IMPLEMENTATION OF ANKLE-BRACHIAL INDEX TO SCREEN FOR PERIPHERAL ARTERY DISEASE IN HIGH-RISK ASYMPTOMATIC POPULATIONS

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Implementation of Ankle-Brachial Index to Screen for Peripheral Artery Disease in High-Risk Asymptomatic Populations

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

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ABSTRACT

Peripheral Artery Disease (PAD) prevalence continues to rise with millions of individuals affected worldwide. PAD affects vasculature of the peripheries and the aorta, but it is also a critical risk factor for cardiovascular and cerebrovascular disease (Fowkes et al., 2008). Diagnosis is easily made utilizing the Ankle-Brachial Index (ABI) with indication of disease at a level of 0.9 or less or 1.4 or higher (American Heart Association, 2016). Risk factors for PAD include smoking, diabetes, hypertension, hyperlipidemia, family history, and chronic kidney disease. Smoking contributes to PAD two to three times more than cardiovascular disease (Rooke et al., 2011).

The resting ABI is the primary method for establishing a PAD diagnosis (Skelly and Cifu, 2015). The ABI is a simple, non-invasive test using equipment readily available in a primary care clinic. Education and training for primary care providers and nurses in rural clinics can provide access to this test for rural communities decreasing commute time and increasing early detection and intervention for PAD.

The purpose of this project was to increase awareness of PAD and ABI screening in a rural primary care clinic, and to increase screening of PAD utilizing the ABI test. Education was given to providers at a rural primary care clinic as well as to clinic registered nurses. Nurse education focused on PAD overview, ABI technique and calculation, and results reporting. Provider education focused on PAD overview, ABI screening guidelines, benefits of screening, barriers, and further referrals and imaging studies. ABI screening was offered to high-risk patients as part of their preventative Medicare Annual Wellness Visit (AWV).

Results of the project demonstrated increased provider knowledge and competence through education. A post-education survey resulted in a positive impression from ABI screening

citing “early identification” and “early intervention” as the predominant benefits. ABI screening results identified three out of 14 (21.4%) patients with a positive screen. All of the patients with positive results had a history of smoking affirming the significant effects of smoking in PAD.

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DEDICATION

I dedicate this dissertation to my family. Matt, your love and support has carried me through this journey. Henrik, you are the best part of my day, your smile and laugh lighten every hard day. Mom and Dad, without you none of this would have been possible. Michael and Jenna, thank you for your support, encouragement, and sibling rivalry to propel me through graduate school.

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CHAPTER 1: INTRODUCTION

Background and Significance

Peripheral artery disease (PAD) is an atherosclerotic disease affecting upper and lower extremity vasculature and the aorta (Berger & Davies, 2018). This disease process causes narrowing of the vessel and consequently reduced blood flow (American Heart Association, 2016). PAD is increasingly problematic worldwide. Prevalence continues to rise with estimates, in 2010, of 200 million people affected throughout the world (Olin, White, Armstrong, Kadian-Dodov, & Hiatt, 2016). In the United States, estimates of prevalence for high-risk populations are upwards to 30% with rates continuing to be higher in African American and Hispanic populations (Olin et al., 2016). Peripheral artery disease encompasses any vasculature other than cardiac or cerebral vasculature. There are multiple causes of PAD, but the most common cause is atherosclerosis (Kullo & Rooke, 2016). Atherosclerosis is the process of plaque building up in the artery causing stenosis. Plaque can build up anywhere in the artery but most commonly accumulates in areas of high turbulence, such as bifurcations (National Heart, Lung, and Blood Institute, n.d.). Stenosis in the artery reduces blood flow resulting in muscle ischemia. Depending on severity of disease, the ischemia can result in muscle cramps and pain to the lower extremity. Risk factors for PAD are similar to those for cerebrovascular and cardiovascular disease including diabetes mellitus, smoking, hypertension, hyperlipidemia, family history, and chronic kidney disease. Smoking and diabetes remain the biggest influence on poor outcomes and mortality. Smoking is especially harmful contributing to PAD two to three times more than cardiovascular disease (Rooke et al., 2011).

Diagnosing PAD has proven difficult as only about 10% of individuals diagnosed present with classic symptoms including leg pain with activity and relief with rest (Alahdab et al., 2015).

There are three categories of PAD presentations including classic, atypical, and asymptomatic. Asymptomatic presentation accounts for about 50% of all cases (Olin et al., 2016). Classic presentation is considered leg pain with activity and relief with rest. Current diagnosis is reliant on symptomatic presentation; however, guidelines have changed to include screening for asymptomatic high-risk populations. The Ankle-Brachial Index remains the primary screen to diagnose PAD (Skelly & Cifu, 2015). According to the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) it is reasonable to screen for PAD using Ankle-Brachial Index (ABI) for anyone 65 and older (Rooke et al., 2011). The Ankle-Brachial Index is a test used to diagnose PAD by measuring systolic pressure at the brachial artery and ankle arteries, then dividing the highest ankle pressure by the brachial pressure. The resulting ratio if <0.9 or >1.4 is indicative of PAD. Age >65 was updated in 2011 based on results from the German Epidemiologic Trial which found 21% of people 65 or older demonstrated asymptomatic or symptomatic PAD (Rooke et al., 2011).

ABI has demonstrated to be the most accurate screening tool for making a diagnosis compared with history taking, questionnaires, or palpation of peripheral pulses (Ghannam, Rodriguez, Ehrmann, & Grossman, 2012). The ABI is a relatively simple measurement that should take roughly 15 minutes. The process involves dividing the highest systolic ankle pressure by the systolic brachial pressure. Prior to taking the pressure, pulses (brachial, dorsalis pedis or posterior tibial) should be found with a handheld doppler. For the ankle pressure, the dorsalis pedis (DP) or posterior tibial (PT) pulses can be used. Pressures should be measured using both pulses and the higher pressure of the two should be used. Similarly, bilateral brachial pressure should be measured, and the higher of the two should be used. Ideally, the patient should be laying supine for 10 minutes in a comfortable room prior to measuring pressures.

Diagnosis for PAD is an ABI of less than 0.9. A measurement greater than 1.4 is considered non-compressible vasculature (Stanford Medicine, n.d.).

Barriers to ABI screening for PAD include lack of reimbursement, time constraints, and availability of resources needed to complete the measurement. Many primary providers are unaware of guidelines relating to screening and diagnosis of PAD (Haigh, Bingley, Golledge, & Walker, 2013). In a study from Haigh et al. (2013) involving 287 general practitioners (GPs), only 5% of general practitioners were aware of guidelines concerning diagnosis of PAD and only 6% were aware of screening guidelines. In the same study, most GPs (65%) cited time constraints as the largest barrier to screening for PAD.

Another barrier to screening for PAD is lack of reimbursement. Currently, the ABI test is not reimbursed for asymptomatic patients (Itoga et al., 2018). In an analysis conducted by Itoga et al. (2018), cost-effectiveness of ABI screening was analyzed for asymptomatic patients. The research group found that cost-effectiveness varies greatly depending on population screened (Itoga et al., 2018). High-risk groups, including individuals who smoke and those with type II diabetes, showed the greatest benefit of screening, with a favorable incremental-cost effectiveness ratio (ICER) to quality adjusted life years (QALY) (Itoga et al., 2018).

Statement of Purpose

Prevalence of peripheral artery disease is increasing in the United States and worldwide, yet it still goes widely undiagnosed. Current guidelines support screening, yet ABI screening is not commonly used in primary clinic settings. Screening for high-risk populations can improve disease management and prevention.

Project Objectives

1. Educate providers and nurses on pathophysiology of peripheral artery disease, the Ankle-Brachial Index screen, and proper technique for measurement of ABI.
2. Develop a risk factor algorithm to identify high-risk patients eligible for ABI screening.

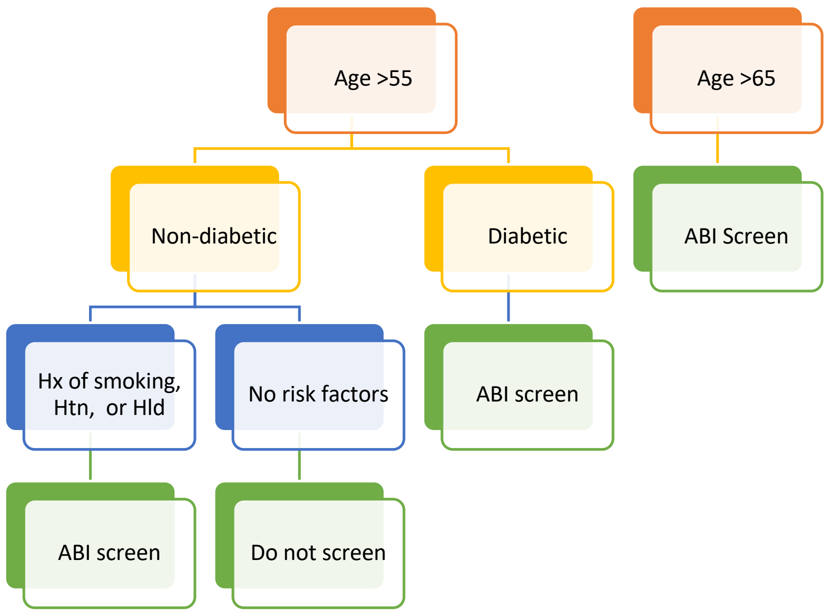

Figure 1. Ankle-Brachial Index Screening Algorithm

3. Increase screening of asymptomatic high-risk populations in the primary care setting during the 2-month period following educational intervention.

CHAPTER 2: LITERATURE REVIEW

Pathophysiology, Diagnosis, and Treatment

Peripheral artery disease is a progressive, atherosclerotic disease. Atherosclerosis can affect the vasculature of the coronary, cerebral, and peripheral arteries and the aorta. Atherosclerosis is a pathologic process that can begin as early as childhood with the development of fatty streaks (Zhao, 2018). Fatty streaks are the first phase of the atherosclerotic process. Lipid-laden macrophages (foam cells) and extracellular matrix accumulate within the intima causing a focal thickening (Zhao, 2018). Fatty streaks also contain smooth muscle cells and can contain T lymphocytes due to inflammation. Foam cells are the hallmark of early atheroma. Fatty streaks progress to fibrous plaque from the accumulation of connective tissue, smooth muscle cells, and a deeper extracellular lipid pool. As atherosclerotic plaque grows, they acquire their own microvascular network from the vasa vasorum, a network of micro-vessels originating in the adventitial layer of large arteries. The microvascular network extends from the adventitia through the media and into the thickened intima (Zhao, 2018). Other types of atheroma include fibrous caps and advanced lesions. Fibrous caps are plaque with a well-defined lipid core and are generally acellular or abundant in smooth cells (Zhao, 2018). Advanced lesions typically contain a necrotic lipid-rich core and often result in calcified lesions (Zhao, 2018). Atherosclerotic changes cause narrowing in the vessels. The accumulation of lipids and fibrous material can also cause plaque to rupture which may result in embolism. The pathogenesis of atherosclerosis is multifactorial including endothelial dysfunction, dyslipidemia, inflammatory and immunologic factors, plaque rupture, and tobacco (Berger and Davies, 2018).

Clinical presentation for PAD varies greatly dependent upon severity of disease and vessels affected. Claudication is the most common presentation of peripheral artery disease, defined by pain with activity that is relieved with rest. Other potential presentations include pain at rest, ulcers, and gangrene. The cause for these symptoms is progressive luminal narrowing, with the potential of thrombosis or embolism resulting in critical leg ischemia. The result of luminal stenosis, thrombosis, or embolism is reduced blood flow to the extremity. Reduced blood flow decreases oxygen to the muscle causing pain and fatigue to the muscle, especially during exercise when oxygen demand increases. Intermittent claudication occurs in about 10-35% of patients with PAD (Kobayashi, Parikh, and Giri, 2015).

Diagnosis

The resting ABI is currently the primary method for establishing a PAD diagnosis (Skelly and Cifu, 2015). The resting ABI is a simple, noninvasive, low-risk and low-cost test that can be done in a clinic or bedside (Neschis and Golden, 2018). Registered nurses or licensed practical nurses, technicians, and providers can complete ABI testing. The patient should be placed in a quiet room for 5-10 minutes in a supine position prior to measuring the ABI. The ABI is completed using a blood pressure cuff and handheld Doppler. Using the Doppler to identify the brachial pulse the blood pressure cuff is inflated until the pulse is no longer heard. The air is slowly released from the cuff and when the pulse is once again audible, that number is indicative of the systolic pressure. The same process is used at the ankle using the posterior tibial and dorsalis pedis arteries. If these measurements are different, the higher of the two measurements should be used (Stanford Medicine, n.d.). The ABI ratio is determined by dividing the ankle systolic pressure by the brachial systolic pressure (Stanford Medicine, n.d.).

