing these identified processes, a protocol to facilitate the performance rate of CDFEs was developed for testing. This method chosen by the PDSA team was predicted to increase the performance rate of CDFEs. Based on the knowledge yielded regarding the processes, barriers,
and facilitators of the CDFE, the chosen intervention should explicitly define the roles of staff members in carrying out the proposed intervention. Clear goals and objectives are a prerequisite for developing performance measurements. The preparation during this phase augments the learning that will take place in the Study Phase.

**Proposed Process Changes for Facilitation of CDFEs**

1. **Scheduling:** The process of scheduling patients remained as it is currently done by the Medical Support Assistant.

2. **Pre-visit Planning:** Pre-visit planning allowed identification of those patients due for the annual CDFE. The EHR provides two methods for pre-visit planning to capture those patients in need of an annual CDFE. The EHR offers a reminder tab, cueing the nurse/certified medical assistant that the CDFE is due. Also a package facilitating the management of population health can be used to print out all guideline driven examinations that are due for the patient. The nurse/CMA noted on the visit form what examinations are due for the visit. Also, with pre-visit planning the nurse labeled a diabetic foot care educational handout for the patients receiving the CDFE. Having been prepared for the patient, the handout was to be provided to the patient by the nurse/CMA as the patients are relocated from the waiting area to be placed in an exam room.

3. **Screening:** The nurse/CMA guided the patient from the waiting area to the exam room. During the time, weight and vital signs were measured and documented, referred to as screening, the patient the nurse/CMA informed the patient that a yearly diabetic foot examination was due. The nurse/CMA placed a “chux” pad on the floor in front of the seated patient. The patient was asked to remove shoes and socks in
preparation for the exam. From that point forward, it was at the discretion of the provider when and how the CDFE was to be performed. This intervention was aimed at increasing the performance rate of CDFEs through facilitation of the exam rather than dictating provider practice change.

4. Patient Diabetic Foot Care Education: In addition to the handouts, each room has a poster hung in a visible area with tips on diabetic foot care.

During this planning session, the team identified outcome measures to determine if the intervention was effective in increasing the performance rate of CDFEs. Roles and responsibilities were defined and a timeline was agreed upon for the implementation of the intervention and follow-up PDSA team meetings. The author, physician and CMA worked to support the implementation of the improvement intervention by adhering to the recommendations and supporting the other members of the coral team in adapting the change. The Medical Support Assistant assumed responsibility of locating a meeting place for weekly PDSA team meetings. The team members also addressed the need to provide an educational handout on diabetic foot care to each patient receiving a CDFE. The RN on the team, a CDE, provided examples of educational handouts and one was chosen by the team. The Medical Support Assistant took responsibility for obtaining color prints of the handout. Approval for reprints for patient education was included on the handout. A date was chosen to implement the QI plan.

The target population was determined to be the four primary care providers on the coral team. A measurement was chosen to determine if the intervention was associated with an increase in the performance rate of CDFEs. The requirements for the data necessary to evaluate
the outcome of the QI intervention are that the data be current, readily accessible, and representative of the group being studied.

2) Do [D]: During the DO phase, the team members implemented the change predicted to increase the performance of CDFEs. While the intervention was being conducted, team members were reminded to monitor for any deviation from the proposed change. As the proposed intervention was implemented, the members of the PDSA Team were observant for any feedback or unexpected occurrence regarding the process and effect of the proposed change. Unexpected occurrences are important to document. The observations were used during the study phase to provide depth to the understanding of the effect of the intervention on performance rates of CDFEs.

3) Study [S]: During the STUDY phase, the team members reviewed and discussed data collected to determine the impact of the intervention on the performance of CDFEs. Summary statistics were used to analyze the data and a run chart was selected to be used as both an assessment and inferential tool at the end of the study. Trends in the data were assessed with the run chart. Finally, during the study phase the PDSA team addressed any barriers in the performance of CDFEs encountered during the previous week and proposed solutions to those barriers.

4) Act [A]: After a period of one week post initiation of practice improvement, the PDSA team met to assess the need for any adjustments in the procedures implemented to increase the performance rate of CDFEs. The team met weekly for four weeks, after the initial meeting where the group worked collaboratively to identify and define a method to improve the performance rate of CDFEs. During those weekly meetings, any needed changes were addressed by the group and voted
on by consensus. The PDSA team reviewed the performance rate of CDFEs and discussed any suggestions for improvement in the intervention on a weekly basis for a total of four weeks. After four weekly cycles of the PDSA, the PDSA team members had data to determine if the intervention is: 1) ready for spread to the entire Primary Care Medicine Clinic; 2) in need of further revision and study; or 3) abandoned (Langley et al., 2009). Due to the time limitations of this DNP project, only the mechanism of process measurement was used. As previously addressed, one month was not sufficient time to assess and capture any measurable change in the healthcare outcomes related to the increased performance rate of CDFEs. The time intervals for data analysis (numbers reflecting performance rate of CDFEs) should be three months, six months, nine months, and one year. Measurement of study effect over the long-term should be monitored for sustainment of performance gains. Additional longer term outcome measurements to consider could be amputation rate, rates of newly developed diabetic foot ulcers, and the number of referrals to podiatry. Impact on other systems in the organization might be measured in assessing the outcomes of the improvement. Once healthcare outcome measurements and process measures are clearly defined, a method of how the data will be collected and task assignments should be clearly designated. The Practice Inquiry was completed when the PDSA team completed the fifth PDSA team meeting. The author, as an APRN with doctoral education, plans to continue facilitating this quality improvement intervention, making adjustments as identified or suggested to improve efforts. Utilizing successive PDSA cycles will allow for timely modifications as needed to maintain the quality and safety of care delivery.
Planning the Study of the Intervention

Process measures to determine if the change resulted in an improvement were identified, along with how the measurement collection. For this practice inquiry, the data reflecting the performance rate of CDFEs was obtained from the data specialist with the Center of Excellence at Phoenix Indian Medicine Clinic. Performance measurements are followed by IHS for different components of care for a variety of chronic disease states. In this instance, data are available showing the performance rates for the annual CDFE for each provider. Data were extracted from the medical records of patients who met inclusion criteria. A de-identified print out was generated by the data specialist that identified those patients eligible for a CDFE as well as those patients who received or did not receive the examination.

As a quality improvement intervention the pre-intervention and post-intervention data were analyzed with a run chart. Data reflecting the performance rate of CDFEs conducted by the chosen clinical team (based on those patients eligible for CDFEs) was obtained for each of the four weeks prior to the implementation of the quality improvement initiative. The data collected prior to the quality improvement initiative was used to compare with post implementation data. One week after implementation of recommendations made by the PDSA Team, the data specialist utilized the electronic health record to provide information to determine any changes in the performance rate in CDFEs. The data specialist conducted a query from the electronic health record of patients seen by each of the four primary care providers to determine the rate of CDFEs performed. The data report supplied to the author was de-identified. The rate of CDFEs was monitored weekly for four weeks. Use of an Excel format for displaying the weekly performance rates was useful to track trends in the performance rate.
Roles of team members were defined in this stage. The roles were defined based on the proposed intervention and the scope of practice of individual staff. This phase is critical to the success of gathering knowledge needed to solve the problem and determining what measures will reflect if the change resulted in an improvement.

