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Project Ankle-Brachial Index: Implementation of an Evidence-based Peripheral Artery Disease Protocol

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A DNP Project Submitted to the
Graduate Faculty
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in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Nursing Practice

By

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Abstract

Background: Peripheral artery disease (PAD) is a narrowing or blocking of the arteries due to plaque buildup, which prevents oxygen, blood, and other nutrients from getting to the legs. When this buildup reaches a certain point, it becomes atherosclerosis, which is more prevalent in a smoker. Smoking intensifies the problem of plaque buildup if an individual already suffers from PAD. When an individual smokes, the nicotine causes the arteries to constrict and narrow, reducing blood flow further. The ankle-brachial index (ABI) is a simple, cost-effective diagnostic test to identify the presence of PAD which will improve patient outcomes.

Purpose: This DNP project aimed to increase routine screening for PAD in high-risk patients by utilizing an evidence-based screening protocol.

Methods: This process change project consisted of modifying the current process used in a cardiology clinic to increase screening of PAD in adult smokers. Data collected from a retrospective chart review before implementation of the protocol was compared to amount of screening that occurred following implementation of the protocol.

Results: There was a statistically significant increase (p=.0007) in rate of screenings from pre-intervention (3.4%) to post-intervention (47.6%). There was no statistically significant difference (p=.018) between the pre-intervention group (3.4%) and the post-intervention group (19.0%) on the detection of PAD.

Conclusion: This project showed the importance of identifying peripheral artery disease in high-risk patients and increased screening for peripheral artery disease in smokers aged 50 and older.

Keywords: peripheral artery disease, ankle-brachial index, smoking

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Project Ankle-Brachial Index: Implementation of an Evidence-based Peripheral Artery Disease Protocol

Gerhard and Gornik (2017) recognized that lower extremity peripheral artery disease (PAD) is a common cardiovascular disease that affects approximately 8.5 million Americans above 40 years of age and 202 million people worldwide. It is associated with significant morbidity, mortality, and quality of life (QoL) impairment. Caused by atherosclerosis or plaque buildup, PAD reduces blood flow in peripheral arteries that carry blood away from the heart to other body parts (Gerhard & Gornik, 2017). In 2016, the American Heart Association (AHA) updated its guidelines for managing patients with lower extremity PAD (Appendix A).

This project aimed to address the lack of consistency in screening for PAD in high-risk patients. The American Heart Association (2021) defines high-risk patients as one of the following: (a) age≥65 years; (b) age 50-64 years, with risk factors for atherosclerosis (e.g., diabetes mellitus, history of smoking, hyperlipidemia, hypertension) or family history of PAD; (c) age <50 years, with diabetic mellitus and one additional risk factor for atherosclerosis, and (d) individuals with known PAD. In patients with a history or physical examination findings suggestive of PAD, the resting ankle-brachial index (ABI), with or without segmental pressures and waveforms, is recommended to establish the diagnosis (American Heart Association, 2021).

Background

Bevan and White Solaru (2020) identified PAD as a chronic, atherosclerotic disease that results in limb-associated complications such as intermittent claudication, gangrene, and functional impairment. Sequelae requiring amputation carry a mortality rate of ≤50% at one year (Bevan & White Solaru 2020). Gerhard and Gornik (2017) recognized that PAD presents in

many clinical forms, many asymptomatic. Knowing the risk factors for lower extremity PAD will assist with diagnosing and treating this disorder.

Tobacco use is one of the most substantial risk factors for lower extremity PAD. There is a robust correlation between smoking and PAD; approximately 90% of patients with PAD have a history of smoking. Smoking even half a pack of cigarettes a day may increase the risk of having PAD by up to 50% (Gerhard & Gornik, 2017). Bevan and White Solaru (2020) observed only about 10% to 25% of adults with PAD have symptoms of intermittent claudication. Another 20% to 50% are asymptomatic and do not have leg symptoms. In 1% to 2% of adult patients, a severe form of lower extremity critical limb ischemia has been observed. The medical community has widely disregarded asymptomatic PAD due to the erroneous belief that it is benign (Bevan & White Solaru 2020).

Contrary to this belief, Criqui and Matsushita (2021) found asymptomatic and symptomatic PAD patients similarly increased cardiovascular mortality risk. Early recognition of the clinical manifestations of PAD and the use of guideline-directed medical treatment will help improve the quality of care for these patients. The ABI can screen for and diagnose PAD in the primary care setting. An ABI of less than 0.9 is associated with a two- to four-fold increase in relative risk for cardiovascular events and all-cause mortality. The AHA recommends ABI screening for patients 50 years and older with a smoking history (Criqui & Matsushita, 2021).

Health Risks

American Heart Association (2021) identified smoking as the leading risk factor for clinical cardiovascular disease directly affecting atherosclerosis. Studies have shown smoking affects the composition and distribution of blood lipids, accelerates the formation of aortic plaques, and increases the total cholesterol content, thereby inducing atherosclerosis. Smoking

contributes to endothelial dysfunction and monocytes' activation in PAD formation. Cigarettes also cause the production of various chemokines and proinflammatory cytokines. PAD is more prevalent in smokers because of the lack of relaxation and contraction of smooth muscle in the arterial wall. PAD can lead to complications, including trouble managing daily activities without help due to reduced mobility, chronic, long-term, or poor blood flow in the leg, called critical limb ischemia, serious infections, or a sudden drop in blood flow to the leg, called acute limb ischemia. Acute limb ischemia (ALI) is a medical emergency. Over half of all amputations are due to vascular conditions, including PAD. These conditions could result in the need for amputation (American Heart Association, 2021).

Health Benefits from Screening

Haigh (2016) found two potential reasons to consider PAD screening. First, screening for PAD may lead to early detection and treatment of PAD before clinical presentation, which may slow the progression of atherosclerosis and resultant functional decline. Second, because PAD is considered an essential manifestation of systemic atherosclerosis, screening for PAD in asymptomatic individuals may lead to early cardiovascular death (CVD) risk-factor modification in individuals with undiagnosed atherosclerosis. The ABI is sensitive, symptom independent, non-invasive, and cost-effective and has proven efficacy for community screening of high-risk patients. In addition to its ability to detect PAD, an abnormal ABI may help improve the calibration or discrimination of traditional risk-factor models to predict cardiovascular death (CVD). It may appropriately reclassify risk in some individuals, leading to more aggressive medical management (Haigh, 2016).