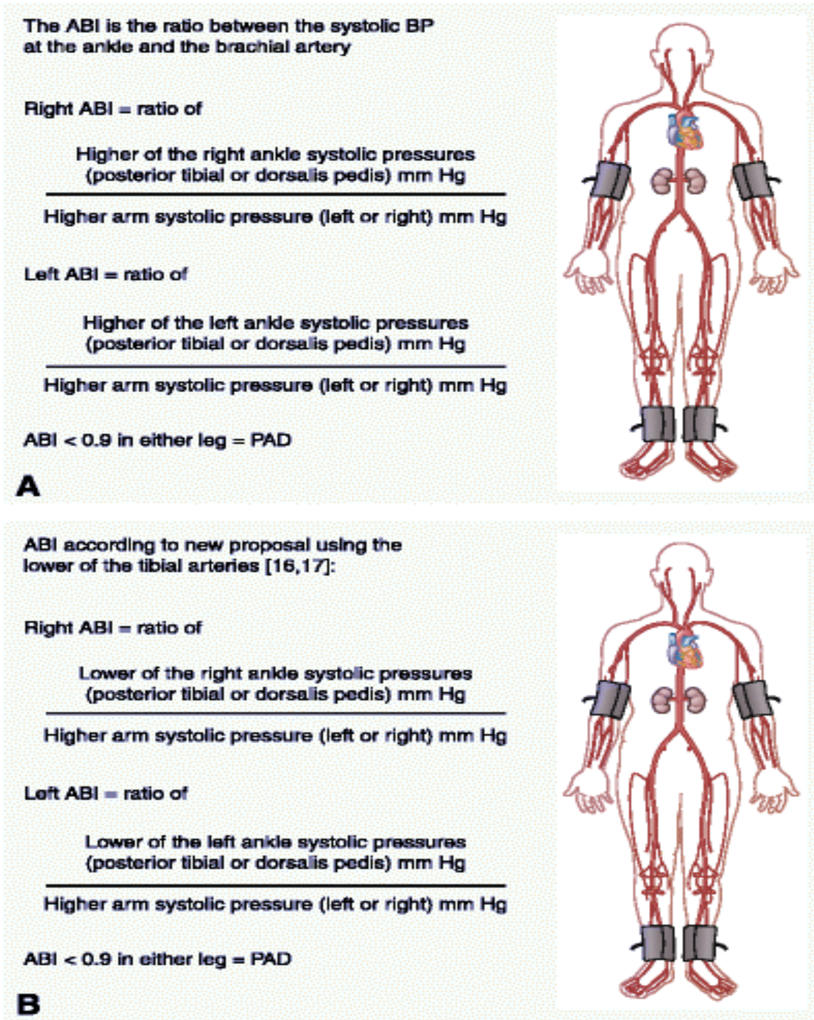

Figure 2. Ankle-Brachial Index Ratio Calculation and Measurement Sites. (Stanford Medicine, n.d.)

There have been minimal studies comparing ABI diagnosis with angiography, so it has been difficult to determine sensitivity of ABIs. The ACC/AHA have determined sensitivity to range from 79%-95% (Alahdab et al., 2013). Specificity on the other hand is much more accurate at >95% (Alahdab et al., 2013). Controversial elements of ABI diagnosis include use in the elderly and individuals with type II diabetes, and the values used for ABI measurements. Xu et al. (2010) found decreased sensitivity for ABI detection in both elderly and individuals with type II diabetes. A consideration for the cause of decreased sensitivity in these two specific populations is the calcification of artery wall leading to overestimation of artery pressure (Xu et al., 2010). Many factors can contribute to sensitivity including age, ethnicity, and health status (Xu et al., 2010).

In a study by Xu et al. (2013), guidelines did not specify whether to use posterior tibial or dorsalis pedis measurements in the leg, to use the lower/higher of the two, or the average of the two. The ACCF/AHA and American Diabetes Association suggest using a value of <0.9 or >1.4 to indicate a positive result (Xu et al., 2013). According to the American Heart Association, a normal ABI is 1.0-1.4, borderline is 0.9-1, significant disease is 0.5-0.9, and severe disease is <0.5 (2016). Calcification or non-compressible disease is indicated if the ABI is >1.4 (American Heart Association, 2016). Non-compressible vasculature is more common in individuals with diabetes or advanced chronic kidney disease (American Heart Association, 2016).

ABI is specific and sensitive enough to establish a diagnosis of PAD, it is not, however, specific or sensitive to the location of the blockage (Neschis and Golden, 2018). In order to locate the area of blockage, further testing may be required. These specific tests include segmental pressures and pulse volume recording, exercise testing, and vascular imaging. Segmental pressures and pulse volume recordings are completed in a vascular laboratory and may be used in conjunction with a formal ABI to determine site and severity of disease (Neschis and Golden, 2018). Exercise testing is also completed in a vascular laboratory and follows a standard exercise protocol using a motorized treadmill for reproducibility (Neschis and Golden, 2018). Exercise testing is most often used for patients who have classical symptoms of claudication but normal resting ABIs (Neschis and Golden, 2018). Vascular imaging is not necessary for the diagnosis of PAD but is useful for differentiating between PAD and other differential diagnoses such as arterial aneurysm (Neschis and Golden, 2018). Vascular imaging is also required when considering revascularization interventions and for ongoing surveillance following intervention (Neschis and Golden, 2018). Resting ABIs can diagnose PAD but may need follow-up for further testing; however, noninvasive management of PAD can be initiated following a positive resting ABI test.

Screening

Early detection of PAD could slow down progression of the disease and improve risk management for future atherosclerotic disease including cardiovascular and cerebrovascular disease (Ferket, Spronk, Colkesen, & Hunink, 2012). There are no recommended screenings for PAD other than the ABI. As discussed earlier, the ABI test is simple, quick, and non-invasive making it the ideal test for screening. Due to minimal studies and lack of randomized control trials, there is little evidence supporting potential benefits or harms of PAD screening (Ferket et al., 2012). However, there have been numerous systematic reviews and guideline reviews establishing barriers, benefits, and potential harms of screening for PAD.

Barriers

Mohler et al. (2004) assessed resting ABI efficacy in primary care clinics during the PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) Program. A primary objective of the study was to determine feasibility of ABI measurement and PAD diagnosis in primary care offices and to evaluate provider knowledge of PAD diagnosis (Mohler et al., 2004). Results for the survey were garnered using the ABI utilization survey, which was administered to 700 clinicians in the PARTNERS program and 2630 clinicians in the Preceptorship program; overall response rates were 38% for the PARTNERS program and 24% for the Preceptorship (Mohler et al., 2004). Prior to the study, 69% of the participants had never measured the ABI and minimal participants utilized the ABI annually, monthly or weekly (Mohler et al., 2004). The majority of participants found the ABI useful for detecting PAD in asymptomatic patients with 89% of the providers reporting ABI testing useful and 96% of providers finding ABI testing useful for symptomatic patients, 86% also found the test could be completed in under 15 minutes (Mohler et al., 2004). The biggest limitations reported for utilizing the ABI in the office were time constraints (56%), reimbursement (45%), and staff availability (45%) (Mohler et al., 2004). Time constraint was the only factor considered either a moderate or a major limitation (Mohler et al., 2004). This study was relatively old but is still relevant when considering awareness of peripheral artery disease and barriers to in-office use of the ABI test.

In more recent studies, similar barriers were identified including time constraints and reimbursement. In a study by Haigh, Bingley, Golledge, and Walker (2018), results indicated that equipment availability, time constraints, staff availability, and lack of training and skills were all moderate to major barriers for ABI screening in primary care clinics. These results were contradictory to the study by Mohler et al (Haigh et al., 2018) which found time constraints to be a moderate or major barrier to screening and moderate barriers of reimbursement and staff availability (Mohler et al., 2004). The Haigh et al. (2018) study was conducted in Australia, results were consistent with data from the United States. For ABIs to be reimbursed in the United States, a waveform recording must be present in the chart (Haigh et al., 2018). This requirement greatly limits primary care offices due to the lack of appropriate equipment (Haigh et al., 2018). In the Haigh et al. (2018) study, most clinicians identified lack of reimbursement as a moderate to major barrier. Itoga et al. (2018), evaluated cost effectiveness of ABI screening for PAD, indicating that while the ABI is a low-cost test, follow-up care may be costly for the patient with potentially limited perceived benefit. Mohler et al. (2004) found ABI utilization increased significantly with the implementation of an educational program. The Haigh et al. (2018) did not include educational intervention as part of the study which resulted in a lack of comfort for providers and nursing staff and limiting the success of screening. Many of these barriers could potentially be reduced with a proper educational program (Haigh et al., 2018).

Criteria for reimbursement for the ABI test has changed for the CPT code 93922 since 2011. The CPT code 93922 is used for single level, noninvasive physiologic studies of upper or lower extremity arteries bilaterally (Jandroep, 2009). CPT code 93923 is used for multiple level noninvasive physiologic studies (Jandroep, 2009). After the AHA reported ABI testing is the gold standard to measure a systolic pressure at both the dorsalis pedis and posterior tibial arteries, Medicare enhanced guidelines for reimbursement. Medicare now requires documentation of both ankle pressures bilaterally and bilateral brachial pressures indicating the need to complete the studies using doppler method (Rogers, 2014). Medicare also requires hard copy output and analysis (Newman Medical, 2017). Indications for reimbursement include symptoms of claudication, resting leg pain, aneurysmal disease, and presurgical workup (Newman Medical, 2017). In general, screening is not reimbursable by Medicare; however, certain diagnoses such as diabetes mellitus 1 and 2, atherosclerotic disease and hypertension may be reimbursable by Medicare (American Society of Echocardiography, 2016). Reimbursement for these diagnoses is not guaranteed and is recommended that individual providers consult with local Medicare representatives (American Society of Echocardiography, 2016).

Benefits and Potential Harms

ABI screening can result in earlier detection of PAD. In a systematic review by Alahdab et al. (2015), early detection did not necessarily lead to reduction in lower extremity events. Probability of significant events such as amputation is relatively low; however, early detection did help to identify individuals needing aggressive therapy to prevent cardiovascular events

(Alahdab et al., 2015). A meta-analysis by Fowkes et al. (2008) indicated that an ABI of <0.9 was associated with approximately twice the 10-year total mortality, cardiovascular mortality, and major coronary event rate; this indicates that a positive ABI has similar implications on cardiovascular risk as family history of premature events in a first-degree relative (Alahdab et al., 2015). Positive ABI screening will result in aggressive risk factor reduction such as statin therapy. Statin therapy has shown to improve 6-minute walk performance and faster walking velocity (Alahdab et al., 2015). Ferket, Spronk, Colkesen, and Hunink (2012) completed a review of guidelines and concluded guidelines supporting screening did so mainly for reduction and prevention of cardiovascular events such as myocardial infarct or a cerebrovascular event.

Potential harms of ABI most frequently discussed are cost-effectiveness and pharmacologic intervention. In a study by Fowkes et al. (2010), asymptomatic PAD patients were randomized into an aspirin group versus placebo group. The aspirin group was found to have a nonsignificant increase in major hemorrhage versus the placebo group (Alahdab et al., 2015). Pharmacologic risk factors will vary depending on the population screened, with high-risk populations at lower risk due to probability of individuals already being on optimal medical therapy (Alahdab et al., 2015).

At the time of the Alahdab et al. review, there had been no reliable studies of cost-effectiveness (Alahdab et al., 2015); however, Itoga et al. (2018) conducted a cost-effectiveness analysis of ABI screening for asymptomatic patients. Cost-effectiveness varies significantly depending on severity of the disease and the comorbidities of the population being screened (Itoga et al., 2018). Medications used to slow disease progression and risk modification to decrease cardiovascular events are relatively inexpensive indicating increased benefit for ABI screening (Itoga et al., 2018). Itoga et al. (2018) also addressed the concern that high-risk patients may already be taking many of the medications that would be prescribed; in the study 96% of patients were considered already on therapy but concluded that 4-5% of patients eligible for new medications may account for 4.9 million US adults with PAD (Itoga et al., 2018). The ABI test itself is relatively inexpensive. Itoga et al. (2018) used the amount of $338 in the base case model compared to no screening. Cost increased depending on results of screening with a positive ABI requiring new medication, additional testing, supervised exercise program, or possible endovascular intervention (Itoga et al., 2018). The conclusions of the study indicated cost-effectiveness of screening with the ABI depends on the prevalence of the disease in the initial population being screened but also indicated the need for further studies (Itoga et al., 2018).