**Provision of Feedback**

Feedback is integral to maintaining group participation and continued efforts for quality improvement. Evidence based research has shown that provision of feedback to providers enhances the sustainability of QI interventions (Peek et al., 2007). While this QI intervention is not considered research, the IHS IRB requires that all human subjects be protected. For protection of the participants, as employees, all data had to be de-identified to protect any participant from being placed in any employment jeopardy. As provider performance feedback is an evidence based quality improvement intervention, the lack of feedback was expected to dampen the increase in performance rates. When QI intervention is no longer a DNP project, the providers and clinical staff should receive timely feedback on the performance rates of CDFEs.

**Methods of Evaluation**

The outcome measure used to determine the effectiveness of this QI project was comparison of the pre- and post-performance rates of CDFEs. It should be acknowledged that this was a multifaceted intervention and no data were collected which could provide insight as to which intervention contributed most to the improved performance rate of CDFEs.

**Analysis**

To determine whether the improvement in performance rate of CDFEs was random or in response to the QI intervention, the run chart was used (Figure 2). The number of times the runs cross the pre-intervention median bar allows inference regarding the relationship between the
quality improvement intervention and the performance rates [Institute for Healthcare Improvement (IHI), 2011].

![Aggregate Run Chart for CDFE Performance Pre- and Post- Intervention.](image)

The performance data was analyzed with the run chart. A median pre-intervention rate and median post-intervention rate was identified to provide a benchmark for comparison. This method also has the ability to allow inference of the data (Figure 2). Based on the number of times performance rates cross the pre-intervention median threshold, using a specific table with defined parameters, it is possible to infer if the post-intervention data is associated with the intervention. As previously stated, in order to sustain an increase in the performance of CDFEs at three months, six months, nine months and one-year intervals post implementation are the recommended intervals for more robust outcome measures.
As this DNP project terminates with development and implementation of the practice improvement, the Principal Investigator (PI) plans to remain involved in leading efforts to sustain optimal performance rates of culturally appropriate, efficient, and evidence-based CDFEs. The author will request that the information technology department monitor performance rates of CDFE quarterly, providing feedback of those data to providers and staff of Primary Care Medicine Clinic. This practice improvement is just a beginning and has several areas for growth such as development of a multidisciplinary team to sustain the growth of efforts to provide evidence-based care to patients diagnosed with diabetes who receive their health care at the Primary Care Medicine Clinic.

The outcome of the QI intervention was expected to be a 10% increase in the performance rate of CDFEs to be measured after four weeks of the introduction of the intervention. While a 10% increase will not bring the composite rate of performance of CDFEs to the 90% goal for all providers, a 10% increase should show the effectiveness of the intervention over a short time period.

To assess for the effect of time on the outcome of the intervention, data were measured and reported on a weekly basis for four weeks. Raw data were calculated to show percent of change in performance rates for each provider. Each week the data were examined for change in performance rates of CDFEs from previous weeks.
CHAPTER THREE: RESULTS

The performance rate of CDFEs for all providers increased when comparing the pre-intervention performance rate with the final week post-intervention performance rate. Unfortunately, this is does not provide all information necessary to determine effectiveness and sustainability of improvement interventions. To better assess the data, a run chart was performed for each provider and aggregately. See Figures 2, 3, 4, 5, and 6 to examine the pre- and post-intervention performance rates for each provider. Based on the low number (nine) of runs, the changes in organizational processes were not statistically associated with the performance of CDFEs. To be statistically significant at $p < 0.05$, the number of runs should be greater than 10 and less than 24 (IHI, 2011).

This chapter will discuss the proposed effects of the setting on the QI intervention and the actual changes in process and outcomes. The data on performance rate of CDFEs showed that pre-intervention median performance rates were slightly higher than post-performance rates (82.3 and 80.6, respectively). Figure 1 provides the raw data on the performance rate of CDFEs for each de-identified provider on a weekly basis. Figure 2 shows the run chart composite performance rates of CDFE for each provider both pre and post intervention. Figures 3, 4, 5, and 6 present the respective de-identified provider data in a run chart format. See Table 1 for specific information and depiction of the change in performance rates of CDFEs.
TABLE 1. CDFE Performance Rates: Raw Data.

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Provider 1</th>
<th>Provider 2</th>
<th>Provider 3</th>
<th>Provider 4</th>
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<td>-4</td>
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<td>-1</td>
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<td>90</td>
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<tr>
<td>post Intervention</td>
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<td>100</td>
<td>88</td>
</tr>
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<td>Average post intervention</td>
<td>79.5</td>
<td>63.75</td>
<td>69.5</td>
<td>91.5</td>
</tr>
</tbody>
</table>

(Note: Weeks 1 thru 4 are pre-intervention raw data. Weeks 5 thru 8 are post-intervention raw data.)

FIGURE 3. Run Chart Provider 1.
FIGURE 4. Run Chart Provider 2.

FIGURE 5. Run Chart Provider 3
Based on the utilization of a run chart examining CDFE rates over time, the changes observed in the performance rate of CDFEs were not associated with the changes in the health care delivery process of the quality improvement intervention. The median performance rate before the intervention was 82.6 with the median performance rate post intervention at 80.2.

**Nature of Setting and QI Intervention**

This QI project was conducted at an IHS adult primary care clinic that provides services for an urban AI/NA population. The clinic is funded by the federal government and the equipment and space needed for CDFEs is readily available. Relevant to this study are the physical resources, organizational culture and past history of change efforts. Physical resources include elements as broad as the clinic setting with examination rooms, tools necessary for the CDFE, infrastructure such as the electronic health record, and the staffing comprised of appropriately and adequately trained individuals.
The administration of Phoenix Indian Medical Center has been striving to implement changes reflective of an organizational culture which values patient centered care that embodies evidence based care. The recent changes at Phoenix Indian Medical Center include the work to transition to a Patient Centered Medical Home. The administration at Phoenix Indian Medical Center has expanded over the past few years to include leadership with a focus supporting evidence based, data driven improvement in the health care delivery system at the facility. Employees are encouraged to participate in PDSA projects, which are intended to streamline patient care. The study targeted four providers and nursing staff, who are IHS employees who each work 40 hours per week in 10 hour shifts. Each provider is paired with the same member of the nursing staff on most days, allowing the pair to better coordinate care efforts as they have the opportunity to learn the preferences and routines of one another. The pairing of a primary care provider with a nurse/certified medical assistant facilitates communication and collaborative planning for patient visits. This method of pairing facilitated the ability of the nurse/certified medical assistant to prepare the patient and the primary care provider for the annual CDFE.

The data specialist provided the measurement data. Collecting the data was not a new process as the data specialist is responsible for querying the database to produce productivity reports, including specific examinations performed by each provider. The data provided, while reported for each of the specific providers, reflected the number of CDFEs performed each week on patients empaneled to each specific provider. As an example, a provider can be absent from the clinic but patients assigned to that provider might be seen by another provider in the clinic. Based on this method of reporting, if the provider seeing the patient, on that day performed a foot exam, the data provided would give credit for the foot exam to the absent provider. Conversely, with the patient seeing a different provider than the provider to whom he/she is
empanelled, if the foot exam were omitted, it would also reflect that the exam was due but not conducted. While the data specialist was most helpful and accessible, both a member of the medical staff and the IRB co-chairperson were also supportive by de-identifying the data and making them accessible for this project. The chief of operations and the Ambulatory Care Acting director both advocated for this study.