Plans to Increase Screening

Efforts to increase screening began with updating the patient intake form. The patient's smoking status and age were added to the already established ABI form the cardiology clinic uses (Appendix B). The intake form was used to identify which patients met the inclusion criteria for the project. If the patient was a smoker over 50, the medical assistant proceeded with the ABI. Gerhard and Gornik (2017) described resting ABI as the most used screening and diagnostic test for PAD. The ABI is the ratio of systolic blood pressure at the ankle to the systolic blood pressure at the brachial artery. Standardized reporting improves communication among healthcare providers. Calculated ABI values should be recorded to two decimal places. The normal ABI is 1.0 to 1.4. Patients with ABI ≤0.90 are diagnosed with PAD. Those with ABI 0.91 to 0.99 may possibly have PAD (Appendix C). Values >1.40 indicate the arteries are not able to be compressed, which is more common among individuals with diabetes mellitus and advanced chronic kidney disease (Gerhard & Gornik, 2017)

Nurse's Delivery of PAD Counseling

Educating patients about PAD and its treatments should begin with explaining the disease, risk factors, complications, and long-term effects. Patient-centered communication in which the clinician aims to understand the individual patient's symptoms and healthcare goals can help patients feel at ease with their care management plan. AHA (2021) acknowledges that knowledgeable patients are more likely to discuss PAD symptoms and treatment recommendations with healthcare professionals. Thoroughly answering questions, and asking patients about their concerns, can also help improve adherence to medical treatments and lifestyle changes (AHA, 2021).

Needs Assessment

The cardiology clinic is privately owned and has no affiliation with any hospital. The clinic prides itself on providing convenient, comprehensive cardiology care. Approximately 200 patients are seen in the clinic each month. The clinic offers comprehensive care and all cardiovascular services, including on-site testing.

Gap Analysis

The cardiology clinic provides screening for PAD and accepts referrals to evaluate for PAD. However, not all high-risk patients are routinely screened. The clinic currently screens patients referred for evaluation with clear evidence of PAD or symptomatic. The patient will either undergo an ABI screening or perform an arterial duplex. The primary population is geriatric cardiac patients with arrhythmias, coronary artery disease, or heart failure complications. Although the primary focus is cardiac, many patients are also seen for vascular disease.

Mayer and Bishop (2017) revealed high-risk patients infrequently receive limb-sparing treatments. The disease often progresses to the point of irreversible damage. Disease progression occurs due to a lack of awareness of both patients and health care providers, limited availability of diagnostic tests, and delayed referral for endovascular evaluation. A review of over 20,000 Medicare patients who underwent a significant amputation for critical limb ischemia showed that 71% had no revascularization attempts, and 46% had no diagnostic angiogram before a major amputation. Another study demonstrated that primary amputation was the first procedure for treating critical limb ischemia in 67% of Medicare patients (Mayer & Bishop, 2017).

Gerard and Gornik (2017) found that measuring the resting ABI is reasonable in patients at increased risk of PAD but without history or physical examination findings suggestive of

PAD. The ABI test is non-invasive, simple to perform, has minimal risks, and is suitable for asymptomatic individuals. Abnormal resting ABI readings are prevalent among asymptomatic patients with risk factors for PAD. Also, asymptomatic patients with an abnormal ABI have poorer cardiovascular morbidity and mortality outcomes than patients with normal ABI (Gerard & Gornik, 2017).

Closing the gap and meeting the need will be achieved by identifying patients at risk for asymptomatic PAD who may benefit from ABI screening. The modified patient intake form determined which patients met the inclusion criteria. Mayer and Bishop (2017) discovered millions of PAD patients are undertreated, despite proven cardiovascular risks and established guidelines for treatment. Often patients with PAD are asymptomatic, so diagnosis frequently occurs after permanent damage has occurred, resulting in a high rate of morbidity, amputation, and loss of life. Early diagnosis with ongoing treatment can reduce debilitating morbidity and improve patient outcomes (Mayer & Bishop, 2017).

SOAR Analysis

A SOAR analysis is a strategic planning framework that focuses on strengths and seeks to understand the whole system. Using a SOAR analysis, an organization focuses on what they are doing well, what can be improved, and what is most important to stakeholders. Using SOAR, strategic plans can be more dynamic, creative, and optimistic (University of Missouri Library, n.d.). SOAR is an acronym for strengths, opportunities, aspirations, and results. The SOAR analysis conducted for the project facility revealed that the clinic's strength was screening patients for PAD referred to the clinic. However, there was an opportunity for growth in identifying PAD in all high-risk patients that came through the clinic. The staff aspires for consistent, quality patient care. Through conversations, it was determined the frequency of PAD

screening could be improved. The office staff revealed they could successfully identify PAD in more patients by identifying high-risk patients and screening with the ABI.

Problem Statement

Gerhard and Gornik (2017) expressed that PAD is underdiagnosed, undertreated, and underappreciated. More than one million people in the United States (U.S.) have lost a limb due to vascular disease, including diabetes, PAD, and critical limb ischemia; approximately half of the individuals with limb loss due to vascular disease die within five years of the amputation. Up to 85% of these amputations could have been delayed or prevented through patient education, lifestyle modification, early diagnosis, and endovascular intervention (Gerhard & Gornik, 2017). Smoking is the greatest single danger to the health of the arteries. Smoking puts individuals at higher risk for PAD. Identification of PAD, through ABI screening, improves the health of high-risk populations.

The PICOT question answered through this project was: Among smokers over 50 (P) seen in a cardiac clinic, does the implementation of an evidence-based peripheral artery disease screening protocol (I), versus no protocol (C), increase screening (O) of PAD over 60 days (T)?

Aims and Objectives

This project aimed to increase screening for PAD in high-risk patients. The overarching objectives of this project were to: The objectives of this project were to (a) increase PAD screening in adult smokers in a cardiology clinic; (b) improve utilization of the ABI to identify PAD; (c) integrate utilization of an evidence-based PAD screening protocol; (d) demonstrate nurse awareness and adherence regarding the delivery and effectiveness of the screening protocol; and (e) enhance nursing documentation of peripheral artery disease counseling.

Review of Literature

A literature review was performed with the following primary considerations: (a) best practice in screening for PAD in high-risk patients and (b) prevalence of PAD in smokers. The databases utilized were CINAHL and PubMed. The following key terms were used in CINAHL: peripheral artery disease, smokers, and screening, which yielded 924 results. Results were narrowed using peer-reviewed academic journal limits from 2016 until now, reducing potential sources to 369. The term screening was added to the search, which narrowed the search to 13 references. Additional articles were eliminated due to content irrelevance if smoking was not a risk factor for the patient and were not available in full text or English.