Guidelines

Currently there are no guidelines recommending routine screening in asymptomatic patients; however, a number of organizations have developed guidelines recommending screening for high-risk populations to stratify potential cardiovascular disease risk reduction. These organizations include the American College of Cardiology Foundation/American Heart Association (ACCF/AHA), Society of Vascular Surgery (SVS), American Diabetes Association (ADA), and European Society of Cardiology (Yang, 2015).

- American College of Cardiology Foundation/American Heart Association recommends ABI screening for high-risk patients including age >65, age >50 with a history of smoking or diabetes, and those with exertional leg pain (Rooke, et al., 2011).
- Society for Vascular Surgery reports ABI screening is reasonable for asymptomatic patients older than 70, smokers, and those with diabetes (Conte et al., 2015).

- American Diabetes Association (2015) recommends ABI screening for individuals with diabetes who are symptomatic or asymptomatic and age >50 or have at least one other risk factor including smoking, hypertension, hyperlipidemia, or duration of diabetes >10 years.
- European Society of Cardiology recommends ABI screening in patients with coronary artery disease (Tendera, et al., 2011).

Management

Peripheral artery disease management is similar to other atherosclerotic disease. The goal of treatment is not to cure, as there is no cure for atherosclerosis, but to inhibit disease progression. There is not one specific treatment for PAD, but rather a multifaceted approach. Non-invasive treatments include medication optimization, lifestyle modification, and supervised exercise program (Kobayashi, Parikh, & Giri, 2015). The most significant lifestyle modification to slow disease progression is smoking cessation (Kobayashi et al., 2015). It is recommended that smoking cessation resources be presented to the patient at every office visit (Kobayashi et al., 2015). Evidence suggests a combination of intensive counseling and pharmacotherapy for smoking cessation has a greater success rate than behavioral therapy or pharmacotherapy alone (Kobayashi et al., 2015).

Multiple studies including a Cochrane review have shown immense benefit from a supervised exercise program (Kobayashi et al., 2015). Benefits from a supervised exercise program include improved 6-minute walk distance, improved treadmill exercise performance, and improved quality of life (Olin et al., 2016). In the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) study, 111patients were randomized into three groups; all groups were given optimal medical care, one group was started in a supervised exercise program, one group received endovascular revascularization, and the last received no additional therapy (Kobayashi et al., 2015). Results of the study showed improved treadmill walking times at 6 months in the exercise group compared to the invasive repair; however, quality of life and symptom relief were greater in the invasive repair group at 6 months (Kobayashi et al., 2015). In a similar study, 151 patients were randomized into a supervised exercise program or upfront endovascular repair. Seven-year follow-up indicated no difference in mortality or quality of life, improved ABI, and a decreased need for invasive interventions for the exercise group as compared to the endovascular repair group (Kobayashi et al., 2015).

In a more recently published trial, ERASE (Endovascular Revascularization and Supervised Exercise), 106 patients were randomized to both endovascular therapy and supervised exercise and 106 patients to supervised exercise alone (Olin et al., 2016). A one-year follow-up showed greater improvement in maximum walking distance and quality of life scores in the combination group compared with supervised exercise alone (Olin et al., 2016). While the combination group had a greater improvement, the supervised exercise group showed marked improvement in maximum walking distance and quality of life as well (Olin et al., 2016). Combination therapy of endovascular repair and supervised exercise program is superior to an exercise program alone; however, cost of therapy must be considered. The cost of endovascular therapy contributes to a higher cumulative cost per patient than supervised exercise alone (Olin et al., 2016). If endovascular revascularization is required, it is more cost effective to include a supervised exercise program than revascularization alone (Olin et al., 2016).

Optimal medical therapy for PAD is similar to that of CAD. However, patients with PAD are optimized less frequently than those with CAD (Olin et al., 2016). Antiplatelet therapy, statin therapy, and aggressive hypertension treatment should be used to lower risk of myocardial infarction or cerebral vascular disease (Kobayashi et al., 2015). The role of antiplatelet therapy has been studied extensively in PAD. In 1996 the CAPRIE study, randomized patients with vascular disease to aspirin versus clopidogrel (Kobayashi et al., 2015). Results showed no significant difference in rates of ischemic stroke, myocardial infarction, or vascular death in the overall population but showed a 23.8% relative risk reduction among the subgroup of symptomatic PAD (Olin et al., 2016). Dual-antiplatelet therapy with low dose aspirin and clopidogrel was studied in the CHARISMA trial, which showed limited significant results except for the subgroup of patients with symptomatic atherothrombosis (Olin et al., 2016). Overall among all studies there is limited evidence supporting DAPT except in cases of symptomatic PAD and those undergoing endovascular repair (Olin et al., 2016). Even among patients who have had revascularization, there is limited evidence guiding duration of DAPT (Olin et al., 2016).

Aspirin monotherapy has been a mainstay therapy for patients with PAD, although the data to support aspirin therapy has not been well-substantiated (Olin et al., 2016). In two studies, POPADAD (Prevention of Progression of Arterial Disease and Diabetes) and AAA (Aspirin for Asymptomatic Atherosclerosis), low-dose aspirin was compared to placebo in patients with a low ABI (Olin et al., 2016). Neither study revealed a reduction in fatal or nonfatal cardiovascular events or revascularization (Olin et al., 2016). A recent meta-analysis examining aspirin for PAD in 18 trials revealed similar results with a nonsignificant reduction of 8.2% in cardiovascular events but did show a significant reduction in nonfatal stroke (Olin et al., 2016). Current guidelines support use of aspirin monotherapy with a Class 1 Level of Evidence A for symptomatic PAD and a class IIa recommendation for asymptomatic PAD with ABI <0.9 (Olin et al., 2016).

Aggressive blood pressure management for treatment of PAD has been well established (Kobayashi et al., 2015). The UK Prospective Diabetes Study was a landmark study indicating a reduction of 10 mmHg in systolic blood pressure resulted in a 16% reduction in rates of limb amputation and death from PAD (Kobayashi et al., 2015). The HOPE (Heart Outcomes Prevention Evaluation) trial placed patients with vascular disease or diabetes plus one other risk factor on Ramipril 10 mg daily or placebo which indicated reduced rates of myocardial infarction, stroke, and cardiovascular death in the Ramipril group compared to placebo (Kobayashi et al., 2015).

The most recent ACC/AHA guidelines recommend high-intensity statins for all patients with PAD, regardless of low-density lipoprotein targets, for reduction of cardiovascular disease (Olin et al., 2015). Multiple clinical trials have shown a significant risk reduction for all-cause mortality in patients on simvastatin vs placebo (Olin et al., 2016). Additional trials, including the REACH study, indicated statin therapy reduced the risk for worsening claudication and adverse limb outcomes. Specifically, in patients with critical limb ischemia, statin therapy was associated with reduced rates of amputation at 30 days, 90 days, and 1 year (Olin et al., 2016). In most studies, <75% of patients with a PAD diagnosis were initiated on statin therapy indicating the importance of provider education and medical optimization for PAD (Olin et al., 2016).

CHAPTER 3: THEORETICAL FRAMEWORK

Diffusion of Innovations Theory

The Diffusion of Innovations Theory was first discussed in 1903 by Gabriel Tarde a French sociologist who developed the S-shaped diffusion curve (Kaminski, 2011). Ryan and Gross later introduced the adopter categories, which were popularized by Everett Rogers in the current theory (Kaminski, 2011). The theory is considered a valuable guide for innovation that meets the needs of all adopters and emphasizes the importance of communication during the adoption process (Kaminski, 2011). The diffusion of innovation is the process in which a new practice or idea is adopted by certain populations. ABI screening to identify PAD in high-risk, asymptomatic individuals is the innovation represented in this project.

Rogers recognized five categories of adopters including innovators, early adopters, early majority, late majority, and laggards (LaMorte, 2018). He also estimated the percentage of the population that would adopt the innovation in each category, as seen in Figure 2. The goal of the theory is not to transition people into new categories but rather meet the needs of individuals in all categories (Kaminski, 2011).

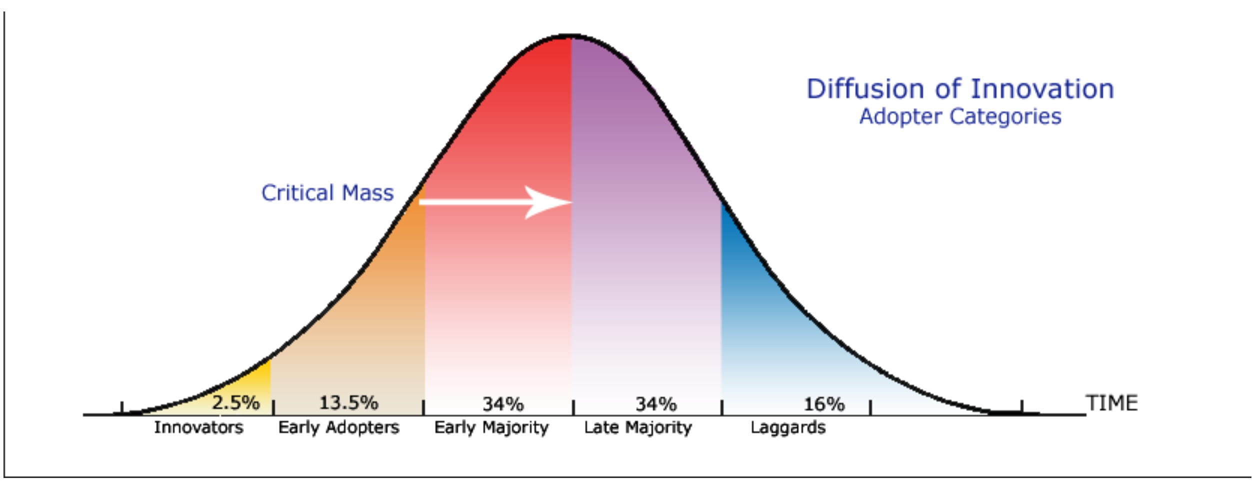

Figure 3. Diffusion of Innovation (LaMorte, 2018)

Innovators account for 2.5% of the population and are considered the change agent. The innovators require the shortest period of time to adopt the new innovation and are considered risk takers. They are often recruited to be peer educators and facilitate the next group of adopters (Kaminski, 2011).

Early adopters account for 13.5% of the population and represent opinion leaders. They embrace change opportunities knowing that change is necessary and need little information to convince them to change (LaMorte, 2018). Early adopters are typically leaders within an organization, because of this; advisement should be sought prior to adopting the innovation. Through clinical experience, early adopters were easy to identify at the implementation clinic. One early adopter was the Advanced Practice Registered Nurse (APRN) who viewed the research and guidelines and assisted in setting up meetings with clinic leadership. Other early adopters included clinic leaders, the medical director and clinic administrator. Through meetings and discussion, early adopters accepted the innovation.

The early majority account for 34% of the population. These individuals are rarely considered leaders but adopt ideas before the average person. The early majority are comfortable with change if it enhances productivity with little risk (Kaminski, 2011). Most of the remaining clinic providers represented the early majority. Through educational sessions outlining the benefits of ABI and screening for PAD, including early identification and risk stratification for cardiovascular disease, the early majority was persuaded to accept the innovation.

Late majority also account for 34% of the population and are more conservative with adopting change. They are more likely to respond to peer pressure and economic necessity (Kaminski, 2011). These individuals often rely on information from a trusted advisor and can be easily influenced by laggards (Kaminski, 2011). One provider at the clinic was considered late majority. This provider had multiple questions regarding guidelines and benefits of ABI screening. Concerns included whether screening would create unnecessary testing for patients without health benefits. This co-investigator and the early adopters addressed these concerns and ultimately the provider supported the project.

Laggards account for 16% of the population and are considered skeptics. They are suspicious of innovations and often consider innovation process lengthy. These individuals are often isolated from opinion leaders and deny change wanting to maintain status quo (Kaminski, 2018).