**Changes in Process of Care and Patient Outcomes Associated with the Intervention**

Based on the data analysis the implementation of the intervention components were not successful. As previously discussed, this QI project was developed to address the low performance rate of CDFEs at Primary Care Medicine Clinic. In 2012, the composite performance rate of CDFEs at Primary Care Medicine Center was 68%. Individuals with diabetes that receive annual CDFEs are shown to have a significantly decreased rate of LEAs when compared to individuals with diabetes who do not receive CDFEs (Boulton et al., 2008). Therefore, it could be anticipated that facilitating the performance of CDFEs should increase the performance rates of CDFEs, contributing to a decrease in LEAs.

Pre-visit planning included the identification of all individuals with diabetes mellitus due for CDFEs. On the day of the visit, the nursing staff communicated with the primary care provider that the patient’s CDFE was due. While no data were collected on the performance of these recommended changes, the providers and nurses did not mention any discrepancies. All rooms were to be properly stocked for CDFEs by the nurse/certified medical assistant. It was observed on occasion that “chux” pads were not stocked in the exam rooms. Each morning the monofilament was placed on the exam room countertop by the nurse/certified medical assistant, specifically where each provider could easily access the monofilament. This process recommendation was faithfully carried out. This study was not designed to assess adherence to
recommended performance changes by nursing staff. It was recommended that as patients were brought back to the exam room by the nurse/CMA, that they be informed that it was time for their yearly CDFE. Once situated in the exam room, and the vital signs were checked, and the purpose of the visit was discussed, the patients were to be asked to remove their shoes and socks in preparation for the provider to perform the CDFE. A “chux” pad was to be placed on the floor to protect the feet. Once the provider entered the room, it was up to the provider to decide if time allowed for the CDFE based on prioritization of the needs of the patient at that visit. An inconsistency in having patients remove shoes and socks and in placing a protective barrier (“chux pad”) on the floor was observed. Since the QI was not designed to measure adherence to improvement recommendation by the nursing staff, no data exist to show the frequency, regularity, or distribution of the occurrence of these omissions. Diabetic foot care educational hand-outs were inconsistently distributed to patients.

While the changes in the processes in care were expected to facilitate the performance of CDFEs, not all recommendations were consistently utilized. This inconsistency most likely contributed to the continued trend of low performance rates of CDFEs.

Many lessons were learned with this QI project. Importantly future exploration for the barriers to conducting the processes recommended by the PDSA team is needed. While the proposed changes were systematically identified by frontline staff, the recommendations to facilitate the CDFE were not consistently performed. This should be approached in a non-judgmental, open-minded fashion. The goal is to identify barriers, not point fingers.

A lesson learned from this QI project was that successful change should be focused and relatively simple to carry out. This was evidenced by the difficulty in finding a method to consistently distribute diabetic foot care handouts to each patient receiving a CDFE. In retrospect
the change of assuring that each patient received an educational handout was adding an additional target of change to the intervention. Lesson learned equated to “Keep it simple.”

Another lesson learned was the re-enforcement of importance of provider feedback. The investigator did not explore for methods that could allow each individual provider to know his/her performance rate of CDFEs while keeping the information de-identified to other providers and the author.

In summary the intervention was designed to facilitate the increase in performance rates and to ameliorate several potential reasons cited for low performance rates. Those reasons included time limitations and lack of identification of those individuals due for an annual CDFE. To address time limitation, several components were designed to streamline the process of increasing the performance rate of CDFEs. In addition to identifying and communicating which patients are due for the annual CDFEs to each provider, the components of the intervention might have played a role in reminding providers of the importance of the exam and the relatively small amount of time required to perform this examination. Having the patient prepared for the foot examination, also addressed a human factor. The provider is cued to the expectation from the patient that a CDFE be performed. No additional healthcare disparities were observed and the improvement intervention did not add to the cost of care. No adverse experiences were voiced by the primary care providers. One primary care provider did comment that time did not allow the performance of the CDFE at the visit, however she was not uncomfortable giving an explanation to the patient as to why she was not performing the CDFE. A program designed to build on the current knowledge gained regarding the factors related to the performance of CDFEs is recommended to improve the performance rates of CDFEs. A method which improves the
performance rates of CDFEs should contain a process imbedded to assure that modifications necessary to maintain a safe and effective method of facilitating CDFEs is recommended.

The benefits of the QI initiative included some process changes, which should yield an increase in early identification of foot changes and a decrease in diabetic foot complications over time. While some of these process changes were not consistently carried out, this produces more insight to inform further QI interventions that should eventually increase the performance rates of CDFEs. Another benefit of the intervention to increase the performance rate of CDFEs was the added opportunity to educate patients on diabetic foot care which, if performed, should also translate to a decrease in diabetes-related foot complications. Improving the process of care delivery resulted in practicing evidence based medicine consistent with currently recommended guidelines. No harm was identified with this intervention. The lack of increase in performance results was an unexpected result. Problems/failures identified were inconsistent distribution of diabetic foot care educational hand-outs and inconsistent performance of process changes introduced with the intent to facilitate the performance rate of CDFEs. When comparing pre-intervention CDFE performance rates with the post-intervention performance rate, there appears to be no improvement in the performance rate of CDFEs. This conclusion is drawn from the use of the run chart comparing each provider with the pre-intervention median performance rate. This is also concluded by the decrease in the median post-intervention performance rate. No missing data were identified, however the time frame for the study was less than ideal as one provider was on leave for two weeks during the study. (A post-intervention median performance rate was calculated omitting the two data points reflecting the absence of the provider. The median rate was unchanged.) This situation caused an inability to collect performance data on that provider for two weeks of a four week study. A four-week space with all four primary care
providers present was not achievable for the implementation of this Quality Improvement intervention due to the rolling nature of provider schedules. Despite the provider’s absence during the first two weeks of the QI intervention, his/her performance rate improved from pre-intervention rates. The sudden rate increase after entering the study late might be attributed to the finding that the CMA paired with that provider had been actively participating in the QI intervention from the start of implementation of change. As previously stated, further exploration is needed to identify the additional barriers not addressed by this QI intervention.
CHAPTER FOUR: DISCUSSION

Summary

Implementation of the intervention components was met with some successes and some areas were identified for further exploration. The composition of the PDSA team reflected a multidisciplinary group of individuals who were committed to improving patient healthcare outcomes through the improvement of health care delivery processes. This commitment and buy-in by the providers and staff produced a quality improvement intervention that while intuitively effective, showed further exploration of barriers is needed to achieve the desired increased performance rate of CDFEs. The recruitment process was successful and facilitated by the aforementioned commitment of staff to improving patient healthcare outcomes. Each PDSA team meeting was productive. The team worked together to brainstorm, all equally participating in completing the fishbone diagram. The input of each team member reflected the mutual respect and democratic atmosphere necessary for a successful PDSA team outcome. The plan to identify patients needing CDFEs and to communicate that information to the providers was effective when performed. Rooms were almost always stocked with needed supplies and the monofilament was almost always in view of the provider. The majority of patients due for CDFEs were asked to remove shoes and socks. The reason for not preparing the patient for exam was often unclear, appearing to be a case of adjusting to a new process. This occurrence was not associated with a specific provider, nurse, or CMA, but appeared to be a random occurrence. Further inferences cannot be drawn because the study was not designed to measure this occurrence. This is an area for further exploration.