The following Mesh key terms were applied in PubMed: *peripheral artery disease, ankle-brachial index, screening, and smokers* with 319 hits. The same inclusion and exclusion criteria were applied to these articles. References of the selected papers were also searched and evaluated for application to the study question. Results were narrowed using limits of five years and additional modifiers to the Mesh terms: peripheral artery disease/methods, smoker/screening, statistics, and numerical data to 46 hits. Many key findings from the literature review included systematic reviews or guidelines suggestions. Some of the significant critical results used to shape the methodology of this project are identified below.

Allison et al. (2020) conducted a multiracial/ethnic cohort study free of known cardiovascular disease (CVD). This study sought to assess the disease burden of lower extremity PAD on total mortality, incident CVD events, and CVD mortality using the non-invasive ABI in a primary prevention population. There were six thousand eight hundred and fourteen non-Hispanic White, non-Hispanic Black, Hispanic, or Chinese men and women 45–84 years of age and free of clinically apparent CVD were recruited from six communities in the United States

and participated in the baseline examination. To score the burden of PAD, individuals were classified as having 0-, 1-, 2-, 3-, or 4-vessel PAD based on the number of ankle arteries with an ABI of ≤0.9. Furthermore, individuals were classified as having unilateral PAD, bilateral PAD, or none based on the number of legs with an ABI of ≤0.9. Of the 6,814 individuals, the authors excluded 138, leaving a final analytical sample size of 6,527. Descriptive characteristics across the number of vessels with PAD were computed by analysis of variance for continuous variables and χ^2 for categorical variables. Over a mean follow-up time of 13years, there were 1,202 (18.4%) deaths, of which 282 (4.3%) were CVD-related. With a mean follow-up time of 12.1 years, there were 656 (10.1%) incidents of CVD events. Of the participants, 5,711 (87.5%) had 0-vessel, 460 (7.0%) had 1-vessel, 218 (3.3%) had 2-vessel, 69 (1.1%) had 3-vessel, and 69 (1.1%) had 4-vessel PAD. Of those with 2-vessel disease, 114 (52.2%) had a traditional ABI of >0.9 in both legs. When examining laterality, 6,285 (96.3%) had no legs with PAD, 173 (2.7%) had unilateral PAD, and 69 (1.1%) had bilateral PAD. The authors found that multivessel PAD had a dose-dependent association with increased risk for mortality, incident CVD events, and CVD mortality in a diverse primary prevention population. This dose-dependent association persisted after adjustment for potential confounders. Furthermore, the dose-dependent association persisted even when conventional ABI values were included in the model (for mortality) and when the analysis was restricted to asymptomatic individuals. These data supported using all four ABI values instead of a single representative value in clinical practice and research. Additionally, the results highlighted the prognostic importance of the magnitude of lower extremity atherosclerosis on mortality, incident CVD, and CVD mortality (Allison et al., 2020).

In comparison, Kieback et al. (2019) observed the most important criterion for the definition of PAD is an ABI reading below 0.90. Low ABI is associated with increased mortality and morbidity. Thereby, ABI is not only a diagnostic indicator but also an important prognostic marker. ABI measurements are rarely performed in the clinic unless the patient has mentioned claudication symptoms. Vascular specialists usually only perform these measurements for PAD diagnosis and follow-up after interventional or surgical PAD treatment. The meta-analysis within the study used data from seven German population-based cohorts performed by the German Epidemiological consortium of Peripheral Arterial Disease (GEPArD) to investigate whether one question about claudication is more efficient for PAD screening than established questionnaires. Claudication was defined based on the answer to one question asking for pain in the leg during normal walking. This simple question was compared with established questionnaires, including the Edinburgh questionnaire. The associations of claudication with continuous ABI values and decreased ABI were analyzed by linear and logistic regression analysis. The results of the studies were pooled in a random effect meta-analysis, which included data from 27,945 individuals (14,052 women, age range 20–84 years). Meta-analysis revealed a significant negative association between claudication and ABI, which was stronger in men (β = -0.07; 95% CI -0.10, -0.04) than in women (β = -0.02; 95% CI -0.02, -0.01). Likewise, claudication symptoms were related to increased odds of decreased ABI in both men (Odds ratio = 5.40; 95% CI 4.20, 6.96) and women (Odds ratio = 1.99; 95% CI 1.58, 2.51). The data demonstrated that even one simple question about claudication could help identify individuals with PAD. However, these results do not negate the advantages of a PAD screening by ABI measurement. An ABI measurement allows for identifying individuals with asymptomatic PAD, especially in older women. Depending on laboratory values, ABI measurements may be less time-consuming and cheaper

than PAD prediction models. With the availability of simple and user-friendly automated systems for evaluating ABI, PAD screening by ABI measurements has become easier. If ABI screenings are not established in healthcare systems, asking one quick, simple question for claudication is preferable to no PAD screening (Kieback et al., 2019).

Jones and Patel (2018) discussed findings from the Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories (PORTRAIT) clinic trial. The researchers aimed to examine smoking rates and cessation interventions offered to patients with PAD by consulting a vascular specialty clinic and assessing changes in smoking behavior over the year following the initial visit. One thousand two hundred and seventy-two patients with PAD and new or worsening claudication were enrolled at 16 vascular specialty clinics. Interviews collected smoking status and cessation interventions at baseline, three, six, and 12 months. Among smokers, transition state models analyzed smoking transitions at each time point and identified factors associated with quitting and relapse. On presentation, 474 (37.3%) patients were active, 660 (51.9%) former, and 138 (10.8%) never smokers. Only 16% were referred to cessation counseling among active smokers, and 11% were prescribed pharmacologic treatment. At three months, the probability of quitting smoking was 21%; among those continuing to smoke at three months, quitting during the next nine months varied between 11% and 12% ($p<0.001$). The probability of relapse among initial quitters was 36%. At 12 months, 72% of all smokers continued to smoke. More than one-third of patients with claudication consulting a PAD provider were active smokers, and few received evidence-based cessation interventions. Patients appeared to be most likely to quit early in their treatment course, but many quickly relapsed, and 72% of all patients smoking at baseline were still smoking at 12 months. Better strategies were needed to provide continuous cessation support. The study

provided current real-world data on smoking behavior and cessation practices in patients with PAD (Jones & Patel, 2018).