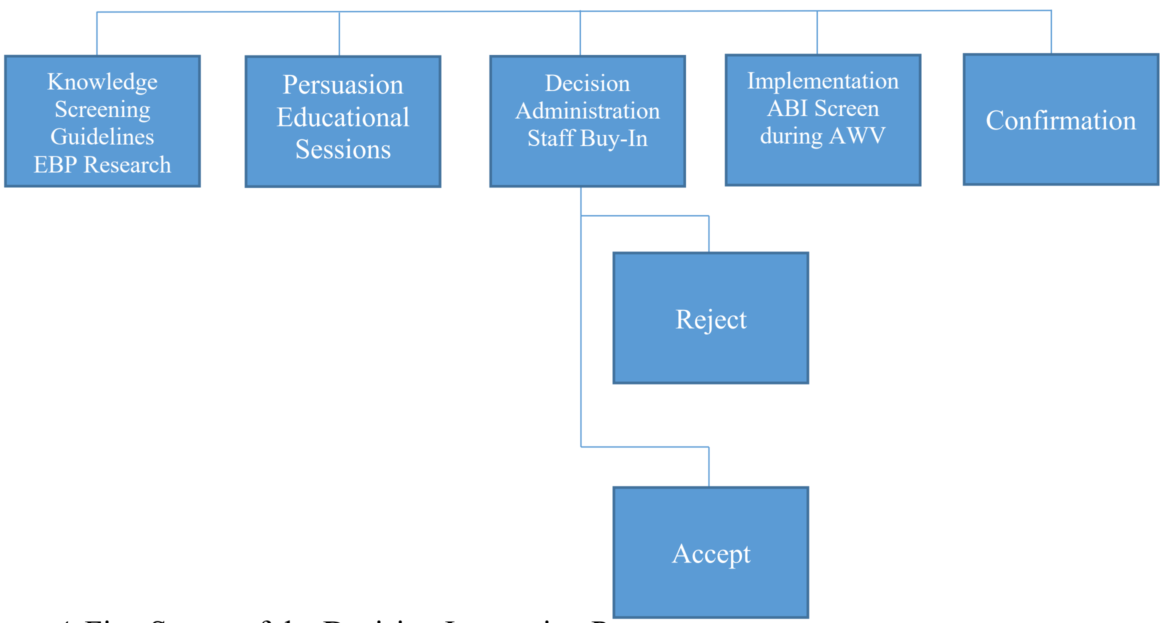

Figure 4. Five Stages of the Decision Innovation Process

Rogers also identifies characteristics that will make an innovation successful. These characteristics include relative advantage, computability, trialability, complexity, and re-invention. Relative advantage is how the innovation is superior and the degree to which it is superior to current practice (LaMorte, 2018). Advantages to ABI use include early identification and intervention for PAD and increased risk stratification for cardiovascular disease. The test is noninvasive and simple to complete making it an ideal test in primary care.

Compatibility is how the innovation is perceived to be consistent with current ideas and needs (Kaminski, 2011). PAD is becoming more prevalent as comorbid conditions become increasingly prevalent. Identifying and treating PAD early is vital in preventing progression of the disease and reducing cardiovascular risk. The ABI is a tool providers can use to promote early intervention such as smoking cessation and an exercise program to improve quality of life and prevent disease progression.

Trialability is the degree to which the innovation can be experienced (Kaminski, 2011). Trialability is critical for adopters when considering the innovation. Adopters were exposed to the innovation through multiple meetings prior to implementation and after implementation through educational sessions. The duration of the implementation period allowed adopters to become comfortable with ABI screening and allow adequate time to decide whether to adopt the innovation.

Complexity is the level of simplicity or difficulty of the innovation (LaMorte, 2018). If the innovation is too complex to integrate into practice, providers will be less likely to adopt the innovation. Educational sessions are easily integrated into the workday through luncheons. The screening itself is more complex, requiring more work to integrate into primary practice. The project design addresses the complexity by integrating it into a routine 60-minute visit with a registered nurse. Integration during this visit allowed for a greater number of screens to be completed and easier access to results.

Re-invention is another important factor when considering innovation. Re-invention is the ability of the innovation to be adapted or modified. The more versatile an innovation, the more likely it will be adopted (Kaminski, 2011). Education regarding peripheral artery disease and Ankle-Brachial Index is multi-faceted. Education increases awareness of PAD and alerts providers to potential risk factors and signs/symptoms of PAD. ABI testing can be utilized to screen or diagnose PAD. Utilizing both aspects of the ABI test, the rural clinic can improve patient satisfaction and retain reimbursable productivity.

Innovations can be adopted by organizations two ways, through collective decision or authority decision. This innovation was adopted through collective decision with providers and clinic management making the final decision to adopt the innovation. Over several meetings, the adoption plan was presented and discussed, highlighting potential benefits and potential harms of the innovation. The decision was based not only on benefits of screening, but also on further utilization of diagnostic ABIs in the clinic. All adopter categories agreed on benefits of PAD and ABI education for providers and nurses to enable the highest quality of care for rural patients.

The Diffusion of Innovation theory guided this project through the implementation process by allowing this researcher to identify opinion leaders and work with them to meet the needs of individual adopters. Working with two early adopters, this researcher was able to identify the needs of the clinic, providers, nurses, and administrators to propel this project forward. The opinion leaders assisted in project progress through discussion of research and potential benefits, including improved vascular scores, to persuade additional members of the change team to adopt this project.

PDSA Model

The quality improvement model chosen for this project was the Plan-Do-Study-Act Cycle. This model provides a framework for developing, testing, and implementing changes leading to improvement. The PDSA model enables the researcher to test change on a small scale prior to disseminating information on a large scale. When applying the PDSA model, three questions must be asked:

Question One: *What are we trying to accomplish?* The purpose of this study is to increase awareness of screening for PAD to allow for early identification and intervention of PAD to delay disease progression and stratify cardiovascular disease risk.

Question Two: *How will we know that the change is an improvement?* Improvement is based on competency, comfort with PAD screening and knowledge of results interpretation and further action, which will ultimately increase screenings at the clinic. These outcomes were measured using a competency checklist, Post-Education Survey, and number of screenings completed at the clinic.

Question Three: *What changes can we make that will result in an improvement?* Educational sessions were organized for registered nurses and providers. The nurse education session included a competency checklist and allotted 40 minutes to practice the new skill. The provider education included an overview of the disease, progression, complications, diagnosis, and management. The education also included screening guidelines, benefits, and limitations.

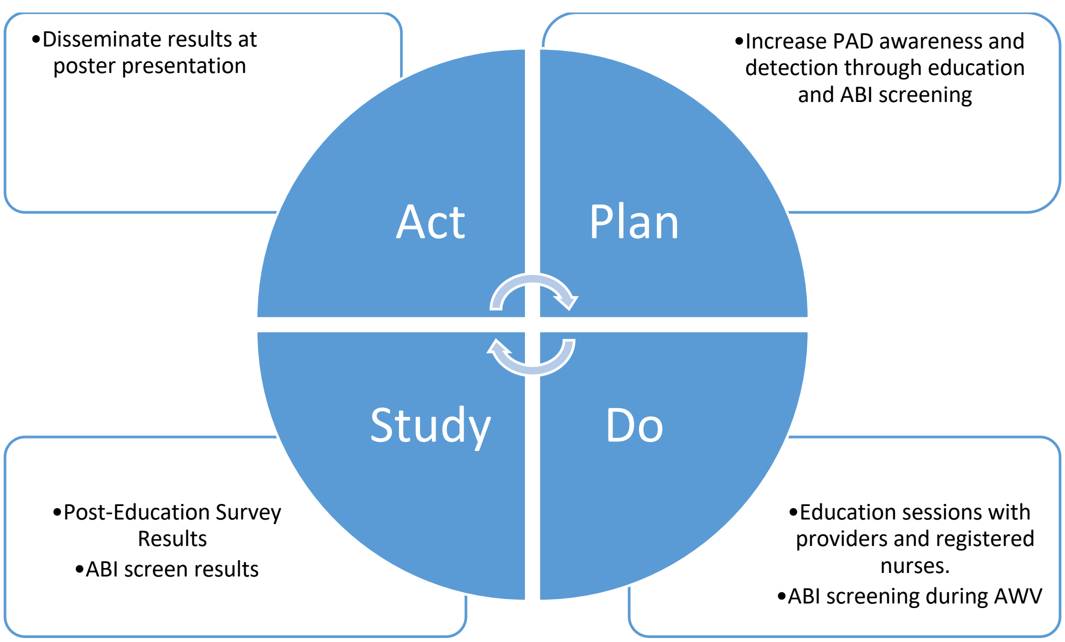

Figure 5. PDSA Model

Step 1: Plan – develop the test, intervention, and implementation, including a plan for collecting data. The plan should include purpose and objectives and make predictions about outcomes (Minnesota Department of Health, n.d.). The project design and evaluation plan are highlighted in Chapter 4. This project took place at Essentia Health – Wahpeton clinic, between the months of December and February. The design included 2 educational sessions for health care workers and implementation of the ABI screen during Medicare AWVs. This co-investigator communicated with the nurses weekly over email or face-to-face to address questions or needs and monitor progress.

Step 2: Do – implement the test on a small scale, documenting problems, and unexpected observations (Minnesota Department of Health, n.d.). This project was implemented December 20, 2018, beginning with the RN education session. ABI screening took place over a 2-month period beginning December 20, 2018 and ending February 20, 2019. The provider education session took place January 15, 2019 with post-education survey collection the same day as the educational session.

Step 3: Study – analyze data and study the results. Compare the data to the previous predictions and make inferences about the results (Minnesota Department of Health, n.d.). Data collected included quantitative and qualitative data. Data was garnered from the post-education survey and included quantitative and qualitative data, and from ABI results. This data was analyzed to make inferences about future research and practice.

Step 4: Act – Refine the intervention based on what was learned from the test. Determine what modifications if any need to be made and prepare for the next test (Minnesota Department of Health, n.d.). Recommendations and limitations of the study are discussed in Chapter 6. Time and room availability were the largest barriers to completing screens. Future studies should consider coordination of planned days for ABI screens. Planned dissemination will take place at a poster presentation in April.

CHAPTER 4: PROJECT DESIGN AND ANALYSIS

Project Design

Design of the project was aimed at increasing knowledge of PAD, the ABI test, and utilizing the ABI for screening. Through education and screening PAD can be detected earlier and disease progression and risk stratification interventions initiated sooner. Essentia Health – Wahpeton was the chosen site for implementation. Wahpeton is a rural clinic about 60 miles from the nearest facility with testing resources. Wahpeton is a larger rural health clinic with a treatment team of four nurse practitioners, one internal medicine physician, one family practice physician, two general surgeons, one physician assistant, an optometrist, and a dentist. The clinic also has four registered nurses who circulate during surgeries, recover surgical patients, and complete Medicare AWVs. The nurses' report completing about six wellness visits each week, or around 320 per year. While the clinic houses multiple providers and surgical resources, patients still have to drive the 60 miles to the nearest urban facility to undergo ABI testing and PAD workup. For many patients, this is a long commute for a test that will take, on average, 15-20 minutes to complete. A bedside ABI requires only a blood pressure cuff and a vascular doppler, and until initiation of this project, the clinic did not have a vascular doppler to assess pedal pulses.

Implementation began with a skills meeting for all (4) of the registered nurses having direct patient contact; however, only 2 nurses attended the meeting. Dr. Duane Strand also attended the skills meeting for clinic oversight in accordance with reimbursement policy. A majority of the educational session (40 minutes) was spent as hands-on training to increase comfort using a doppler, since the two nurses in attendance did not have experience using a doppler to find peripheral pulses prior to this session. The education given to the nurses included a PowerPoint (Appendix D) with an overview of peripheral artery disease, peripheral artery anatomy, and slides pertaining specifically how to complete the Ankle-Brachial Index. A video from the Stanford School of Medicine was also utilized to demonstrate how to accurately complete the test. A skills checkoff was utilized to demonstrate competency of the test (Appendix A). The two nurses in attendance completed the skill checkoff without problem. Questions and concerns of the nurses were addressed at the meeting including what room to utilize and what to do if unable to locate a pulse with the doppler.

Provider education occurred at the clinic during a luncheon and was attended by eight providers. Educational materials included a PowerPoint presentation (Appendix E), algorithm, and ABI range handout (Appendix F). The materials included purpose of the project, overview of peripheral artery disease including pathophysiology, epidemiology, risk factors, clinical presentation, diagnosis, and management. Ankle-Brachial Index education included ABI measurement technique, ratio calculation, and utilizing index in practice. Screening guidelines and recommendations were also discussed during the presentation. Practice implications including barriers and improvements from previous research studies were reviewed and steps taken to avoid barriers were discussed. This project went through an Essentia Health compliance and budget review board prior to implementation to ensure the test would be reimbursable if providers choose to continue to utilize the screen after the implementation period has concluded. A Post-Education Survey was distributed to providers at the conclusion of the education session. The survey was a combination of six Likert-style questions and two qualitative questions addressing barriers and benefits of the project.

Implementation of ABI screening took place between December 2018 and February 2019. The primary goal of the screening was to identify individuals at high risk for PAD, specifically looking at individuals older than 65, those with a smoking history (current or former), and those with diabetes. Current guidelines support screening of high-risk asymptomatic individuals but do not recommend screening for asymptomatic individuals without risk factors. Additionally, the in-office use of ABI screening is simple and non-invasive but is not highly utilized in rural primary care clinics. Proficiency to perform ABI testing in both symptomatic and asymptomatic high-risk individuals improves access to care and removes barriers. This study targeted individuals with a smoking or diabetes history due to the markedly increased risk for peripheral artery disease. While there are other risk factors for PAD, age, smoking, and diabetes are the most significant risk factors.

