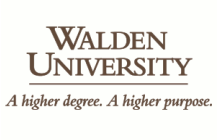

2015

Screening for Peripheral Artery Disease

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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by

Cheryl D. Gordon

Post Masters, Texas A&M University, 2012

MS, Texas A&M University 2007

BS, University of Incarnate Word, 2005

Project Submitted in Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

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Abstract

Peripheral artery disease (PAD) affects 8 to 10 million Americans, and the incidence of PAD is expected to increase as the population ages. A high percentage of the PAD is undiagnosed prior to the onset of a serious cardiovascular event; therefore, the inability to screen and diagnose for PAD in the early stages could hinder efforts to decrease adverse consequences of cardiovascular disease. Individuals with PAD have a 3 to 5 times increased risk of cardiovascular disease (CVD) mortality when compared to people without PAD. Guided by the Stetler model, the purpose of this project was to evaluate the relationship between level of PAD, as measured by skin perfusion pressure, and HbA1c using secondary data obtained from charts of patients within the clinic setting. Data included patient gender, age, degree of PAD, and HbA1c. A Pearson's correlation investigated the relationship between the patients' HbA1c and level of PAD. There was a significant relationship between HbA1c and LT PAD (r = .21, p =.009). There was no relation in RT PAD (r =.01, n = 149, p = .90). There was a significant relationship between HbA1c and age (r = .34, p = .00). Ultimately, the goal of this study was to improve PAD recognition, encourage early intervention, and facilitate effective preventive methods. Critical limb ischemia might be delayed or prevented if it is identified earlier by screening methodologies. Early identification and treatment of PAD can improve the quality of life and care for individuals suffering with PAD.

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Section 1: Screening for Peripheral Artery Disease

Peripheral artery disease (PAD) affects 8 to 10 million Americans and it is expected to increase as the population ages and chronic diseases continue to rise (Hirsch, Hartman, Town & Virnig, 2008). Peripheral artery disease is defined as atherosclerosis of the abdominal aorta, iliac, and lower-extremity arteries (Olin & Sealove, 2010). According to the Sage Group (2010), the direct cost of PAD in the United States has been estimated to be between $164 and $290 billion dollars. According to the U.S. Preventive Services Taskforce (USPTF), PAD is a manifestation of systemic atherosclerosis that has demonstrated a significant correlation with other atherosclerotic, cardiovascular diseases (CVD) and cardiac related events (USPTF, 2013). A high percentage of the PAD population is undiagnosed before a serious cardiovascular event; therefore, the ability to screen and diagnose this disease could have a dramatic impact on the efforts to decrease cardiovascular disease (Norgren et al., 2010). Individuals with PAD have a three to five times increased risk of CVD mortality when compared to people who do not have PAD (Criqui et al., 1992).

There is a high prevalence of PAD in the primary care setting but the diagnosis by providers is relatively low. Patients with PAD have similar arteriosclerotic risk factors such as hyperlipidemia, hypertension, and diabetes but they received less intensive treatments unlike patients with confirmed CVD (Hirsch et al., 2001). The underdiagnosis of PAD in primary care practice could be a barrier to effective secondary prevention of the high ischemic cardiovascular risk associated with PAD (Hirsch et al., 2001).

Additionally, the consistent correlation between PAD and future CVD events has influenced the American Heart Association (AHA) and the National Cholesterol Education Program (NCEP) to establish recommendations for intensive atherosclerotic risk factor reduction

for PAD and CVD patients (NCEP, 1993). Early identification of patients with PAD has the potential to impact CVD and, in doing so, to create opportunities for aggressive management of the risk factors leading to this disease. Common disease and lifestyle factors have been directly linked to PAD and CVD; therefore, health promotion has been focused on risk reduction (AHA, 2013).

Significant strides have been made in the risk reduction of this disease through modification of health behaviors such as tobacco use, sedentary lifestyle, and obesity (Spring et al., 2013). Disease management of hypertension, diabetes, and hyperlipidemia has proven to have significant impact on atherosclerosis (Olin & Sealove, 2010). Secondary prevention involves screening for diseases before they have had an impact on the individual. Screening high-risk patients with diabetes and hypertension who are asymptomatic for PAD is an example of secondary prevention. The ultimate goal of prevention is to impact the prevalence and incidence of disease.

The ability to access care has a profound effect on an individual's health. One in four Americans does not have a primary care practitioner or insurance for medical care (U.S. Government of Health and Human Services, 2013). This disparity leads to decreased access to preventive health initiatives. In 2002, Dillingham, Pezzin, and MacKenzie demonstrated an increased risk of amputations with age for all comorbidities and were highest among blacks with CLI amputations. The risk of amputations was increased among elderly and minority populations, is of concern and warrants further investigation. Clinical preventive services such as screening for disease are necessary for the prevention of chronic diseases, such as hypertension, diabetes and various cancers (U.S. Government of Health and Human Services, 2013).

Purpose Statement

The purpose of this project was to evaluate whether there is a relationship between glycosylated hemoglobin (HbA1c) levels and peripheral flow or PAD severity measured with skin perfusion pressures (SPP). Glycosylated hemoglobin is a lab test that represents the patient's average level of blood glucose over the previous three months. A normal value is less than 5.7%; higher numbers of 7.0% or greater represent a lack of glycemic control which causes significant changes to the vasculature of diabetic patients (American Diabetes Association, 2014). The purpose of this study was to evaluate whether there is a relationship between skin perfusion pressures (SPP) and HbA1c.