In contrast, Szilagyi and Toth-Vajna (2019) indicated smoking was a significant risk factor. Smoking increased the risk of occurrence two to six times. These risk factors further improved with the amount and years of smoking. Smoking has a closer connection with lower extremity PAD than with coronary diseases. The percentage of active smokers was highest in the clear PAD-positive group, one and a half times the Hungarian average. The rate of former smokers was also the highest, as opposed to the clear PAD-negative group, which was at half the Hungarian average. Nearly a quarter of the population fell into the non-compressible artery and ABI-negative symptomatic groups, defined as the 'murky zone'. When screening for PAD, these patients deserve special attention due to the insufficient selectivity and sensitivity of measurements. Further assessment may be considered if there is high clinical suspicion of PAD despite typical ABI values. The general practitioner's (GP) role is vital in preventing and early recognition of PAD. The researcher's complex approach enabled the practitioner to identify at-risk patients who belong to the 'murky zone.' These patients would remain invisible to doctors using instrumental measurements only, requiring further examination from a differential diagnostic perspective. In the long run, launching a complex screening program at the GP level makes PAD patients easier to diagnose, leading to an earlier start of treatment and significantly improving the patients' quality of life and life expectancy (Szilagyi & Toth-Vajna, 2019).

Anand et al. (2018) discovered patients with lower extremity PAD are at increased risk of major adverse limb events (MALE). Cardiovascular Outcomes for People
Using Anticoagulation Strategies (COMPASS) was a multi-center, double-blind, randomized, placebo-controlled trial. The authors analyzed outcomes in 6,391 patients with lower extremity

PAD enrolled in COMPASS. A total of 128 patients experienced an incident of MALE. After MALE, the 1-year cumulative risk of a subsequent hospitalization was 61.5%, 20.5% for vascular amputations, and 8.3% for death. The authors found the prevention of MALE is of paramount importance among individuals with lower extremity PAD. The prognosis after experiencing MALE is dire, with a three-fold increase in death and a 200-fold increase in the risk of subsequent vascular amputation, making prevention of this condition of utmost importance (Anand et al., 2018).

Likewise, Gundrum et al. (2018) conducted an extensive, observational study to characterize hospitalizations and outpatient endovascular revascularizations following peripheral artery revascularization, assessing temporal trends for outcomes and identifying factors associated with subsequent MALE hospitalization. Data for this study were from the Premier Healthcare Database, which contained de-identified data from >687 million patient encounters or approximately one in every five discharges in the United States. Patients ≥18 years of age with at least one diagnosis code for PAD and one procedure code for peripheral revascularization were discharged between January 1, 2009, and September 30, 2014, for inclusion in this study. Multivariable logistic regression was used to identify factors associated with hospitalization for MALE within one year after discharge from the index encounter. In this study of 381,415 patients undergoing peripheral artery revascularization, subsequent hospitalizations and outpatient endovascular revascularization procedures were common. Within one year after the index revascularization, many patients were hospitalized for limb-related and cardiovascular causes, with one in 10 admitted for MALE. Although subsequent hospitalizations trended down during the study period, the residual risk for post-procedure limb-related and cardiovascular events remained high. The authors identified multiple demographic, patient, and procedural

factors associated with MALE's one-year hospitalization risk. Based on these findings, efforts to reduce the burden of comorbidities, improve surgical revascularization techniques and implement a multidisciplinary approach to the care of PAD patients represented actionable strategies to reduce hospitalization for MALE (Gundrum et al., 2018).

Lee and Lin (2016) conducted a retrospective cohort study. The study was conducted at the Division of Endocrinology and Metabolism in Taichung Veterans General Hospital. The researchers reviewed the medical records of adults who had undergone ABI assessment because they were suspected of having a high risk of PAD based on their clinical manifestations, including intermittent claudication, pulseless, pallor, paralysis, or paresthesia in the lower extremities. A total of 314 participants were included in the analyses. The $\chi 2$ test examined differences in categorical variables across study groups. Participants with ABI ≤ 0.9 showed the highest mortality rate (45%) and higher risk of all-cause mortality after adjustment for ABI, pulse wave velocity, age, sex, blood pressure, serum cholesterol, and history of cardiovascular disease and diabetes. The researchers demonstrated a high percentage of mean arterial pressure based on pulse volume recording in participants with ABI<0.9 could predict all-cause mortality during 20.3 months of follow-up (Lee and Lin, 2016).

Similarly, in a cross-sectional analysis, Mostaza and Rio (2017) acknowledged an ABI <0.90 indicated the presence of a flow-limiting arterial disease affecting the limb. The authors also found the accuracy of the ABI for detecting >50% stenosis in the leg arteries is high, with a 75% sensitivity and 86% specificity. One thousand five hundred and sixty-eight subjects (43% males) were randomly selected from the population. A fasting blood sample was obtained to determine glucose, lipids, and HbA1C levels. An oral glucose tolerance test was performed on non-diabetic subjects. PAD was evaluated by ankle-brachial index or having a prior diagnosis.

PAD prevalence was 3.81% (95% CI, 2.97–4.87). In men, PAD prevalence was significantly higher than in women [5.17% (95% CI, 3.74–7.11) vs. 2.78% (95% CI, 1.89–4.07); p = 0.014]. There were statistically significant differences between ABI categories concerning smoking status. The analysis revealed that ABI was a consistent independent risk factor for cardiovascular events and mortality. Furthermore, the ABI is recommended to detect subclinical PAD and offer early therapeutic interventions to lower the risk of cardiovascular events and mortality. The positive association between smoking status and PAD is well established and habitually found in most research studies, and this study is consistent with these findings (Mostaza & Rio, 2017).

Szilagyi and Toth-Vajna, (2019) conducted a qualitative study that revealed lower extremity PAD is often diagnosed late in general practice. Current recommendations suggest the use of non-invasive ABI measurement for screening. The ABI measurement of sensitivity and specificity for lower extremity PAD can be estimated between 79% and 96%. ABI may indicate abnormalities even before the patient develops complaints of claudication. Based on ABI measurements, the study categorized nearly a quarter of all examined patients into the clear PAD-positive group. Eight hundred and sixteen patients were screened. The researchers used the Edinburgh Questionnaire and recorded medical histories, major risk factors, current complaints, and medication. Physical examinations were performed, including ABI testing. Thirty-three percent complained about lower extremity claudication, 23% had abnormal ABI values, 13% of the patients within the normal ABI range had complaints of dysbasia, and 12% were in the non-compressible artery group. The ABI-negative symptomatic group's risk factor profile was similar to the clear PAD-positive and non-compressible artery groups. These findings match the data of similar analyses. It is important to note a quarter of these patients were asymptomatic, as the lack

of complaints further hinders the recognition of PAD by the general practitioner (Szilagyi & Toth-Vajna, 2019).

Chen et al. (2019) summarized the Atherosclerosis Risk in Communities (ARIC) study that enrolled 15,792 participants aged 45 to 64 from four U.S. communities. In this community-based cohort with nearly three decades of follow-up, all smoking measures (pack-years, duration, intensity) demonstrated considerably stronger associations with PAD than coronary heart disease (CHD) or stroke. Baseline characteristics of the study population were compared according to smoking status (current, former, never) at baseline. Cox regression models were used to quantify the associations between smoking measures (pack-years of smoking, duration, intensity [packs/day], and cessation) and the incidence of PAD. Smoking cessation was associated with the most significant risk reduction for PAD among these atherosclerotic diseases. Compared with current smokers, those with smoking cessation for five to <10 years showed a hazard ratio of ~0.4 for PAD (Chen et al., 2019).