Screening was completed during the Medicare AWV. This visit was utilized to allow nurses enough time to complete the test without reducing patient time with the provider. Another reason this visit was chosen was the patient population represented. All patients that are eligible to receive Medicare are 65 or older, and thus automatically qualify based on age for screening. By utilizing this visit, time spent scrubbing charts to identify eligible patients was eliminated. Upon rooming, the nurse educated the patient on the screening process and offered patients the choice to proceed. The patient was instructed to lay supine for 5-10 minutes on the exam table in a dimmed room. During this time, the nurse left the room to complete charts and gather required equipment. The nurse then re-entered the room and completed the screen working in a "U" shape checking the right brachial pressure first. After the nurse completed the screen, results were reported in two locations, the electronic health record (EHR) for providers and in a spreadsheet without patient identifiers for this researcher. Providers were notified of where to look for results in the EHR during the educational session. Providers were notified of positive results either through an EHR message or face-to-face. Providers discussed next steps with the patient either during the following visit or over the phone. If a patient had a positive test result, further diagnostic testing or confirmative segmental ABI testing was ordered.

Evaluation Plan

Evaluation plan was designed to assess completion of project objectives. Each objective is stated below with the specific plan for evaluation.

Objective One

Educate providers and nursing on pathophysiology of Peripheral Artery Disease, the Ankle-Brachial Index screen, and proper technique for measurement of ABI. During an educational meeting, nurses were evaluated on technique and proficiency of their skill and performance. Skill check-off was required prior to any nurse completing the screening on a patient.

A post-education survey was utilized to assess confidence, perceived competency, and perceived patient outcomes related to abnormal ABI values. The survey was distributed during the presentation and collected prior to meeting dismissal. The post-education survey can be viewed in Appendix B.

Objective Two

Develop a risk factor algorithm to identify high risk patients eligible for ABI screening. The algorithm was distributed to each provider working in the clinic either at the educational session or via email. Prior to implementation, the algorithm was reviewed with the co-investigator and providers at the clinic. The algorithm was approved for use and demonstrated simplicity and ease of use.

Objective Three

Increase screening of asymptomatic high-risk populations in the primary care setting during the 2-month period following educational intervention. Screening took place during the Medicare AWV. The researcher was present for the initial test day; however, only one patient was available for screening and declined. Further oversight by this researcher included weekly check-ins either in person or through email. Questions were answered in a timely manner as to not delay the screening process. Results were recorded on a spreadsheet (Appendix C) to access key information such as age, smoking status, diabetes status, and ABI results.

Institutional Review Board

Project participants included clinic providers and nurses. Project design included a post-education survey and screening test, neither of which required protected personal information. Institutional Review Board (IRB) approval from North Dakota State University was deferred as no personally identifying information was used. The letter stating IRB approval was not necessary can be seen in Appendix E. Essentia Health defers IRB status to NDSU. Approval of this project for Essentia Health was obtained from Katherine Dean, MBA.

CHAPTER 5: RESULTS

This project was implemented December 20, 2018 at Essentia Health in Wahpeton. The target population included primary care providers in a rural clinic who provide care to individuals at high-risk for PAD and registered nurses at a rural health care clinic. Eight providers participated in the study including four family practice nurse practitioners, one internal medicine physician, one physician assistant, one optometrist, and one licensed independent social worker. Target population included primary care, including family practice and internal medicine, providers; however, an invitation to the educational session was sent to all clinic providers. Two registered nurses participated in the education session and implementation of ABI screening during AWVs.

Quantitative Survey Results

Quantitative data was garnered through a Post-Education Likert-style survey that was dispersed at the educational session on January 15, 2019 with clinic providers. Eight providers participated in the meeting and eight surveys were completed. The first three questions were used to determine relevance of the information provided. The three consecutive questions were used to determine perceived impact on patient outcomes and practice change.

Question One

Did this session meet your educational needs? This question was created to examine the significance of the information presented, and if the information addressed the knowledge disparity regarding PAD including screening and diagnosis. Seven (87.5%) of the participants responded "yes" indicating the information met the needs of their education. Only one (12.5%) of the eight participants responded "somewhat," while no participants answered "no."

Question Two

Did the information presented reinforce and/or improve your current skills? This question was designed to assess effect of the information on perceived skill level of the participant. Eight (100%) participants responded, five (62.5%) participants responded "yes," and three (37.5%) responded "somewhat."

Question Three

Did the information presented provide new ideas/information you expect to use? This question was created to assess validity of the information. Eight (100%) participants responded, seven (87.5%) responded "yes," one (12.5%) responded "somewhat."

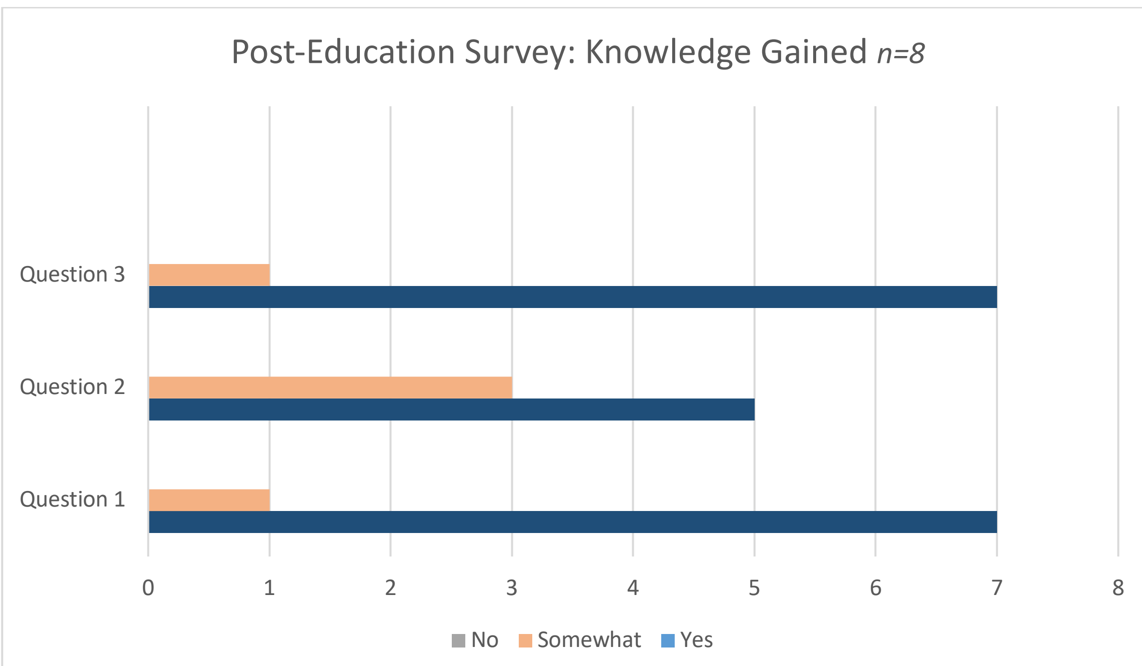

Figure 6. Post-Education Survey Responses

Question Four

The statement "*This activity increased my competence*" was included to determine provider confidence of ABI screening to diagnose PAD in high-risk asymptomatic patients. Of the eight participants, six (75%) responded “moderate increase” in competence while two (25%) participants responded, “great increase.”

Question Five

This activity will improve my performance. This statement was designed to determine effect of the new information on participant’s perception of improved skill and ability. Eight (100%) participants responded, six (75%) responded “moderate increase” and two (25%) responded “great increase.”

Question Six

This activity will improve my patient outcomes. The final statement was designed to determine if the perceived that the information presented would positively affect patient outcomes. All (N=8) participants responded to this question, six (75%) responded “moderate increase” and two (25%) responded “great increase.”

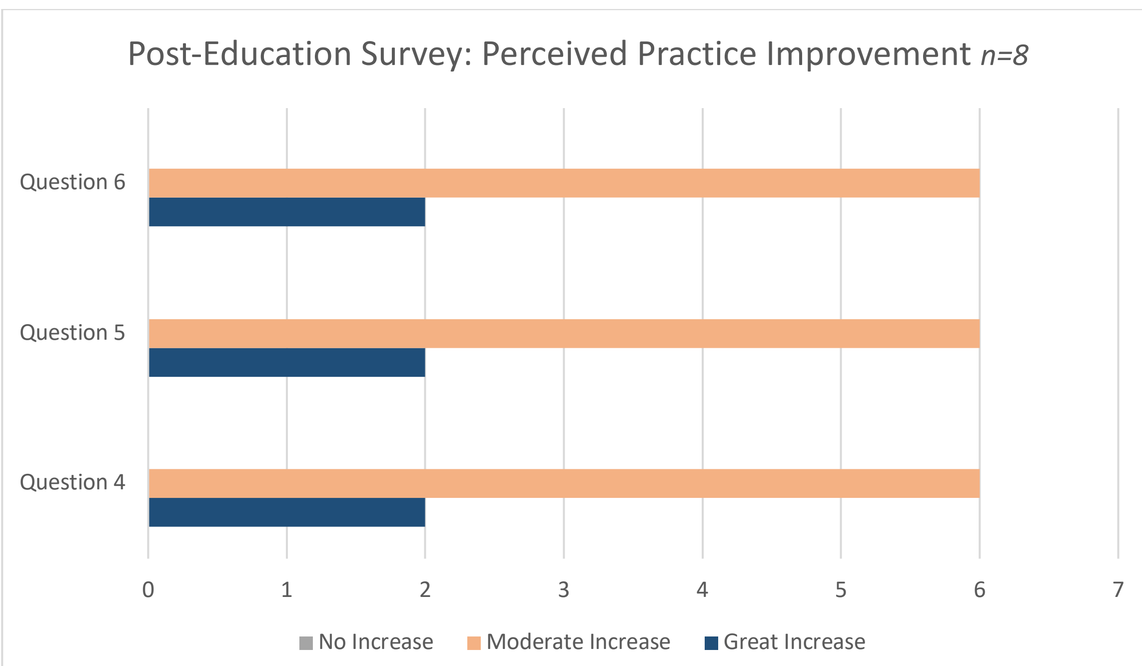

Figure 7. Post-Education Survey Responses

Question Seven

What barriers, if any, do you foresee regarding implementation of ABI screening within the clinic? This question was answered by five of the eight participants. Of the five, four (80%) indicated that time would be the biggest barrier. Responses included "time," "time limitations," and "time may be a limiting factor." One (20%) participant identified "Patient compliance with preventative strategies; staff availability for screening and interest" as potential barriers.

Question Eight

What benefits, if any, do you anticipate regarding implementation of ABI screening within the clinic? Six (75%) participants responded with common themes of early intervention and improved patient outcomes. Three (50%) participants responded, "early identification." Other responses included "improved outcomes for asymptomatic patients," "early intervention for patients," and "early intervention and possible prevention of atherosclerotic disease."

Ankle-Brachial Index Screen Results

Ankle-Brachial Index screens were completed with a registered nurse during the AWV during a 2-month period between December 20, 2018 and February 20, 2019. Participants were Medicare eligible and thus eligible for the screen based upon age alone. Fourteen patients were screened, and were categorized based on age, smoking status (former, current, or never), and diabetes status (type 1, type 2, prediabetes, or none). All of the 14 patients had a left and right ABI measured. The RN recorded the findings on a spreadsheet (Appendix C), for the co-investigator to review and for the patient in their electronic record. Patients ranged in age from 66 to 85, with a median age of 73. Of the 14 patients, seven (50.0%) had a history of smoking, two (14%) are current smokers, and five (37.5%) never smoked. One patient had a diagnosis of diabetes type 2, and one patient had a diagnosis of prediabetes. Three of the 14 (21.4%) patients had a positive ABI result. The first identified positive ratio was 2.3 bilaterally. This patient had risk factors of age 75 and history of smoking. Due to the extent of elevation, the nurse completing the test measured the patient's ABI pressures twice to ensure accuracy of the test result, after which the findings were discussed with the primary provider. The provider had expected positive ABI results due to patient history of uncontrolled hypertension, hyperlipidemia, and extensive smoking history. The second patient with a positive result had a calculated ABI of 1.45 on the left and 1.16 on the right, with risk factors of age (85 years) and a history of smoking. The third individual with a positive result had a resting ABI of 0.84 on the right and 1.07 on the left; risk factors included age (73 years) and current occasional smoking. The remaining patients had results between 0.9 and 1.28 with a median result of 1.07 on the right and 1.13 on the left. In the event of a positive screening, confirmatory tests and/or referral to cardiology were recommended.