While the selection of a diabetic foot care educational handout was a step in the right direction, inconsistency in distributing the handouts was encountered. This topic will be
addressed in the future at Primary Care Medicine Clinic, as this is also a standard of care defined by IHS.

Phoenix Indian Medical Center has experienced and supported many organizational changes over the past few years. Looking at the recent history of successful change interventions, the Primary Care Medicine Clinic is currently undergoing changes to transform to a Patient Centered Medical Home. This evolution has not been an easy process. The implementation of this QI project went smoothly considering the historical background where some changes have not been well accepted by staff, adversely affecting implementation of the change process. The unsuccessful attempts of previous organizational changes may be explained through the tenet of evidence based research, which stresses the importance of buy-in by all stakeholders. The success of the team process used in developing and implementing changes for this QI project can be attributed to a multidisciplinary approach with transparency of the processes and expectations generated by the PDSA team.

The particular strength of this study was the teamwork that was associated with developing process changes based on identified barriers to CDFE performance. Lending to the effectiveness of the teamwork was the agreement on a need to improve and facilitate the performance rate of CDFEs.

**Relation to Other Evidence**

Other studies have shown the superior outcomes of quality improvement interventions, which are developed and conducted with a multidisciplinary approach, involving the healthcare staff engaged in the process which is in need of improvement and the regular provision of feedback to the involved participants (O’Brien et al., 2003; Peek, Cargill, & Huang, 2007). Interestingly, a search of the literature did not reveal any APRN led interventions dedicated to
the increase of comprehensive diabetic foot exams. The literature regarding quality improvement initiatives targeted at increasing the performance rate of CDFEs showed the importance of utilization of a multidisciplinary team both for planning and execution of the initiative. Physicians led most of the initiatives. (Fitzgerald, Mills, Joseph, & Armstrong, 2009; Hinkes, 2009; Hughes, 2008; Shojania, Ranji, & McDonald, 2006).

One study (Prothe, 2014), conducted by a DNP targeted compliance rates to guidelines for diabetes foot care with the goal of improving the diagnosis and prevention of diabetic peripheral neuropathy, diabetic foot ulcers, and lower extremity amputations. This study focused on nurse practitioners and included an educational component, pre/post testing of knowledge and a blinded comparison of pre/post educational intervention performance rates of CDFEs. The discussion did not address any changes in diagnosis or delay in diagnosis of diabetic neuropathy, diabetic foot ulcers or lower extremity amputations. The pre-educational intervention performance rate of guideline driven CDFEs in this study group was higher than that rate reported in similar studies. The post education rate did not increase from baseline in this intervention.

A study to assess the adherence to diabetes guidelines of care among primary care physicians was conducted by Kirkman, Williams, Caffrey, and Marrero (2002). Baseline data showing pre-intervention adherence to recommended guidelines for diabetes care were collected. Next the authors facilitated a group consensus for a diabetes care protocol. Improvements were reported in foot exams, referrals for eye exams, urine protein screening, lipid measurements, self-blood glucose monitoring, and blood pressure measurements during the first year. By the second year, all but blood pressure measurements and foot exams remained significantly elevated from baseline data. Kirkman et al. (2002) concluded that demanding primary care
practices lacking the ability to track performance and provide feedback regarding performance would have difficulty in attaining and maintaining sustained improvements in care delivery.

The efficacy of the use of reminders, feedback to providers, and continuing medical education targeted at effective care guidelines among resident physicians was examined in a study conducted by O’Brien et al. (2003). As previously discussed, this provider-based intervention included two lectures and an announcement that a Quality Assurance chart audit would soon be performed. Similar to the DNP project at Phoenix Indian Medical Center, the staff had patients remove shoes and socks once the patient was in the examination room. This intervention was associated with an increase in performance of CDFEs at three and six months. As with most successful interventions to change provider performance, data collection measuring the change was shared with the targeted providers.

A meta-analysis performed by Peek, Cargill, and Huang (2007) examined intervention studies for improvement of health care delivery among minority populations with diabetes. A total of 573 studies were reviewed with 43 studies meeting the inclusion criteria. The methods of the different studies included randomized controlled trials (n=22), controlled trials (n=7), pre/post studies (13), and one observational study. This systematic review attempted to analyze the efficacy of provider based QI programs and disease management in ethnic or minority populations, with primary outcome measures of all studies being post intervention HbA1c, blood pressure and cholesterol. As previously discussed, various interventions were studied, however, sustained improvements were observed with the use of practice guidelines and CME. Provider feedback and reminders were also shown to be associated with improved quality of care. This research again showed the power of encouraging the use of evidence based, guideline driven care, continuing medical education, and performance feedback. The findings of this meta-
analysis, similar to the DNP project conducted at Phoenix Indian Medical Center, support the strength of utilizing evidence based guidelines to improve the quality of health care delivery.

In summary, a review of the literature regarding practice improvement related to quality of healthcare outcomes for adults diagnosed with T2DM supports provider based approaches that are evidence based and provide performance feedback. Models that are multidisciplinary, utilize information technology, and reminder prompts have been shown to significantly increase the performance rate of CDFEs (Shojania, Ranji, & McDonald, 2006). Perhaps the findings of this DNP project would be similar to other studies highlighting the success of provider-based approaches, which are multidisciplinary, aligned with a reliable reminder system, and driven by evidence based guidelines, had it provided feedback to providers and data been collected for a longer period. No NP-led interventions to increase the performance rate of CDFEs by providers in an IHS clinic with AI/NA patients were identified in the published literature.

**Limitations**

Confounding, bias, or imprecision in design, are potential sources of limitation. It is important to note that this study was conducted during a time frame when one of the providers (one of the targets of the study) was on leave. As previously mentioned, this scenario is difficult to avoid in a practice with multiple providers.

The inconsistencies with adherence to process change recommendations are recognized as a limitation to the study. Without consistent adherence to recommendations proposed to facilitate the performance of the CDFE, no increase in CDFE would be expected. Future efforts should consider a closer look at how to best measure if those efforts to facilitate CDFE are consistent. In the context of this study the measurement would include the staff and RNs who
contribute to the patient education and preparation for the CDFE, as well as meeting with support staff to identify barriers to consistent preparation of the exam room.

Another aspect of the design, which could not be adjusted, was the method of data collection. In the particular EHR data program, performance rates of CDFEs can only be reported in terms of the designated primary care provider. While the provider team is an accurate reflection of the composite performance of CDFEs, it is not an accurate measurement of individual provider performance. A more precise measurement would measure the exams performed by each provider regardless of whether the provider was the primary care provider. Every attempt is made to appoint the patient with the respective primary care provider, especially for chronic care follow-up visits, however it is not always possible. It is likely that the number of patients seen by someone other than the primary care provider is similar among all four providers.