According to Chen et al. (2019), a significantly elevated risk was observed for up to 30 years for PAD with never smokers as a reference. The results further highlighted the importance of smoking prevention and early smoking cessation. The authors indicated the need for public statements to consider PAD when acknowledging the impact of smoking on overall cardiovascular health. All smoking measures tested in the study were strongly associated with a long-term risk of three major atherosclerotic diseases, but the association was robust for PAD. The elevated risk of PAD was prolonged up to 30 years after smoking cessation. The study provided evidence for an anti-smoking campaign to continue to advocate smoking prevention and cessation. Although public statements about smoking have focused on coronary artery disease and stroke, these results indicated the need to take account of PAD and comprehensively

acknowledge the effect of smoking on overall cardiovascular health. The results of this cohort study have important public health implications. It is essential to recognize that the risk of atherosclerotic diseases started to decline after smoking cessation in a short timeframe of <5 years, which would encourage persons attempting or considering quitting smoking (Chen et al., 2019).

Duval et al. (2015) equally correlated tobacco use to increased PAD-related hospitalizations, coronary heart disease, PAD procedures, and significantly greater costs. A retrospective, cross-sectional study design was used. The researcher restricted the study population to individuals with 12 months of continuous plan enrollment to assure that clinical event and cost data collection were maximally complete. The primary study population focused on all continuous medical plan enrollees (the total PAD cohort). A PAD cohort of 22,203 was identified, comprising 1,995 (9.0%) tobacco users. A subgroup of 9,027 with pharmacy benefits included 1,158 (12.8%) tobacco users. The total cohort experienced 22,220 hospital admissions. The pharmacy benefits subgroup experienced 8,152 admissions. Within one year, nearly one-half of the PAD tobacco users were hospitalized, 35% higher than nonusers in the total cohort ($p < 0.001$) and 30% higher in the subgroup ($p < 0.001$). In both cohorts, users were more frequently admitted for peripheral or visceral atherosclerosis ($p < 0.001$). Observed costs in the total cohort were $64,041 for tobacco users versus $45,918 for nonusers. Tobacco users' costs were also consistently higher for professional and facility-based care, persisting after adjustment for age, sex, comorbidities, and insurance type. Tobacco use in patients with PAD is associated with a considerable increase in hospitalized clinical events. When individuals with PAD smoke, a much higher fraction of hospitalized events are due to adverse cardiac and PAD ischemic events. The tobacco-related detrimental health impact was associated with a substantial 30% increase in

annual health expenditures. This smoking-attributable health and economic burden strongly suggested that tobacco cessation programs would be especially cost-effective for this population (Duvall et. at, 2015)

In summary, lower extremity PAD is a global public health issue that has been systematically understudied and underappreciated. Healthcare professionals, researchers, expert organizations, healthcare organizations, government agencies, industry, and the community should collaborate to increase the awareness and understanding of PAD and improve the quality of PAD diagnosis, management, and prognosis. Key findings in the literature review supported implementing a PAD screening protocol utilizing the ABI. Research indicated early identification of PAD through screening significantly improved patient outcomes.

Theoretical Model

The theory utilized to guide this project is Jean Watson's Theory of Human Caring. Nursing is defined by caring. Caring is a mutually beneficial experience for the patient, the nurse, and health team members. For Watson, the transpersonal caring relationship characterizes a special human care relationship. It describes how the nurse goes beyond an objective assessment, showing concerns toward the person's subjective and deeper meaning regarding their health care (Ryan, 2016).

Ozon (2015) stated Jean Watson's theory of caring provides nurses with a moral compass from which to work. It helps nurses bring a humanistic and philosophical piece to their patients' care. This theory helps frame this project by listening to patients, seeing the person behind the disease, and paying attention to their actions, allowing them to take care of themselves. Identifying high-risk patients and performing the ABI exudes compassion and caring (Ozon, 2015).

Watson (2012) embraces the mind/body/spirit approach to healing that guides nurses in a holistic approach to their jobs. The caring theories proposed by Watson encourage nurses to integrate their compassion and spirituality into their practices as an adjunct to the science of medicine. Watson's theory is a reminder that the primary purpose of health care professionals is not to assess vital signs or fill out forms but to help people heal and provide comfort for these people. (Watson, 2012).

Methodology

This process change DNP project improved adherence to an evidence-based PAD screening protocol. The primary intervention of this project increased the utilization of an evidence-based PAD screening protocol for smokers in a cardiology clinic. The literature has been referenced for best practices and guidelines to achieve the aims and objectives.

Setting

The clinical setting where this project took place was a privately owned suburban cardiology clinic. The patients in the cardiology clinic have various medical problems, but the focus of care was cardiovascular. The daily census averaged two to five new patients a day.

Population

The population of interest was adult smokers aged 50 and older who were new patients to the clinic. Table A below outlines the inclusion and exclusion criteria that guided nurses when identifying patients for this intervention.

Table A: inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Age 50 and older	Less than 50 years old
Smoker	Non-Smoker
New patient	Established patient

Consent

Consent and agreement to participate were obtained from all study participants before the project intervention (Appendix D). It was emphasized that this was a DNP student project to standardize routine PAD screenings on high-risk patients. The principal investigator (PI) running this project had no influence over administrative responsibilities in the cardiology clinic concerning scheduling, staffing, evaluation(s), and promotion(s). It was conveyed to staff nurses that the cardiology clinic had no influence or participation in this project. The PI maintained privacy and confidentially of all identifiable collected data.

Design

Knowledge-to-Action (KTA) was utilized as the implementation framework for this project. KTA consists of two components, knowledge creation and an action cycle. Daya and White (2020) explained knowledge creation aims to create 'knowledge tools', such as practice guidelines or training courses. Knowledge creation is the descriptive process by which knowledge about an intervention passes through several stages: accumulative evidence, aggregation of evidence, and practical synthesis of evidence. The action cycle describes a dynamic knowledge application process designed to change current ways of doing things so that innovative, evidence-based interventions are used in practice (Daya & White, 2020).

The process change project used a sampling of patients in a cardiology clinic. Before implementation, the investigator received project approval from the Jacksonville State University Institutional Review Board (Appendix F). The goal of this process change was an early diagnosis and appropriate referrals to improve patient outcomes. The process change project began by performing a retrospective chart review. Charts were reviewed for 60 days, utilizing the same inclusion criteria used in implementation, to gather pre-implementation data regarding the number of patients screened for PAD.