CHAPTER 6: DISCUSSION AND RECOMMENDATION

Survey Results Interpretation

The Likert-style survey was distributed during the educational session with the primary care providers. All participants (8) completed the survey. This project was implemented in a rural clinic due to limited access to healthcare. However, the rural nature of the clinic limited participation as only seven primary care providers are employed by the clinic.

Quantitative

The majority of the providers found the presented information to be significant in improving comprehension and skill of identifying PAD, utilizing ABI test results in practice, and screening patients with the ABI test. Distributing the survey immediately following the education session improved participation.

Qualitative

The response rate for the qualitative questions was less robust than the Likert scale questions. Five (62.5%) of eight participants completed the potential barriers portion of the survey and six respondents (75%) listed potential benefits. Information gleaned from the qualitative question regarding potential barriers validated limitations of previous PAD screening studies and potential limitation of the current project. Inferences were made that time may be a limiting factor, and thus taken into account during the design of the project. Deductions previously made that screening may lead to earlier detection and slowing of possible disease progression were validated in the comments of the providers after the educational session. Results of the qualitative questions suggested if barriers, such as time constraints, can be managed, potential benefits of screening may be great.

ABI Screen Results Interpretation

The population involved in this screening was limited to patients age greater than 65 who are currently enrolled in Medicare. By utilizing Medicare AWVs, nurses were able to capture anyone over the age of 65 that seeks primary care at the implementation site. This population was chosen to reduce time constraints of nurses scrubbing the charts of all clinic providers to identify eligible patients. The AWV is a 60-minute visit with the nurse, making it an ideal visit to integrate the screen. Many preventative screenings and questionnaires are completed during this visit, which coincides with goals for this project and ABI screening. In addition to time allowance during the visit, the AWV with the nurse often coincides with a physical or chronic disease follow-up with the provider. This enables the provider to discuss results immediately following the screen and explain further testing or referral if necessary.

The nurses were able to screen 14 patients during the two-month period. Of the 14 patients, 11 (78.6%) had ABI ratios within the normal limits (0.9-1.4). All three patients that had positive results had a smoking history, either current or former. Results from the ABI screen reinforce the assertion that smoking is the most harmful PAD risk factor, contributing to PAD 2-3 times more than to cardiovascular disease (Rooke et al., 2011). Only one patient screened had a diagnosis of diabetes, and ABI results for that individual were within normal limits. Another patient had a diagnosis of prediabetes and ABI results were within normal limits. While diabetes is a significant risk factor for PAD, the sample size of this study was too small to make inferences based on ABI results.

Advanced Practice Nursing Implications

Advanced practice nursing allows nurses to practice at the highest level of skill and training, making it imperative to stay current with the latest recommendations. Advanced practice registered nurses are leaders in the profession at the pinnacle of their education and as such are often early adopters of new evidence-based practices.

Patients in a rural community often encounter barriers for testing available in their home clinic causing them to commute long distances to complete necessary testing. ABI testing is commonly referred to an urban facility despite primary care facilities capacity to complete the test in the office. Education and training for primary care providers and nursing staff can improve patient care and satisfaction by providing bedside ABI testing in-office.

Objective One

The first objective of the project was to educate providers and nursing staff on proper technique for measurement of the index, screening guidelines, and general PAD overview. Due to the quantity of education material, education sessions were completed separately for RNs and providers. Registered nurses were given a brief overview of arterial anatomy and pathophysiology of PAD, in addition to proper measurement technique and calculation instruction. Data collected from this education session was limited to a competency checklist. The RNs completed an ABI screen on a practice “patient” after adequate training, completed the screen without problem or concern, and the checklist was given to the manager to keep on file indicating competency in the skill.

The ABI test is simple, noninvasive, and requires a minimal amount of equipment. This makes it an ideal test to utilize in a clinic. The testing takes around 20 minutes to complete, and thus was implemented with cooperation from the nursing staff, during the AWV. During this exam, patients meet with a RN for 60-minutes, ensuring adequate time to complete the screen. AWVs were also chosen for the population of patients captured. All patients are older than 65, and many have comorbid conditions including, past or current smoking history and/or other high-risk diagnoses (hypertension, hyperlipidemia, or diabetes). For this reason, the AWV was ideal for screening implementation. Throughout discussions with the nurses completing the exams, time was rarely a barrier in completing the exam during the visit.

An additional benefit to ABI education for registered nurses is the ability to utilize the test as both a screen and a diagnostic test. Unlike the radiologic centers in urban facilities, rural clinics often do not have the ultrasound capabilities to conduct an ABI with ultrasound. Patients in rural areas are typically referred to an urban facility for testing and diagnosis in the presence of symptoms such as leg pain with exertion or non-healing ulcers. Having nurses trained in the skill of ABI measurement allows these patients to be tested for PAD during the same visit rather than travelling to an urban facility. Having this skill available in the clinic can save multiple patients long commutes to an urban facility for a 20-minute test.

The second education session took place with providers and detailed arterial anatomy, PAD overview, diagnosis, screening guidelines, ABI technique, results, and proper referral when ABI testing yields positive results. Data received from the Post-Education Survey was overall positive with all providers indicating moderate or great increase in confidence, patient outcomes, and perceived performance improvement. Providers also indicated that the information presented provided relevant information that increased perceived skill and knowledge level. Information gleaned from the qualitative survey response indicated that providers found the screening has potential to improve patient outcomes through earlier detection and early intervention. The responses also indicated potential barriers for time and interest. The survey showed a majority of positive feedback that if utilized can lead to improved patient outcomes.

Objective Two

The second objective of the project was to develop a risk factor algorithm to identify high-risk patients eligible for ABI screening. The algorithm was created prior to the proposal of the project and reviewed with the primary investigator and a sample of providers at the implementation site. Positive feedback was received for the algorithm's simplicity and ease of use, and the decision to utilize the algorithm was approved. The algorithm was given to providers and nurses during the educational session along with an ABI reference range chart. Providers were able to keep this document in their office to refer to when considering preventative screenings. The algorithm quickly highlights who is eligible to receive PAD screening with an ABI. Utilizing this algorithm may identify clinic patients that do not fall into the AWV category. In addition to individuals age greater than 65, individuals with a history of smoking (current or former) and one other risk factor are eligible for screening; as well as individuals older than 50 with a comorbid condition or with a history of diabetes of at least 10 years. Utilizing the algorithm rather than relying solely on AWVs may identify many more individuals at high-risk for PAD.

Objective Three

The final objective was to increase screening of asymptomatic high-risk populations in the primary care setting during the two-month period following educational intervention. Prior to implementation of ABI screening, the only screening process for PAD was the patient interview when asked if the patient has leg pain with walking. When this was discussed with providers, many indicated that they occasionally forget to ask patients about leg pain or cramps with activity. Providers also indicated they were unaware of the simplicity of a bedside ABI. Prior to implementation if a patient had a positive response of leg pain with activity, the patient was sent to an urban facility for further testing, no testing was completed in the rural facility. No patients were screened for PAD using bedside ABI prior to implementation. Post implementation, 14 patients had been screened, three (21.4%) patients had positive results requiring further evaluation. Utilizing ABI screen promotes earlier identification of PAD increasing risk reduction interventions.

Project Limitations and Recommendations for Future Use

Limitations

Staff availability was the most significant limitation, which became more prevalent as the project progressed. One of the clinic RNs is utilized primarily as a surgical nurse and does not typically complete AWVs. The other RN that was unable to complete the competency was out of the clinic throughout the majority of the project. Having limited RN staff resulted in the two RNs, who were competent in ABI screening, being required to take on additional tasks. This left LPNs to complete some of the AWVs during the project timeframe, in which case ABI screening was not completed.

Limitations in primary care may also include inadequate resources to complete an ABI in the clinic. Though minimal resources are required, having the proper equipment to complete the test is imperative. For a primary care clinic to complete this screening equipment required include a handheld vascular doppler, a manual blood pressure cuff, and an exam room with an exam table allowing a patient to lay supine.

In order to locate brachial and pedal pulses, a vascular probe for a handheld doppler is necessary for ABI screening. The implementation clinic had a handheld doppler but only had a fetal probe for the doppler. Vascular and fetal probes use different frequencies to identify varying pulse tones. Vascular probes use a higher frequency and “pencil” style probe to assess deeper tissues and are more specific arterial structures. As a result of the project, a “pencil” style probe was purchased by the clinic and utilized throughout the project. Not all clinics own or are able to purchase the vascular probe to perform optimal ABI tests.

The exam room unavailability presented a barrier for the nurses completing the test. Typically AWVs are completed in a consult room which contain only a desk and chairs, no exam table. As discussed previously, an exam table is required to complete the test as the patient needs to lie supine. The RNs utilized exam rooms as able; however, this proved to be one of the largest barriers to implementing screenings during the AWVs and may continue to be a barrier moving forward in this and other clinics.

Another limitation of the project was implementation duration of two-months. Ideally, screening duration would take place over a 4-6-month period. Project duration was limited due to the proposal timeline and clinic administrative/compliance concerns. This project was limited to a 2-month period, a longer period may have yielded a larger number of screening exams. Prior to implementation this project was brought to a compliance and billing committee to approve utilization of RNs to complete the test. Ultimately, approval was granted contingent on MD or DO supervision of the project (Appendix F).

Recommendations for Future Research

Results of this study provide evidence that there are asymptomatic patients with possibly significant PAD. Further research utilizing a longer implementation period would allow researchers to identify a number of things including further breakdown of high-risk groups, the ability to follow patients through intervention and potentially outcomes, and to partner with providers to guide them in decision making based on ABI results.

As PAD prevalence continues to rise, awareness too will increase. Future research in preventative interventions such as screening and initiation of walking programs will greatly benefit patients. Patients with a PAD diagnosis are now eligible for cardiac rehab, though there is a lack of research supporting cardiac rehab and vascular outcomes. Future research including intervention follow-up could enhance risk stratification and minimize atherosclerotic disease. Long-term follow-up of patients' disease progression and intervention outcomes would contribute to the evidence base for PAD screening and management.

The focus of this project was to increase screenings utilizing evidence-based guidelines. An additional benefit of a longer implementation period would be to include additional PAD risk factors such as gender, race and ethnicity, socioeconomic status, high-risk diagnoses including hypertension and hyperlipidemia, and social behaviors including exercise frequency and alcohol consumption.

Recommendation for Future Practice

Education for providers and nursing staff can enhance awareness of occult PAD and help the provider to become more vigilant to potential signs and symptoms of PAD, as well as more active regarding PAD screening, diagnosis, and treatment planning. ABI education enables rural clinics to offer increased testing that would otherwise be completed in an urban facility. Educating primary care providers on the different ways to utilize the non-invasive and simple to administer ABI test can improve patient care and outcomes.

Time was identified as a barrier to ABI screening in primary care. As a result, this co-investigator recommends the utilization of a visit where screening can be built into the allotted time slot. As this screening may take up to 20 minutes, a 60-minute appointment slot would be the preference for time allotment. Utilizing the AWV worked well for time allowance as the registered nurse had 60-minutes with the patient. In addition to ensuring a 60-minute visit, the visit should be scheduled in a specific room with an exam table.

The Ankle-Brachial Index has been utilized as a tool to diagnose PAD for many years while utilization as a screening tool is a relatively new practice. Bringing the knowledge of how to accurately measure the Ankle-Brachial Index to a rural clinic benefits more than individuals eligible for screening. Registered nurses are able to complete the test on symptomatic or asymptomatic patients, and the test can now be used as an additional screening and diagnostic tool for the providers in the rural clinic area.

The Diffusion of Innovation theory was used to guide this project from conception. As a relatively new idea in the selected primary care clinic, ABI screening was a challenge to implement into the clinic area. Many of the providers perceived there to be more potential drawbacks with the screening including time constraint, unnecessary testing and travel time for the patient, and potentially unnecessary treatments. Through education and support from early adopters, this project brought new information and increased skill to a rural health clinic. PAD and ABI education for rural primary care clinics ultimately benefits patients by reducing unnecessary commutes and improving care through earlier PAD detection and diagnosis.