Organizational factors that could affect the outcomes of this intervention include the setting, which is a government facility where providers are paid a salary which is not directly related to the number of patients seen. The providers have little control over the number of patients examined each day. This can have a much different effect on ability, and sometimes motivation to accommodate certain practice changes. However, the resources needed to perform the CDFE are readily available in this setting. The utilization of services, specifically the attendance to regularly scheduled appointments, or lack there-of, could vary between settings due to socio-economic factors. Many individuals cared for at the Primary Care Medicine Clinic, have a variety of factors which affect whether they schedule or attend scheduled follow-up visits. Another factor, which could affect annual completion of CDFEs is the ability of patients to maintain communication with the facility. The inability to get through on the phone lines,
frequently changing addresses, and homelessness impacts appointment scheduling and attendance. The issue of missed medical appointments deserves deeper exploration, however the performance rate of CDFEs in this study was limited to those who completed their annual visit.

Organizational culture is important in considering the success of a quality improvement intervention (Grol, et al., 2013). In this situation formal leadership, on all levels supported this initiative. Initially, the structure of informal leadership did not fully support the project to increase performance rate of CDFEs. With teamwork and education, those informal leaders seemed to support the quality improvement efforts.

As with any quality improvement effort, to truly maintain quality in care, processes have to be in place to monitor and facilitate performance. To address staffing changes over time, an orientation program would need to include the processes for facilitating the performance of CDFEs. Change is a constant and it is likely this intervention will need adjustments over time for sustainability. As previously discussed, the PI will continue to work to achieve improved performance rates of CDFEs, and work with administration to sustain the improvements.

The limitations of the study regarding one provider being on scheduled leave, might have affected the adoption of the change process by other team members or other teams in the clinic. The other limitation was the duration of the study. Due to time constraints related to this intervention, a longer study would have shown if and how the improvement in performance rates continued.

**Interpretation**

Interpretation of the findings of this study is that further intervention with this group of providers and staff is necessary to significantly increase performance rates of CDFEs. The median performance rate of the composite performance scores was lower post implementation
than the median performance rate pre-intervention. Further assessment is needed to fill the gap in knowledge related to barriers to performance and performance rates of CDFEs among Coral Team providers and staff. The outcome of the quality improvement intervention clearly showed a difference among providers regarding the percentage increase in the rate of CDFEs performed.

The limitation of de-identifying provider data could be addressed with a similar QI intervention in which the data specialist provides each provider with their specific identifier code so that the provider is blinded to others, but provided feedback regarding his/her own performance. In this manner, each provider would remain de-identified to one another and the researcher. This process should be considered by those who are conducting QI interventions as the feedback would inform providers of their individual performance.

A future QI study including the consumer would enrich the work of the PDSA team. The input of the consumer provides a view from experiences not available to most clinic staff. A good source for finding consumers interested in participating in the QI intervention is the Clinic’s community advisory board. These participants have leadership characteristics, knowledge of some clinical processes, and experiential knowledge of areas where delays may be occurring in the processes, which precede the CDFE. A consumer can bring ideas forth that may not be thought of by the clinical staff.

A future study examining the impact of offering CDFEs after hours or on the weekend would be fertile ground for attempts to improve healthcare delivery to the American Indian/Native Alaskan population. When coupled with the other recommended standards of preventive care, this intervention could allow those patients with work schedules that serve as barriers to clinic attendance, to improved access to care.
The only cost of this intervention was the donation of lunchtime by the PDSA team members. The resources necessary for the performance of CDFEs were already available in the clinic. While the intervention involved a re-arrangement in the order of processes used to prepare the patient for a foot examination, this was neither measured nor seen as a cost. Most importantly, evidence repeatedly shows the decrease in diabetic lower extremity foot complications equates to savings in both dollars and quality of life (ADA, 2013; Amputee Coalition Organization, 2012; Arizona Department of Health Services, 2011; Bild et al., 1989; Boulton et al., 2005; Clayton & Elasy, 2009; Crosby & Miller, 2005; del Godoy, Braile, Buzzato, Longe, & Fontesm, 2010; NIDDK, 2011; Rui, Zhang, Barker, Chowdbury, & Zhang, 2010). Any change in the number of referrals to the podiatry clinic was not measured and would be a good indicator to examine in the future.

Conclusions

While this quality improvement intervention did not result in significant improvement of CDFEs performance rates, it did provide a starting template for providers and staff to improve the process in the future. The de-identification of study targets with resulting lack of provider-feedback likely contributed to the lack of increase in CDFE performance rates. However, additional data points or extending the post-intervention assessment by an additional six weeks may have resulted in a different provider trend. The study targets found the PDSA process useful for consensus of system-level problems that created barriers to achieving standards of practice, identification of contributing factors, and resolution of those problems. This is only a beginning at Primary Care Medicine Clinic for improvement in performance rate of CDFEs. The next step will utilize the PDSA framework in examining how best to consistently implement the processes designed to facilitate the performance of CDFEs. If this proves successful, that intervention will
be spread to the second of four clinical pods at Primary Care Medicine Clinic. As the program moves forward, if it continues to be successful and is rolled out to the entirety of Primary Care Medicine Clinic, the development of a process for sustaining improvement is essential. The program to sustain improvement has a dual focus. The improvement must be maintained, however the systems involved in the QI intervention must remain vital and adjusted to reflect changes that will occur in the system (Agin, 2011). Some of these changes specific to Phoenix Indian Medical Center can include staff turnover, improvements in technology, potential change in staffing arrangements, change in hour of operations, changes in the science behind CDFEs, plus many other unforeseen changes over time.

Other suggestions for improvements to this study have been discussed. A major improvement suggested for improving the strength of this study is the measurement of data and repeated PDSA cycles over a longer period of time. The choice of any quality improvement intervention must consider the context in which the intervention is being considered. Since many IHS facilities are located in rural areas, rather than urban areas where this study was conducted, it is important to consider replicating this study in a rural setting, allowing for the changes necessary to have the intervention fit the setting.

**Significance to Nursing**

This study has significance to nursing as it will add to the body of research literature addressing the effectiveness of nurses, including certified diabetes educators, as well-informed, essential members of multidisciplinary teams with the goal of introducing and sustaining quality improvement initiatives. This study highlights the role of the doctorally prepared advanced practice nurse (DNP) in designing and facilitating efforts to implement and evaluate a practice change project that increases the rate of CDFE for the AI/NA population. Improved healthcare
delivery is critical to the national effort to address and improve healthcare disparities in minority populations. This QI project provides a design, which can be replicated at Primary Care Medicine Clinics for other quality improvement initiatives targeting improved healthcare outcomes and can also be considered for adoption by other IHS settings. Also contributing to the body of knowledge and profession of nursing is the exemplification of the DNP as an effective leader in transforming the healthcare delivery system. This study lends credibility and support for the strength of the nursing profession in refusing to accept the status quo of healthcare delivery. Nurses engaged in systematic analysis of the healthcare system are developing initiatives to build a culture of safety and quality and improving healthcare outcomes (Hughes, 2008). This study, while not producing the desired increase in performance of CDFEs, does add to the body of research related to quality improvement initiatives in healthcare. The nursing profession has long encouraged a practice, which is guided by an analytical and probing stance. This stance aids in continual focus on providing care, which is targeted at improving healthcare outcomes through transformation of the healthcare delivery system. Finally, this QI project is an example of the outcome producible through the synthesis and utilization of knowledge gained from the DNP Essentials for Education.
APPENDIX A:

LETTER OF APPROVAL FROM PHOENIX INDIAN MEDICAL CENTER
24 February 2014

Cynthia Claus, MD
Chair, Phoenix Area IRB
Two Renaissance Square
40 North Central Avenue, Suite 600
Phoenix, AZ 85004-4450

Dear Dr. Claus:

The Administration of the Phoenix Service Unit has reviewed the Quality Improvement project proposal “Multidisciplinary Quality Improvement Initiative to Increase Performance Rate of Comprehensive Diabetic Foot Examinations in Native Alaskans/American Indians.”