Chart Review

A retrospective chart review was performed to analyze how many new, high-risk patients were seen over 60 days and were screened for PAD. Instead of screening every high-risk patient, the office was screening patients referred for evaluation, having clear PAD evidence, or being symptomatic. During the 60-day chart review, the identified gap in practice was a lack of routine screening for PAD in high-risk patients. High-risk patients were identified as smokers aged 50 and older. Approximately 30 new patients were seen in the clinic each month, but only 5% of those patients were screened for PAD.

Risks, Benefits, and Compensation

There was no risk for any of the patients participating in this project. Benefits include early diagnosis, which leads to early intervention and improves patient outcomes by preventing complications associated with PAD. There was no compensation for any participant in this project.

Timeline

The timeline table delineates the required proposal and project components and incorporated course, college, and university deadlines. The timeline established expectations by

providing an overview of the DNP project process requirements from the project proposal through dissemination (Appendix E).

Budget and Resources

It was essential to consider the budget and available resources, as with any project. Most times, the cost associated with a DNP project is nominal. In general, budgets consider both expenses and revenue related to the project. These expenses include direct and indirect costs. The clinic absorbed the minimal cost of the project. The final expenditure was $5.00 for paper and ink.

Evaluation Plan

Statistical Considerations

The PAD screening and detection rates between the pre-intervention and post-intervention groups were compared using Fisher's Exact Test. The rates were calculated using frequency and percentage statistics. All analyses were performed using SPSS Version 28 (Armonk, NY: IBM Corp.), and statistical significance was assumed at an alpha value of 0.05.

Data Maintenance and Security

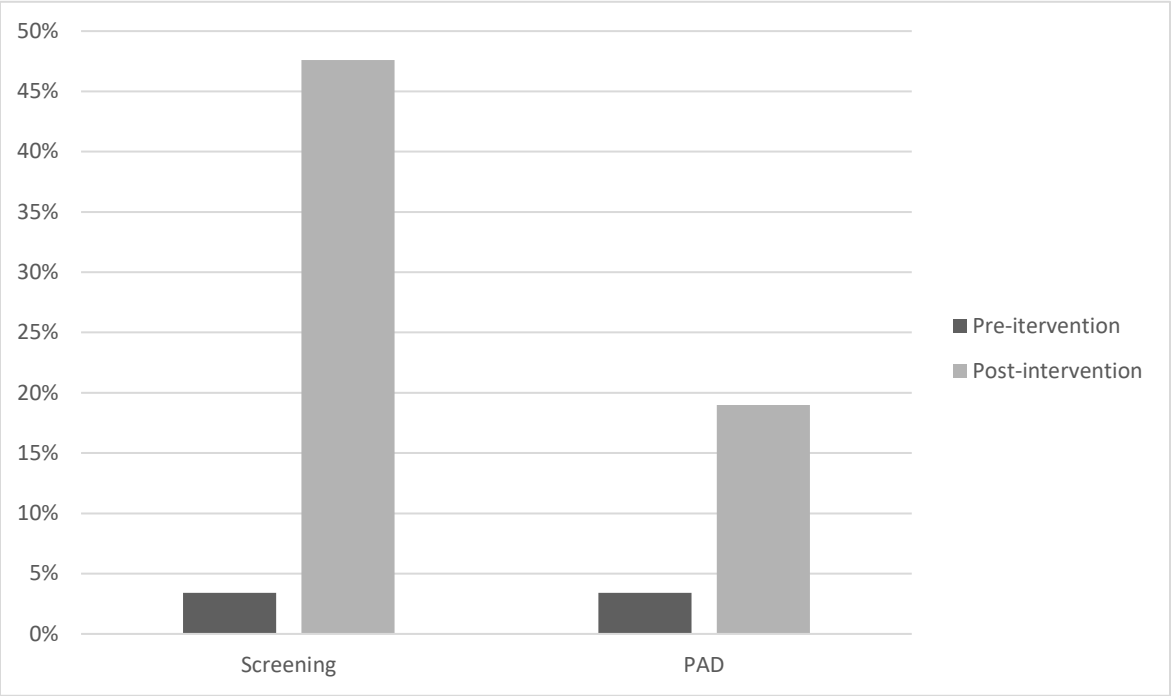
After the project was completed, the IRB was closed, and the final manuscript was completed. All data was destroyed following the clinic's guidelines. Hard copies of data, including patient medical record numbers and nurse employee numbers, did not leave the clinic and were destroyed via clinic policy.

Results

There was a statistically significant increase in the rate of screenings from pre-intervention (3.4%) to post-intervention (47.6%), $X^2(1) = 11.39$, $p = 0.0007$. There was no difference between the pre-intervention group (3.4%) and the post-intervention group (19.0%) on

the detection of PAD, $X^2(1) = 1.79$, $p = 0.18$. The rates of the outcomes are presented graphically below in Figure 1.

Figure 1: Statistical analysis of pre-and post-intervention



Discussion

This project sought to address the lack of PAD screening in high-risk patients in a cardiology clinic. The main aims were to increase screenings of smokers aged 50 and older and identify those patients who have PAD. With a p-value of 0.0007, the statistical analysis provided evidence the project successfully increased the rate of PAD screenings in high-risk patients. Quantitative data was used to measure the ability of this project to meet those aims. The DNP process change project was influential in helping the staff screen high-risk patients. While there was no statistical significance, with a p-value of 0.18 in pre-intervention and post-intervention data on the rate of PAD detection, there was clinical significance. The patients identified as

having severe PAD were referred to the appropriate interventionalist. Early identification and treatment improved patient outcomes.

Implications for Clinical Practice

The project's aims were met by demonstrating an increase in screening for PAD among smokers 50 years old and older. This project showed the importance of screening for PAD in smokers and identifying those high-risk patients and offered an increase in PAD identification. The literature review of evidence-based research indicated identifying PAD early improved patients' outcomes. This project enhances the existing literature and continues to show the importance of screening.

Implications for Healthcare Policy

CMS has policies regarding non-invasive vascular studies. These studies are considered medically necessary if the ordering physician has reasonable expectations that their outcomes will potentially impact the patient's clinical management. Services are deemed medically necessary when significant signs/symptoms of arterial or venous disease are present. There is room for improvement when deciding what is medically necessary. The research demonstrates patients can have PAD without significant signs/symptoms. Therefore, routine screening should be performed on all high-risk patients. Smoking cessation education should be discussed at all visits, as this is a modifiable risk factor and has the potential to improve patient outcomes significantly.