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APPENDIX A: ANKLE-BRACHIAL INDEX COMPETENCY CHECK-OFF

1. Explain purpose of ABI screening and steps of procedure to patient.	
2. Instruct patient to remove shoes, socks, and long sleeves.	
3. Instruct patient to lie down in supine position.	
4. Position appropriately sized cuffs at each location of measurement including: Bilateral brachial and bilateral ankle.	
5. Allow patient to relax in supine position for 5-10 minutes.	
6. Takes artery measurement in "U" configuration starting with the right brachial artery, followed by the right dorsalis pedis, right posterior tibial, left dorsalis pedis, left posterior tibial, and left brachial.	
7. For each artery measurement: 1. Locate artery using doppler probe, place prove at a 45-60-degree angle to the surface of the skin. 2. Locates maximum flow, or the best quality sound, of artery with doppler probe. 3. Inflates cuff quickly to at least 20 mmHg above maximal pressure. 4. Deflates at 2 mmHg/second until a sustained (3 pulses in a row) systolic pressure is audible. 5. Deflates cuff quickly and completely. 6. Records systolic pressure at which a sustained pressure is heard in EMR.	
8. Notify provider of brachial systolic pressure >180.	
9. Calculate and record Ankle Brachial Index ratio in EMR.	
10. Inform patient results will be explained by provider during the provider portion of the visit.	

APPENDIX B: POST-EDUCATION SURVEY

Please answer the following questions below on the presented education:

1. Did this session meet your educational needs?

   ☐ Yes ☐ Somewhat. ☐ No

2. Did the information presented reinforce and/or improve your current skills?

   ☐ Yes ☐ Somewhat. ☐ No

3. Did the information presented provide new ideas/information you expect to use?

   ☐ Yes ☐ Somewhat. ☐ No

Please rate the projected impact of this education activity on your competence, performance, and/or patient outcomes:

4. This activity increased my competence

   ☐ Great Increase ☐ Moderate Increase ☐ No Increase

5. This activity will improve my performance

   ☐ Great Increase ☐ Moderate Increase ☐ No Increase

6. This activity will improve my patient outcomes

   ☐ Great Increase ☐ Moderate Increase ☐ No Increase

**Competence is defined as giving providers new abilities/strategies/knowledge with a strategy, or what a professional would do in practice if given the opportunity.*
*** Performance is defined as helping providers modify their practices.*

What barriers, if any, do you foresee regarding implementation of ABI screening within the clinic?

____

____

What benefits, if any, do you anticipate regarding implementation of ABI screening within the clinic?

____

____

APPENDIX C: ABI RESULTS TABLE

Patient Number	Age	Smoking Status	Diabetes Status	Right ABI Ratio	Left ABI Ratio
1	75	History Smoking	Not diabetic	2.3	2.3
2	73	History Smoking	Not Diabetic	1.06	1.05
3	73	Never	Not Diabetic	1.05	1.08
4	85	History Smoking	Not Diabetic	1.16	1.45
5	66	Never	Not Diabetic	0.92	1.16
6	75	History Smoking	Diabetic	1.25	1.04
7	73	Current Smoker	Not Diabetic	1.07	1.17
8	73	Occasional Smoker	Not Diabetic	0.84	1.07
9	68	Never	Not Diabetic	1.23	1.21
10	70	Never	Not Diabetic	1.1	1.1
11	74	Never	Not Diabetic	0.9	0.98
12	73	History Smoking	Not Diabetic	1.28	1.22
13	66	History Smoking	Not Diabetic	1.2	1.22
14	69	History Smoking	Pre-Diabetes	0.9	1.09

APPENDIX D: RN EDUCATION POWERPOINT

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PAD Brief and ABI Instruction

Kristen Hogan, RN, DNP-s
NDSU School of Nursing

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Peripheral Artery Disease

- Increasing prevalence worldwide, estimates of 200 million people affected
  - US prevalence 30% in high risk populations
    - Higher in African American and Hispanic populations
- Atherosclerotic disease – affects lower and upper extremities and the aorta
  - Atherosclerosis – build up of plaque in the artery causing narrowing of the artery
  - Most commonly occurs in areas of high turbulence such as bifurcations

Risk Factors

- Similar to risk factors for cerebrovascular and cardiovascular disease
  - Diabetes mellitus
  - Smoking
  - Hypertension
  - Hyperlipidemia
  - Family history
  - Chronic kidney disease

Symptoms

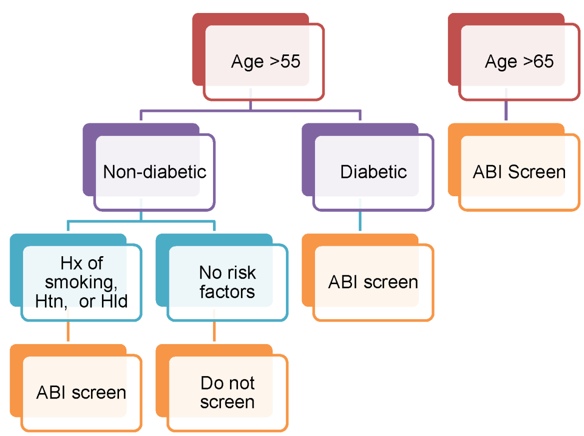
- 3 Categories of PAD presentation
  - Classic: claudication pain - leg pain with activity, relieved with rest
    - Luminal stenosis, thrombosis, or embolism resulting in reduced blood flow
    - Occurs in 10-35% of patients
  - Atypical: pain at rest, ulcers, or gangrene
  - Asymptomatic: accounts for about 50% of all cases

ABI Diagnosis

- Resting ABI is currently the primary method for establishing a PAD diagnosis
  - Simple, noninvasive, low-risk and low-cost test
  - Sensitivity 79-95%, Specificity >95%
- Can be completed by RN, LPN, technicians, and providers

Guidelines

- American College of Cardiology/American Heart Association (2011)
  - High-risk patients age >65, age >50 with a history of smoking or diabetes, and those with exertional leg pain
- Society for Vascular Surgery (2015)
  - Reasonable for asymptomatic patients age >70, smokers, and diabetics
- American Diabetes Association (2015)
  - Diabetics who are symptomatic
  - Asymptomatic diabetics, age >50 with at least one other risk factor (smoking, hypertension, hyperlipidemia, or duration of diabetes >50 years)
- European Society of Cardiology (2011)
  - Patients with coronary artery disease



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ABI Steps

- Equipment: Blood pressure cuff and handheld doppler
- Place patient in a quiet room for 5-10 minutes in a supine position
- Place blood pressure cuff on extremity
- Identify pulse with doppler
- Inflate cuff until pulse is no longer heard
- Release air slowly from cuff, when pulse is heard, that number indicates systolic pressure
  - Only need systolic pressure for this test, after systolic number is garnered, can release cuff
- Repeat process at ankle using posterior tibial and dorsalis pedis arteries
- https://stanfordmedicine25.stanford.edu/the25/ankle.html

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Calculating Ratio

- ABI ratio is determined by dividing the ankle systolic pressure by the brachial systolic pressure
  - If PT and DP pressures are different, the higher of the two should be used

$$\text{Right ABI} = \frac{\text{Highest Pressure in Right Foot}}{\text{Highest Pressure in Both Arms}}$$

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ABI Value	Interpretation	Recommendation
Greater than 1.4	Calcification / Vessel Hardening	Refer to vascular specialist
1.0 - 1.4	Normal	None
0.9 - 1.0	Acceptable	
0.8 - 0.9	Some Arterial Disease	Treat risk factors
0.5 - 0.8	Moderate Arterial Disease	Refer to vascular specialist
Less then 0.5	Severe Arterial Disease	Refer to vascular specialist

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Next Steps

- Results will be sent to providers
- Further testing
- Medication adjustments
- Referrals

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APPENDIX E: PROVIDER EDUCATION POWERPOINT

IMPLEMENTATION OF ANKLE-BRACHIAL INDEX TO SCREEN FOR PERIPHERAL ARTERY DISEASE IN HIGH RISK ASYMPTOMATIC POPULATIONS

Kristen Hogan, RN, DNP-s
North Dakota State University
School of Nursing

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Objectives

- Overview of peripheral artery disease
- Identify patients at risk for PAD
- Discuss role of Ankle-Brachial Index in diagnosis and screening of PAD
- Discuss next steps for abnormal ABI results

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Statement of Purpose

Prevalence of peripheral artery disease is increasing in the United States and worldwide, yet it still goes widely undiagnosed. Current guidelines support screening, yet ABI screening is not commonly used in primary clinic settings. Screening for high-risk populations can improve disease management and prevention.

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Peripheral Artery Disease: Epidemiology and Risk Factors

- Increasing prevalence worldwide, estimates of 200 million people affected
  - In Europe and North America, estimated 27 million individuals are affected by PAD
    - Accounts for about 413,000 inpatient admissions annually
  - Prevalence increased by 29% in low/middle income regions
- Risk Factors: similar to those for cardiovascular disease
  - Diabetes mellitus, Smoking, Hypertension, Hyperlipidemia, Family history, and Chronic kidney disease

Peripheral Artery Disease: Pathophysiology

- Progressive, atherosclerotic disease
  - Atherosclerosis affects vasculature of coronary, cerebral, and peripheral arteries and the aorta
  - Atherosclerotic process:
    - Fatty streaks
    - Foam cells
    - Fibrous plaque
  - Pathogenesis of atherosclerosis: endothelial dysfunction, dyslipidemia, inflammatory and immunologic factors, plaque rupture, and tobacco
- Plaque build up in the artery causes stenosis and reduced blood flow to the extremity
  - Plaque most commonly accumulates in areas of high turbulence

Peripheral Artery Disease: Clinical Presentation

- 2005 ACC/AHA guidelines suggest distribution of clinical presentation of PAD in patients >50:
  - Asymptomatic (20-50%)
  - Atypical leg pain (40-50%)
  - Classic Claudication (10-35%)
  - Threatened limb (1-2%)

Peripheral Artery Disease: Clinical Presentation Atypical Leg Pain

- May be more common than classic claudication due to comorbidities, physical inactivity and alterations in pain perceptions
  - Comorbidities that may make it difficult to separate contributions to extremity pain: arthritis, neuropathy, spinal stenosis, fibromyalgia, and statin-inducing myalgia
- Ischemic rest pain
  - Caused by severe decrease in limb perfusion
  - Typically localized to the fore foot and toes
  - Usually made worse with elevation of extremity and when the patient reclines
- Nonhealing wound/ulcer – usually begin as minor traumatic wounds that fail to heal due to insufficient blood supply

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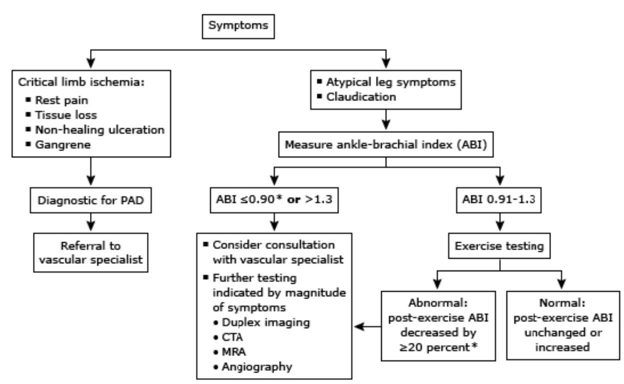
Peripheral Artery Disease: Clinical Presentation Classic Claudication

- Exertional leg pain beginning after a certain walking distance, causes patient to stop, resolves within 10 minutes of rest
  - Typically pain will reoccur after the same distance walking
- Can present unilaterally or bilaterally: buttock and hip, thigh, calf, or foot pain
  - Buttock and hip claudication: aortoiliac disease
    - Leriche syndrome: triad of claudication, absent or diminished femoral pulses, and erectile dysfunction
  - Thigh claudication: Common femoral artery
  - Calf claudication (most common complaint)
    - Pain in upper 2/3 of calf: superficial femoral artery
    - Pain in lower 2/3 of calf: popliteal
  - Foot claudication: tibial and peroneal vessels
    - Isolated foot claudication rare in PAD

Algorithm for vascular testing in symptomatic PAD



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Peripheral Artery Disease: Diagnosis

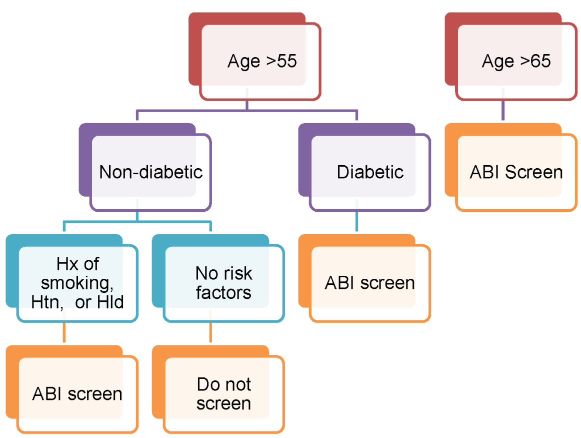
- Risk factors, symptoms, and physical exam findings may be enough to establish diagnosis
- Abnormal Arterial exam/tissue loss
- Ankle-Brachial Index
  - Formal lab testing may be required pending results of bedside ABI

Peripheral Artery Disease: Ankle-Brachial Index

- Simple, accurate, and relatively inexpensive
- Sensitivity 79-95%, specificity >95%
- Rationale for screening:
  - Early detection, early intervention to prevent disease progression and complications
  - Identify patients at increased risk for CAD and other CVD

Guidelines

- American College of Cardiology/American Heart Association (2011) ABI screening for high-risk patients including age >65, age >50 with a history of smoking or diabetes, and those with exertional leg pain.
- Society for Vascular Surgery (2015) ABI screening is reasonable for asymptomatic patients older than 70, smokers, and those with diabetes.
- American Diabetes Association (2015) ABI screening in diabetics who are symptomatic or asymptomatic and age >50 or have at least one other risk factor including smoking, hypertension, hyperlipidemia, or duration of diabetes >10 years.
- European Society of Cardiology (2011) ABI screening in patients with coronary artery disease.