This proposal has been reviewed for:
1. The proposed project concerns an issue in a field consistent with the mission and priorities of the Phoenix Indian Medical Center.
2. The project officer/investigator has given assurance that IRB approval will be sought and that appropriate research and privacy practices will be followed.
3. Dr. Stephanie Markman, Center of Excellence Department Chief (acting) will serve as liaison between the project officer/investigator and the CEO.

This project has the endorsement of the Phoenix Service Unit Administration to seek approval for research by the Phoenix Area Institutional Review Board. All research must have both Service Unit Endorsement and Phoenix Area IRB approval prior to initiation or publication. While it is customary for the IRB to send copies of approvals to the Phoenix Service Unit, it is the duty of the researcher to assure that the Service Unit has received notification of approval before commencing research or publication.

CAPT Michael Weahkee
Chief Executive Officer
Phoenix Indian Medical Center

Cc. Research File
APPENDIX B:

STUDY PROTOCOL FOR INDIAN HEALTH SERVICES INTERNAL REVIEW BOARD
Multidisciplinary Approach to Quality Improvement Intervention to Increase Performance Rate of Comprehensive Diabetic Foot Examinations in Native Alaskans/American Indians

Protocol

Project Summary
This proposed QI program is designed for the purpose of improving the rate of CDFEs performed on American Indian/Native Alaskan (AI/NA) patients receiving care at PCMC of PIMC. The baseline rate of performance for CDFEs performed in 2012 was 68.5%, falling below the target proposed by the Chronic Care Model of 90%. Performance data will be available from the data specialists at PIMC and will be reported without any personal identifying information. The CDFE performance rate of four primary care providers from PCMC at PIMC will be reviewed for each of the four weeks prior to implementation of the practice improvement. After the intervention is implemented, the performance rate of CDFEs by the same providers will be reported for each of the next four weeks. A PDSA team member will be appointed to tally and report the number of CDFEs due each week, based on pre-planning, adjusting for any planned visits in which the patient did not keep the appointment. With this method of data collection, the PI is blinded to any patient personal identifying information. Knowing the number of needed CDFEs during this four week time frame, helps to provide a separate source of information related to CDFEs. Comparison of pre- and post-practice improvement performance rates will also be reported based on group (composite rate for all four providers). To tailor this practice improvement to best fit the providers, clinical staff, and patients from PCMC at PIMC, the PDSA framework will be utilized. The PDSA team members will identify barriers or potential facilitators to the performance of CDFEs as experienced at PCMC. The PI will lead the PDSA meetings and the practice improvement will be planned, conducted, outcomes studied and analyzed. This democratic method of quality improvement based on small tests of change will allow for needed adjustments, shaping the improvement to the setting and needs of the patient population.

Name and Address of Sponsor/Funded: N/A
Name and Address of Principal Investigator (PI):
Janet S. Bennett, MSN, FNP-C, Doctoral Candidate at University of Arizona
2421 W. Hearn Road, Phoenix, AZ 85023
Phone: 602-803-7234; email: janet.bennett@ihs.gov or jsbennet@email.arizona.edu

Site:
Phoenix Indian Medical Center, Primary Care Medicine Clinic, Coral Team
4212 North 16th Street, Phoenix, AZ 85023

University Association:
University of Arizona

Advisor Contact Information:
Marylyn Morris McEwen, PhD, PHCNS-BC, FAAN, Associate Professor
520-626-6926; email: marylynm@email.arizona.edu

Rationale and Background Information:
AI/NA (AI/NA) have the highest age-adjusted prevalence of diabetes (16.1%) among all U.S. racial and ethnic groups (ADA, http://www.diabetes.org/in-my-community/programs/native-american-programs/?keymatch=american-indians ) and a 3-4 fold higher rate of lower extremity amputations (LEAs) than the general U.S. population (National Limb Loss Information, 2012). In one study American Indians with diabetes suffered a morbidity
rate greater than 50% of the rate found in insured non-AI U.S. adults (O’Connell, Yi, Wilson, Manson, & Acton, 2010). In 2005 American Indians experienced a relative risk ratio for non-traumatic lower extremity amputation (NLEA) when compared to the average U.S. adult relative risk of 14.4% (O’Connell et al., 2010).

Some sources cite that up to 85% of all lower extremity amputations in individuals with diabetes can be prevented (Bild et al., 1989; NIDDK, 2011). A mortality rate post amputation has been cited to be at 40% (Hinkes, 2009; Robins et al., 2009). More striking is the five-year mortality rate post amputation that has been cited to be anywhere between 43-74% (Hinkes, 2009; Robins et al., 2009). Standards of diabetes care (American Diabetes Association, 2012; Boulton et al., 2008; Indian Health Service, 2009) routinely include an annual CDFE. The comprehensive foot examinations are critical to the early detection of diabetic ulcers or finding of risk factors that predispose patients to the development of foot ulcers which often lead to NLEAs. The average rate of CDFEs for patients seen in 2011 at the PCMC at PIMC who received care was 68.5%. Various studies show a cost savings in practice improvements implementing increased performance of efficient diabetic foot exams. Studies also highlight the concept that costs of lower extremity amputations cannot be captured by dollars alone.

A multidisciplinary intervention successful in improving the rate of comprehensive diabetic foot exams should improve healthcare process and therefore, outcomes.

**Study Goals and Objectives**

The proposed practice improvement is an increase in the performance rates of CDFEs conducted by providers in the Primary Care Medical Clinic of Phoenix Indian Medical Center – with the target population of AI/NA. The purpose of this practice inquiry is to develop and implement a quality improvement project at Phoenix Indian Medical Center, Primary Care Medical Clinic, division of IHS.

The project has three specific aims:

1. Develop and implement a quality improvement program as a PDSA with providers and staff at an urban IHS Clinic.
2. Assess if involvement of providers and clinical staff in the PDSA, in particular identification of CDFE barriers to CDFEs and resolution of low CDFE rates (68%), leads to an increase (10%) in the rate of performance of CDFEs within two months post-intervention.
3. Develop a quality improvement process that the clinic staff may replicate for future quality improvement initiatives.

**Study Design**

Methods to improve the performance rates of CDFE at PIMC, PCMC will be developed from evidence based research, and input from providers and clinical staff from the focus groups, and the PDSA team.