Implications for Quality/Safety

This process change DNP project improved the consistency of screening high-risk patients for PAD, which led to PAD identification in more patients. Improving patient outcomes should always be at the forefront of healthcare. PAD screening is a simple, cost-effective tool

that can significantly improve the quality of a patient's everyday life. The ABI poses no harm to the patient and is a safe, effective way to identify PAD. Smoking is one of the most correlated risk factors, and increasing the patient's knowledge of the impact of tobacco can reduce future complications.

Implications for Education

Multiple studies demonstrated the need for education regarding the prevalence of PAD in high-risk patients. Smoking is the single most modifiable risk factor for the development of PAD. This DNP process improvement project further supported this by bridging the gap between evidence and practice. As evidenced by the findings in the statistical analysis, this project translated the evidence into practice and further supported the need for routine PAD screening in smokers.

Limitations

Limitations of this project included the small sample size of patients. Due to the unexpected closure of the clinic, the post-implementation data collection time frame was limited to 30 days. Additionally, the project was implemented in only one clinic in a suburban setting. This project could be held in a larger metropolitan facility with more participants to increase generalizability.

Dissemination

The findings of this research study have been disseminated through the three P's: poster, presentation, and paper. The DNP Project was presented via poster and short presentation at the University's Virtual Dissemination Day. Additionally, the DNP manuscript was placed in the Jacksonville State University's Digital Commons repository. Another path of dissemination, such as the utilization of social media, may be explored.

Sustainability

The DNP process improvement project aligned with the clinic's philosophy and mission; however, implementation ended abruptly, with the clinic closing permanently and giving the staff only a 10-day notice. This project has many opportunities for sustainability, as screening for PAD in high-risk patients can occur in any environment. The screening should not be limited to the cardiology setting. There is an excellent opportunity for sustainability in urgent care, family practice, and pain clinics. Gerhard and Gornik (2017) stated the AHA and American College of Cardiology (ACC) guidelines also support screening for PAD in people aged 65 and older, age 50–64 years with risk factors for atherosclerosis (e.g., diabetes mellitus, history of smoking, hyperlipidemia, hypertension) or family history of PAD, age <50 years with diabetes mellitus and one additional risk factor, and individuals with known atherosclerotic disease (Gerhard & Gornik, 2017).

Plans for Future Scholarship

Future research with a larger sample size is recommended to determine if the results are related to screening early in the year when deductibles have not been met, and patients are less likely to visit the doctor. The study was cut short due to the office closing permanently, so it is also recommended to repeat the study for an extended time. While this DNP process improvement project adds to the existing data supporting the need for PAD screening in high-risk patients, further research is needed to stress the importance of these findings. There is a lack of awareness of PAD. This project suggests room for improvement in the primary care diagnosis of symptomatic PAD. This could be achieved by clinicians simply asking about claudication symptoms during routine consultations. Practical strategies to raise public awareness of this disease are also needed. On a simplistic level, this could involve displaying PAD posters in

general practice waiting rooms and pharmacies; more sophisticated strategies, such as social media, could also be developed and implemented.

Conclusion

In conclusion, Bevan and White Solaru (2020) agreed PAD is a devastating disease with high morbidity and mortality. Tobacco smoke increases endothelial cell permeability by forming reactive oxygen species, enabling atherosclerosis to settle within vessel walls. The magnitude of this effect is clinically evident, with the prevalence of PAD increasing two to three times in current smokers. Smoking promotes PAD and augments complication rates. Despite the multitude of medical treatment options available, PAD is chronically undertreated. Future advancements in management strategies and improved application of available medical therapies will prevent complications and improve the quality of life for patients with PAD (Bevan & White Solaru, 2020). This DNP project illustrated the importance of routine PAD screening in smokers. It also demonstrates the need for smoking cessation. Expanding this project to other high-risk groups will be essential moving forward when chronic disease is rising.

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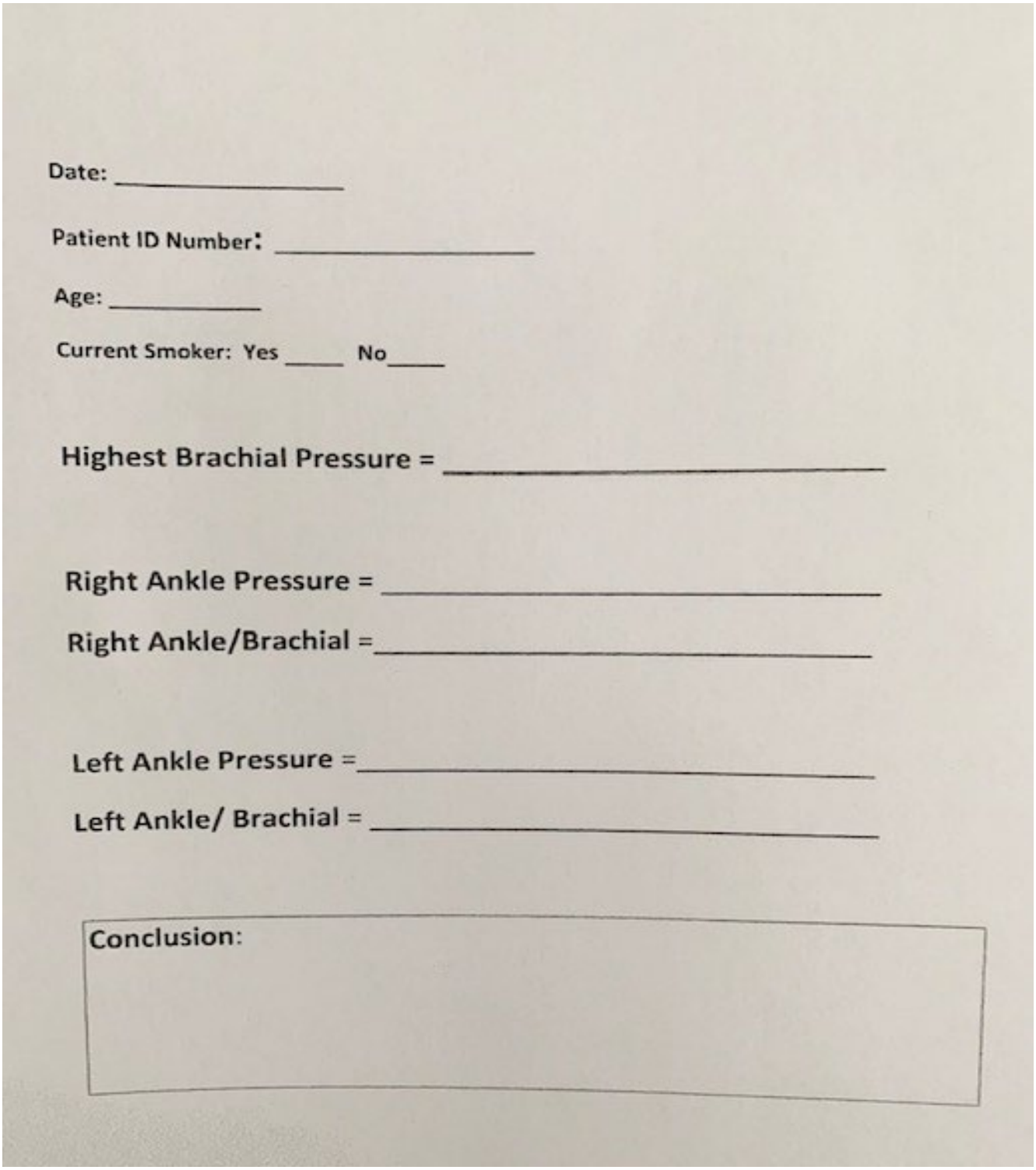
Appendix A