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Ankle-Brachial Index: The Test

- Systolic pressure measured at the brachial, posterior tibial and dorsalis pedis arteries, bilaterally, working in a "U" shape
- Ratio calculated by dividing highest ankle pressure by highest brachial pressure

$$\text{Right ABI} = \frac{\text{Highest Pressure in Right Foot}}{\text{Highest Pressure in Both Arms}}$$

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ABI Value	Interpretation	Recommendation
Greater than 1.4	Calcification / Vessel Hardening	Refer to vascular specialist
1.0 - 1.4	Normal	None
0.9 - 1.0	Acceptable	
0.8 - 0.9	Some Arterial Disease	Treat risk factors
0.5 - 0.8	Moderate Arterial Disease	Refer to vascular specialist
Less then 0.5	Severe Arterial Disease	Refer to vascular specialist

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Additional Testing

- Segmental pressures – used to determine level and extent of disease
- Exercise testing – Sensitive test to further evaluate for disease if bedside ABI is normal and symptoms are present
- Ultrasound – used to evaluate location and extent of disease, arterial hemodynamics, and lesion morphology
  - Mainstay for noninvasive imaging, able to provide precise anatomical localization and accurate grading of lesion severity
- Advanced Imaging
  - CT angiography
  - MR angiography

Peripheral Artery Disease: Intervention

- Risk factor modification
- Smoking cessation
- Supervised exercise program
- Blood pressure management
- Statin therapy
- Aspirin therapy

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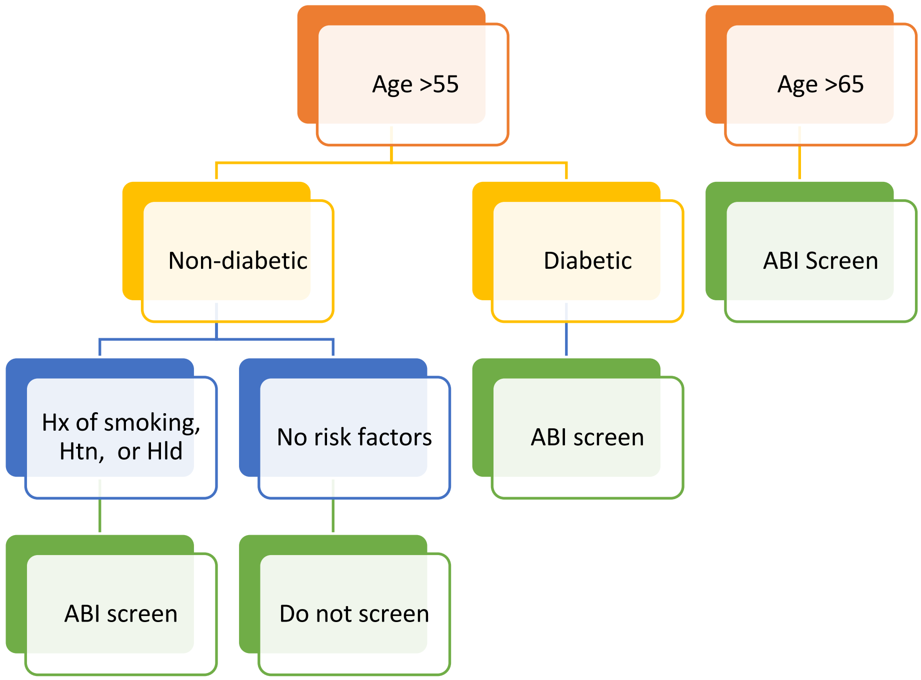
APPENDIX F: ABI SCREEN ALGORITHM AND ABI RANGES HANDOUT



ABI Value	Interpretation	Recommendation
Greater than 1.4	Calcification / Vessel Hardening	Refer to vascular specialist
1.0 - 1.4	Normal	None
0.9 - 1.0	Acceptable	
0.8 - 0.9	Some Arterial Disease	Treat risk factors
0.5 - 0.8	Moderate Arterial Disease	Refer to vascular specialist
Less then 0.5	Severe Arterial Disease	Refer to vascular specialist

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APPENDIX E: IRB APPROVAL LETTER

NDSU NORTH DAKOTA STATE UNIVERSITY

November 28, 2018

Dr. Mykell Barnacle
School of Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH19100, "Implementation of Ankle-Brachial Index to Screen for Peripheral Artery Disease in High-Risk Asymptomatic Populations"

Co-investigator(s) and research team: Kristen Hogan
Date of Exempt Determination: 11/28/2018 Expiration Date: 11/27/2021
Study site(s): Essentia Health - Wahpeton
Sponsor: n/a

The above referenced human subjects research project has been determined exempt (category #2b) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the protocol submission (received 11/21/2018).

Please also note the following:
- If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
- The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.
Sincerely,

Kristy Shirley

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX F: COMPLIANCE AND BILLING REQUIREMENTS

Rosenberg, Julie <Julie.Rosenberg@EssentiaHealth.org>
Fri 12/7/2018 10:49 AM
Hogan, Kristen

We are scheduled to meet with compliance next week on Wednesday.

Yes we will need to complete the education which we will do and have record of their competency. This may need to be provided/co-signed by Essentia staff.

Compliance indicates this must be supervised by MD or DO and not an NP. We should be able to accommodate this.

They want to research if this is being done in any other locations.

More to come……….sorry this is taking so long but this is often the process and delays we experience with these new projects.

Julie

APPENDIX G: ESSENTIA HEALTH PROJECT APPROVAL

Essentia Health

December 4, 2018

To whom it may concern,

Re: Implementation of Ankle-Brachial Index to Screen for Peripheral Artery Disease in High Risk Asymptomatic Populations

Thank you for submitting the Human Subject Research Determination Form and information for the project listed above. Based on a review of the documentation you provided, this project does not meet the definition of research with human subjects, according to the Office of Human Research Protections (OHRP) guidance: "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Because the project does not meet the federal definition of human subjects research, it will not require further review by the Essentia Health Institutional Review Board or a scientific review committee. If during the process of data collection or analysis it becomes clear that findings could be generalizable or benefit others, please submit your project for IRB review at that time.

If you have any questions concerning this letter, please contact me at 218-576-0489.

I wish you success with your project.

Sincerely,

Deneice Kramer

Deneice Kramer, MBA, MA, CCRP
Manager, Human Research Protection Program

502 East 2nd Street
Duluth, MN 55805

essentiainstitute.org

APPENDIX H: EXECUTIVE SUMMARY

IMPLEMENTATION OF ANKLE-BRACHIAL INDEX TO SCREEN FOR PERIPHERAL ARTERY DISEASE IN HIGH RISK ASYMPTOMATIC POPULATIONS

STATEMENT OF PURPOSE

Prevalence of peripheral artery disease is increasing in the United States and worldwide, yet it still goes widely undiagnosed. Current guidelines support screening, yet Ankle-Brachial Index (ABI) screening is not commonly used in primary clinic settings. Screening for high-risk populations can improve disease management and prevention.

PROJECT OBJECTIVES

1. Educate providers and nurses on pathophysiology of peripheral artery disease, the Ankle-Brachial Index screen, and proper technique for measurement of ABI.
2. Develop a risk factor algorithm to identify high risk patients eligible for ABI screening.
3. Increase screening of asymptomatic high-risk populations in the primary care setting during the 2-month period following educational intervention.

EVALUATION PLAN

Objective one: *Educate providers and nursing staff on pathophysiology of peripheral artery disease, the Ankle-Brachial Index screen, and proper technique for measurement of ABI*. During an educational meeting, nurses were evaluated on technique and proficiency of their skill and performance. Skill check-off was required prior to any nurse completing the screening on a patient.
A post-education survey was utilized to assess confidence, perceived competency, and perceived patient outcomes related to abnormal ABI values. The survey was distributed during the presentation and collected prior to meeting dismissal.

Objective two: *Develop a risk factor algorithm to identify high risk patients eligible for ABI screening*. The algorithm was distributed to each provider working in the clinic either at the educational session or via email. Prior to implementation, the algorithm was reviewed with the co-investigator and providers at the clinic. The algorithm was approved for use and demonstrated simplicity and ease of use.

Objective three: *Increase screening of asymptomatic high-risk populations in the primary care setting during the 2-month period following educational intervention*. Screening will take place during the Medicare Annual Wellness Visit (AWV). The researcher was present for the initial test day; however, only one patient was available for screening and declined. Further oversight by this researcher included weekly check-ins either in person or through email. Questions were answered in a timely manner as to not delay the screening process. Results were recorded on a spreadsheet to access key information such as age, smoking status, diabetes status, and ABI results.

RESULTS INTERPRETATION

SURVEY RESULTS

Quantitative data was garnered through a post-education Likert-style survey. Eight providers participated in the meeting, and eight (100%) participants responded to the Likert-style questions. The first three questions were used to determine relevance of the information provided. The three consecutive questions were used to determine perceived impact on patient outcomes and practice change. The majority of the providers found the presented information to be significant in improving comprehension and skill of identifying PAD, utilizing ABI test results in practice, and screening patients with the ABI test.

The response rate for the qualitative questions was less robust than the Likert scale questions. Five (62.5%) of eight participants completed the potential barriers portion of the survey. Of the five, four (80%) indicated that time would be the biggest barrier. One (20%) participant identified “Patient compliance with preventative strategies; staff availability for screening and interest” as potential barriers. Six respondents (75%) listed potential benefits with common themes of early intervention and improved patient outcomes. Three (50%) participants responded, “early identification”.

Information gleaned from the qualitative question regarding potential barriers validated limitations of previous PAD screening studies and potential limitation of the current project. Inferences were made that time may be a limiting factor, and thus taken into account during the design of the project. Deductions previously made that screening may lead to earlier detection and slowing of possible disease progression were validated in the comments of the providers after the educational session. Results of the qualitative questions suggested if barriers, such as time constraints, can be managed, potential benefits of screening may be great.

SCREENING RESULTS

The nurses were able to screen 14 patients during the two-month period. Of the 14 patients, 11 (78.6%) had ABI ratios within the normal limits (0.9-1.4), and three (21.4%) patients had positive ratio results. All three patients with positive results had a smoking history, either current or former. Results from the ABI screen reinforce the assertion that smoking is the most harmful PAD risk factor. Only one patient screened had a diagnosis of diabetes, ABI results for that individual were within normal limits. Another patient had a diagnosis of pre-diabetes and ABI results were borderline with a right ABI ratio of 0.9. While diabetes is a significant risk factor for PAD, the sample size of this study was too small to make inferences based on ABI results.

RECOMMENDATION FOR FUTURE PRACTICE

Education for providers and nursing staff can enhance awareness of occult PAD and help the provider to become more vigilant to potential signs and symptoms of PAD, as well as more active regarding PAD screening, diagnosis, and treatment planning. ABI education enables rural clinics to offer increased testing that would otherwise be completed through referral to an urban facility. Educating primary care providers on the different ways to utilize the non-invasive and simple to administer ABI test can improve patient care and outcomes.

Time was identified as a barrier to ABI screening in primary care. As a result, the researcher recommends the utilization of a visit where screening can be built into the allotted time slot. As this screening may take up to 20 minutes, a 60-minute appointment slot would be the preference for time allotment. Utilizing the AWV worked well for time allowance as the registered nurse had 60-minutes with the patient. In addition to ensuring a 60-minute visit, the visit should be scheduled in a specific room with an exam table.

The Ankle-Brachial Index has been utilized as a tool to diagnose PAD for many years while utilization as a screening tool is a relatively new practice. Bringing the knowledge of how to accurately measure the Ankle-Brachial Index to a rural clinic benefits more than just screening. Registered nurses are able to complete the test on symptomatic or asymptomatic patients, and the test can now be used as an additional screening and diagnostic tool for the providers in the rural clinic area.