The research design is a pre/post study, involving quantitative data collection regarding the performance rates of CDFEs. Descriptive statistics will compare baseline data regarding CDFE. A t-test will compare the means of the performance rates pre and post intervention.

The setting for this Practice Inquiry is an ambulatory care outpatient clinic in Phoenix, Arizona. The clinic is associated with Phoenix Indian Medical Center, an entity of the Indian Health Services (IHS). Primary Care Medical Clinic (PCMC) is an ambulatory care center which houses providers and staff providing health care for all federally recognized AI/NA tribes. The
study participants will include physicians, RNs, an LPN, Certified Medical Assistants (CMA), and Medical Support Assistants (MSAs).

The target population is involved in the health care delivery system in an ambulatory care clinic. IHS standard of care specific to the provision of CDFE to patients seen at PIMC, PCMC will be followed. The duration of the study should be eight weeks.

Methods

From the coral pod team members, a PDSA Team will be formed. The team should include representation from provider staff, one nurse, one certified medical assistant and one medical staff assistant. Recruitment flyers (Appendix B) will be posted in the work areas of the coral team for the purpose of recruiting volunteers for the PDSA team. This will comprise a group of five PDSA team members, allowing input from all aspects of direct care delivery.

The PDSA Team will collaboratively plan, conduct, and analyze a method to improve the performance rate of CDFEs. The Team will be reviewing data provided by the data specialist based on the performance rate of CDFEs conducted by the five primary care providers during the defined time spans. Based on the analysis of the data collected, the PDSA Team will make a recommendation regarding future utilization of the quality improvement method. The steps composing this PDSA framework are described below. There are four phases of the Quality Improvement project: Plan, Do, Study, and Act:

P: During the planning phase, all team members will contribute to the identification and prioritization of issues posing barriers to the performance of CDFEs. The objective of the initiative has been defined as improving the performance rate of CDFEs at PCMC. A cause and effect diagram (also referred to as a fishbone diagram) will be utilized to facilitate collection and organization of contributing factors to the low performance rate of CDFEs. The fishbone diagram provides an organizational tool to map the processes necessary for a patient to receive the CDFE. The diagram will aid in summarizing the input from the PDSA Team members. This approach has been used to delineate the steps and persons involved in the process being studied. These findings facilitate the PDSA Team in shaping an approach to improve the performance rate of CDFEs. Using the information gathered from the PDSA Team will generate a clear hypothesis suggesting why the CDFE is not being performed as recommended by IHS guidelines. From the identified barriers, a method to facilitate the examinations will be developed. It is this method chosen by the PDSA Team that is predicted to increase the performance rate of CDFEs. Based on the knowledge yielded regarding the processes, barriers, and facilitators of the CDFE, the chosen intervention should explicitly define the roles of staff members in carrying out the proposed intervention. Clear goals and objectives are a prerequisite for developing performance measurements. The preparation during this phase augments the learning that will take place in the Study Phase.

D: During the DO phase, the team members implement the change predicted to increase the performance of CDFEs. While the intervention is being conducted, it is important that a team member is assigned to monitor for any deviation from the proposed change. The PI will monitor for daily compliance with the components of the proposed change. As the proposed intervention is implemented, the members of the PDSA Team will each make and document observations regarding the process and effect of the proposed change. Unexpected occurrences are important to document. These observations will be used
during the study phase to provide depth to the understanding of the effect of the intervention on performance rates of CDFEs.

S: During the STUDY phase, the team members review and discuss the effect of the intervention on the rate of performance of CDFEs. The method for collecting information for this review is planned during the planning phase. Testing methods should be based on a clear definition of what is being tested, including who, what and how the intervention will be conducted. Specific to this practice inquiry, summary statistics and the t-test will be utilized. To better illustrate the statistics reflecting changes over time a run chart is planned to be used. It is important that the PDSA team agree on the statistical methods and means of depicting them. Other useful statistical tests would be indicated if spread of the intervention occurs. These tests could include correlation analysis, regression analysis, variance component analysis, reliability analysis, and time series analysis. The utilization of each of these tests has a specific purpose and would provide useful data for determining continued appropriateness of the intervention and/or aid in determining which factors are affecting a certain trend in the intervention (Langley, Moen, Nolan, Nolan, Norman, & Provost, 2009). The selection of which statistical method of analysis and which diagram best reveals the findings would not be a part of this practice inquiry, but rather is suggested for future evaluation of the effectiveness of the care provided to patients with Diabetes at this facility.

A: After a period of one week post initiation of practice improvement, the PDSA team will meet to assess the need for any adjustments in the procedures implemented to increase the performance rate of CDFEs. Any needed changes will be addressed by the group and voted on by consensus. The PDSA team will review the performance rate of CDFEs and discuss any suggestions for improvement in the intervention on a weekly basis for a total of four weeks. After four weekly cycles of the PDSA, the PDSA team members should have data to determine if the intervention is: 1) ready for spread to the entire PCMC; 2) in need of further revision and study; or, 3) abandoned. Due to the time limitations of this Practice Inquiry, the mechanism of outcome measurement will only be discussed. As previously addressed, one month is not sufficient time to assess and capture any measureable change in the performance rate of CDFEs. The time intervals for data analysis (numbers reflecting performance rate of CDFEs) should be three months, six months, nine months, and one year. Measurement of study effect over the long-term would need to show improvement in healthcare outcomes. Measurements to consider could be amputation rate, rates of newly developed diabetic foot ulcers, numbers of referrals to podiatry. Impact on other systems in the organization might be measured in assessing the outcomes of the improvement. Once healthcare outcome measurements and process measures are clearly defined, a method of how the data will be collected and task assignments should be clearly designated. The Practice Inquiry will be completed when the PDSA team completes the first cycle. The PI, as an advanced practice nurse with doctoral education plans to continue facilitating this quality improvement intervention, making adjustments as identified or suggested to improve efforts. Utilizing successive PDSA cycles will allow for timely modifications as needed to maintain the quality and safety of care delivery.
Safety Considerations
All consents will be protected in a locked drawer by the PI and then stored and locked for six years at the University of Arizona, Division of Nursing Research. No identifying information from the study subjects, who are primary care providers and clinical staff, will be utilized. Participation in or choosing not to participate in the study will not result in any risk related to employment or health.

Follow up
Pre- and post-implementation data will be shared with the study participants in a typed summary and sent by email. Findings and conclusions of the PDSA team will also be included in the typed summary.

Expected Outcomes of the Study
1. Increased performance rate of CDFEs at PIMC/PCMC
2. Assess if involvement of providers and clinical staff in the PDSA, in particular identification of CDFE barriers to CDFEs and resolution of low CDFE rates (68%), leads to an increase (10%) in the rate of performance of CDFEs within two months post-intervention.
3. Develop a quality improvement process that the clinic staff may replicate for future quality improvement initiatives.

Dissemination of Results and Publication Policy
Pre and post implementation data will be shared with the study participants in a typed summary and sent by email. Findings and conclusions of the PDSA team will also be included in the typed summary.

The information generated by this study will be compiled and included in the Practice Inquiry document titled Multidisciplinary Approach to Quality Improvement Intervention to Increase the Performance of Comprehensive Diabetic Foot Examinations in Native Alaskans/American Indians. The document will be kept on file in the University of Arizona Health Sciences Library. Any further use or publication of the study can only be carried out with the consent of PIMC Administration Department and Phoenix Area IHS IRB.