Screening Recommendations for PAD

Organization Name	Recommendation
American College of Cardiology and American Heart Association	Screen adults ≥65years old, adults ≥ 50 years old with a history of diabetes, and adults of any age with exertional leg symptoms or non-healing wounds (American Heart Association, 2021).
American Diabetes Association	Screen patients with diabetes who are symptomatic or are asymptomatic and > 50 years old or have at least one other risk factor (smoking, hypertension, hyperlipidemia, or duration of diabetes) > 10 years (American Heart Association, 2021).
European Society of Cardiology	Screen symptomatic patients or are symptomatic and > 65 years old or >50 years old with risk factors or a family history of PAD (American Heart Association, 2021).

Appendix B

Patient Intake Form



Date: _____

Patient ID Number: _____

Age: _____

Current Smoker: Yes _____ No_____

Highest Brachial Pressure = _____

Right Ankle Pressure = _____

Right Ankle/Brachial =_____

Left Ankle Pressure =_____

Left Ankle/ Brachial = _____

Conclusion:

Appendix C

ABI Interpretation

ABI Value	Interpretation	Recommendation
Greater than 1.4	Calcification/Vessel hardening	Refer to a vascular specialist
1.0-1.4	Normal	None
0.9-1.0	Acceptable	None
0.8-0.9	Some arterial disease	Treat risk factors
0.5-0.8	Moderate arterial disease	Refer to a vascular specialist
Less than 0.5	Severe arterial disease	Refer to a vascular specialist

Appendix D

Consent and Agreement to Participate

Participant Consent Form

TITLE OF STUDY: Project Ankle-Brachial Index: Implementation of an evidence-based peripheral artery disease protocol.

Care Setting
Principal Investigator: Rene Banks, CRNP

This consent form is part of an informed consent process for a DNP student project, and it will provide information that will help you decide whether you wish to volunteer for this project. It will help you understand what the study is about and what will happen during the project. If you have questions at any time during the project, you should feel free to ask them and should expect to be given answers that you understand entirely. You are not giving up any of your legal rights by volunteering for this research project.

Why is this project being done?
This project aims to address the lack of consistency in screening for peripheral artery disease in a cardiology clinic. A lack of structure and guidelines within a clinic setting leaves room for omitting proper screening. This project plans to improve screening of peripheral artery disease over 50 that smoke. This study also plans to improve the early identification of peripheral artery disease in high-risk patients. The study will run for 60 days with an estimate of 40-50 patients involved.

What will you be asked to do if you take part in this research project?

If you are identified as a smoker over the age of 50, the medical assistant will then proceed with the ankle-brachial index test. The ankle-brachial is the most used screening and diagnostic test for peripheral artery disease and will be performed by taking a series of blood pressure readings in your legs and arms. The PI will then provide an educational session that will include results of the ankle-brachial index score, smoking cessation, and any further diagnostics that may be needed, depending on your score.

What are the risks or discomforts you might experience if you take part in this project?
No expected harm can occur from participating in this study. This project has no influence or involvement from upper management, and participation is voluntary. Upper management will be excused from participation and not provided any information regarding survey results or nurse participation in this project. Participation in this project is of no cost to you.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Only a patient number will be placed on your intake form without the addition of any other personal identifiers. Scores will remain within the clinic, and information will not be removed from the premises until all identifiable information is removed.

What will happen if you do not wish to participate in the project or if you later decide not to stay in the project?

Participation in this project is voluntary. Suppose you do not want to enter the project or decide to stop participating. You may choose not to participate, or you may change your mind at any time. In that case, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Rene Banks at mbanks@jsu.edu.

Who can you call if you have any questions?
If you have any questions about taking part in this project you can call the principal investigator:

Rene Banks, CRNP

Cardiology Clinic

245-996-0415

AGREEMENT TO PARTICIPATE

1. Subject consent: I have read this entire form, or it has been read to me, and I believe I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____
Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent: To the best of my ability, I have explained and discussed the study's complete contents, including all of the information contained in this consent form. All questions of the research subject and those of their parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____
Signature:_____ Date: _____

Appendix E

Timeline

Completion	Pre-Design	Design	Implementation	Evaluation
Summer 2021 DNP 796	Define the clinical problem. Develop the initial PICOT. Complete an initial review of the literature.			
Fall 2021 DNP 797	Finalized PICOT question. Communicated with university faculty about project ideas. Met with preceptor and office staff. Additional review of the literature. Select theoretical methodology. Complete CITI training	Began the draft of the project proposal. Obtained PERC approval. Obtained IRB approval.		
Spring 2022 DNP 798			Implement the DNP project.	Data collection and statistical analysis. Final project manuscript submission.
Summer 2022 DNP 799				Project dissemination, poster presentation, and submission of ePortfolio.

Appendix F

IRB Approval Letter

JSU | INSTITUTIONAL REVIEW BOARD
JACKSONVILLE STATE UNIVERSITY

Institutional Review Board for the Protection of Human Subjects in Research
203 Angle Hall
700 Pelham Road North
Jacksonville, AL 36265-1602

November 29, 2021

Melaney Banks
Jacksonville State University
Jacksonville, AL 36265

Dear Melaney:

Your protocol for the project titled "Project Ankle Brachial Index: Implementation of an Evidence-based Peripheral Artery Disease Screening Protocol" 11292021-02 has been granted exemption by the JSU Institutional Review Board for the Protection of Human Subjects in Research (IRB).

If your research deviates from that listed in the protocol, please notify me immediately. One year from the date of this approval letter, please send me a progress report of your research project.

Best wishes for a successful research project.

Sincerely,

Lynn Garner
Associate Human Protections Administrator, Institutional Review Board