Duration of the Project
The project is planned over a period of eight weeks (Appendix A). The first two weeks will include introducing the study to the coral team and the placing of the recruitment poster (for participation on the PDSA team) in areas restricted to clinical providers and staff, concluding with the selection of the PDSA team. During week three the team will develop a plan to increase the performance rate of CDFEs. During weeks three through six, the plan will be implemented the team will review weekly performance data. Also during these weeks the PDSA team will also evaluate for any needed adjustments of the intervention. The PDSA team will meet during week seven to review the data and determine if this intervention should be adopted, adapted or abandoned. Study outcomes will be reviewed and shared with providers and clinical staff.

Problems Anticipated
No anticipated problems are associated with this study. This is a quality improvement process that is consistent with the goals, mission and vision of the Phoenix Indian Medical Center. Staff is interested in improving the quality of the health care delivery system at this facility.
**Project Management**

PI has the role and responsibility of the oversight of this project. Oversight includes: leadership of the PDSA team; consulting with the data specialist in the center of excellence for data collection of pre and post intervention data; summarizing finding and sharing the findings with participants. The PI is also responsible for insuring appropriate research and privacy practices are followed.

PDSA team members will bring experience and ideas to the PDSA meetings to collaborate in forming a cohesive plan to facilitate the performance of CDFEs.

**Ethics**

Ethical considerations in this study concern beneficence, respect, and justice. Patients will be receiving standard of care practices. As the study group participants are employees of PIMC this group could be considered a vulnerable population. Employees are assured that participation or non-participation with this study will not be associated with any positive or negative actions by the employer. All identifying information will be sanitized. Data from the data specialist will be reported for provider 1, 2, 3, 4, and 5.

**Informed Consent Forms**

Providers will participate in the study on voluntary bases. A consent form will be obtained from each provider. All participants are conversant in the English language.

**Budget**

This research is not associated with financial cost. While the employees of PIMC are participating in this study, the quality improvement initiative is consistent with current goals of the clinic.

**Other support for the Project**

No funding has been provided for this project.

**Collaboration with other scientists or research institutions**

The PI will collaborate with the University of Arizona, specifically the Practice Inquiry Committee Members, with chairperson: Marylyn Morris McEwen, PhD, PHCNS-BC, FAAN, Associate Professor520-626-6926; email: marylynm@email.arizona.edu

**Curriculum Vitae of PI**

Janet S. Bennett, MSN, FNP-C 2421 W. Hearn Rd., Phoenix, AZ 85023; email jbennettfnp@gmail.com; janet.bennett@ihs.gov

- **EDUCATION**
  - 1996-1999 MSN FNP at Marshall University
  - 1988-1991 BSN Marshall University, Cum Laude
  - 1972-1974 AA in Nursing Morris Harvey College

- **CREDENTIALS**
  - Board Certified American Nurses Credentialing Center (ANCC) first taken 1999, recertified in 2009, 2014. Licensed by Arizona Board of Nursing 2006-present
  - BLS and ACLS certifications expire 9/2015

- **WORK EXPERIENCE**
  - FNP
    - 1999- Present
    - 5/2011 to current FNP at Phoenix Indian Medical Center, Primary Care Clinic
    - 10/2010 to 5/2011 Independent Contractor Nurse Practitioner at Phoenix Indian Medical Center. Worked independently in Express Care (Urgent Care) and currently in Primary Care Division
    - 2006-2010 FNP at Fort Defiance Indian Hospital, Fort Defiance AZ. Currently see all ages at main clinic also in remote clinic about 60 miles from Fort Defiance.
    - 1999-2006 In collaborative practice with James M. Bennett, MD
St. Mary’s Hospital Staff nurse. The gaps in my employment were spent at home raising our children and pursuing my education.

Registered Nurse
1974- 1999
Charleston Area Medical Center (CAMC)

AFFILIATIONS • American Nursing Association; Sigma Theta Tau (International Honorary Society of Professional Nurses) American College of Nurse Practitioners; Volunteer Preceptor for FNP students past association with Marshall School of Nursing; Current association as FNP preceptor with Georgetown University and Frontier School of Nursing; Past Adjunct Faculty Member of Marshall School of Nursing.
APPENDIX C:

TIMELINE FOR IMPLEMENTATION OF QUALITY IMPROVEMENT INTERVENTION
## MONTH 1 2014

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<td></td>
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<td>Family Practice Dept. Meeting 8-9</td>
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<td>Announce Planned PI</td>
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<td>Post Recruiting Poster for PDSA Team</td>
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<td>Select members of PDSA Team</td>
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<td>Tentative first PDSA Team Meeting 4:30pm</td>
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<td>Implement intervention Week 1</td>
<td>Continue intervention, be available for questions, guidance.</td>
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<td>PDSA Meeting # 2</td>
<td>4:30pm</td>
<td>Review data, observation, adjustments</td>
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<td>Receive data from data specialist</td>
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<td>Week 1 post Intervention</td>
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<td>Adopt, adopt or abandon</td>
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APPENDIX D:

PROCESS MAP FOR COMPREHENSIVE DIABETIC FOOT EXAM
Process Mapping for CDFE

Patient calls to schedule DM followup appointment

Medical Support Assistant schedules appointment

Patient arrives for appointment, “checks in”, waits in reception area

Nurse/CMA notified patient has “checked in”

Nurse/CMA escorts patient to exam room

Nurse/CMA obtains and records weight, bp, p, r, and temperature

Patient waits in exam room for provider to enter.

Provider enters room and provides “follow-up diabetes care and examination

After provider leaves room, the nurse/CMA returns to instruct the patient on any follow-up recommendations, visit is completed
APPENDIX E:

PROJECT FLYER
A Research Study about Improving Performance Rates of Diabetic Foot Exams

As a doctoral candidate at the University of Arizona, College of Nursing, I am interested in increasing the number of diabetic foot exams with a multidisciplinary team. This research study is for clinical staff involved in the care of patients at PRIMARY CARE MEDICINE CLINIC.

Research is always voluntary!

**Would the study be a good fit for me?**

This study might be a good fit for you if:

- Are you a member of the Coral Team at PRIMARY CARE MEDICINE CLINIC?
- Do you enjoy brainstorming to improve healthcare?
- Can participate in two thirty minute PDSA meetings?

**What would happen if I took part in the study?**

- If you decide to take part in the research study, you would:
  - Become a PDSA team member
  - Identify and review barriers that might affect the number of diabetic foot exams at PRIMARY CARE MEDICINE CLINIC
  - Design a plan to improve health care delivery at PRIMARY CARE MEDICINE CLINIC

Possible benefits if you take part in the study:

- An opportunity to work collaboratively to improve the quality of healthcare at PRIMARY CARE MEDICINE CLINIC
- Add to the body of knowledge about using multidisciplinary teams to improve diabetes care delivery

**To take part in this research study or for more information, please contact Janet Bennett, APRN at 602-803-7234**

The Principal Investigator for this study is Janet S. Bennett, APRN, University of Arizona
REFERENCES


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