Currently, the evidence does not support the screening of asymptomatic patients, but this study will attempt to look at early screening and its impact in the identification of PAD (USPTF, 2013). Early identification of PAD can lead to a decrease in the development of severe CVD through initiation of early prevention and intervention strategies.

Project Objectives

The objectives for this evidence-based project are as follows:

1. Evaluate the relationship between HbA1c levels and PAD severity.
2. Add to the current literature on Diabetes and PAD.
3. Highlight the importance of tight glycemic control.

Guiding Practice

Practitioners do not routinely screen for PAD, unless there are complaints of claudication, or signs of PAD, which includes hairless lower extremities, decreased peripheral pulses, and limb coolness. Symptomatic patients receive screening using ankle brachial index (ABI), which provides information about limb perfusion using a blood pressure ratio between the arm and the

leg (Mukherjee & Cho, 2009). Pulse volume waveform analysis is another technique that is used to evaluate the extent of PAD. This project has the potential to decrease the gaps in the evidence related to late recognition of the problem. Early recognition could lead to prevention of disease progression and timely intervention (Hirsch et al., 2006).

Significance of the Project

Reduction of Gaps

The gaps in access to care would be reduced and gaps in the literature regarding PAD and HBA1c correlation would be decreased. This would help to reduce the disparities in the access to care and would also provide support for early screening of asymptomatic patients.

Implications for Social Change

By providing access to care with early screening, the community would see a marked decrease in the cost of PAD care. This would also result in a decrease in the number of amputations due to PAD. Additionally, the end result could potentially prevent cardiovascular disease.

Definition of Terms

Table 1
Definition of Terms

Medical Term Abbreviation	Definition of Term
PAD	peripheral artery disease
ABI	ankle brachial index
SPP	skin perfusion pressure
CLI	critical limb ischemia

Assumptions, limitations and delimitations

Secondary data collected have inherent assumptions about the measurement and reliability of the data collected. The skin perfusion pressure (SPP) testing was completed by the various clinic assistants and, therefore, there may be inconsistencies in the screening. The studies were read by providers at all the clinics and there could be a reader bias towards over-reading or under-reading the SPP.

Limitations

There were three limitations to this project. Primarily, the correlation between HbA1c and PAD disease level had not been studied previously. Secondly, asymptomatic patients had not been studied previously and were not recognized as current practice in the literature. Thirdly, this study should include a longitudinal assessment in order to obtain outcomes that can truly be broadly generalized; therefore, the short timeframe of this study not producing as much data as was needed was a limitation.

Summary

This project set out to evaluate whether or not there was a relationship between peripheral artery disease and glycemic control. The secondary data of patients with diabetes and hypertension were evaluated and screened for peripheral artery disease (PAD).

Section 2: Review of Literature and Theoretical and Conceptual Framework

Review of Literature

A review of the literature was conducted using Cumulative Index to Nursing and Allied Health (CINAHL) and Medline Plus. The search was limited to the years 1992 to 2014. The key words used in the search were *peripheral artery disease*, *PAD*, *critical limb ischemia* and *screening*. The studies were reviewed and used to clarify the significance of PAD and to identify the limitations of symptomatic screening. Furthermore, the literature review demonstrated the importance of exploring asymptomatic screening.

Literature Related to Peripheral Artery Disease

Peripheral vascular disease has a negative physical and psychological effect on individuals who are struggling to save a limb. Critical limb ischemia (CLI) can lead to amputations, which can affect an individual's ability to make a living. Critical limb ischemia is defined as chronic ischemia causing pain at rest, ulcers and or gangrene, which can be attributed to long-standing arterial occlusion. Ziegler-Graham, MacKenzie, Ephraim, Travison, and Brookmeyer (2008) reported that in the year 2005, 1.6 million people were living with the loss of a limb. Additionally, 42% were nonwhite and 38% had an amputation caused by diabetes related vascular disease (Ziegler-Graham et al., 2008). In their study they projected that the number of people living with limb loss will more than double up to 3.6 million people by the year 2050. Additionally, if the rate of secondary vascular disease can be reduced by 10%, this number would be lowered by 225,000 (Ziegler-Graham et al., 2008).

According to Sprengers et al. (2010), critical limb ischemia will develop in 500 to 1000 patients in a Western population of one million people and will lead to surgeries, hospitalizations, deaths and 5-year survival rates of only 50%. Peripheral artery disease and

CLI creates functional impairments for the population, which can affect their psychological well-being. Stauber et al. (2013) demonstrated significant relationships between disease severity and the psychological risk factors of depression, anxiety, and *type D personality* (a tendency towards negativity) in a cross-sectional study. Patients with PAD and depression had an increased decline in their physical functionality than patients without depression (Ruo et al., 2007). The chronicity of the disease and the severity of the pain impacted the individual's ability to cope and to complete daily activities. Stauber et al. discovered higher levels of depression in patients with PAD than those with CVD. Peripheral artery disease patients with higher levels of depression also have greater revascularization failure rates, which lead to additional difficulties in their ability to manage their condition (Stauber et al., 2013).

Baser, Verpillat, Gabriel, and Wang (2013) analyzed the annual prevalence and incidence of CLI in the elderly population in the United States by retrospectively collecting and analyzing clinical characteristics from January 2007 to December 2008 Medicare beneficiaries. Their analysis revealed that patients over the age of 65 years had an overall prevalence and incidence rate of CLI at 0.23% and 0.20% respectively. This result was constant in each year. The age-specific annual rates, demonstrated a rise in prevalence and incidence in patients from 65 years to 69 years of age (prevalence: 0.15%, incidence: 0.13%) to patients aged 85 and older (prevalence: 0.36%, incidence: 0.31%).

Literature Regarding Preventing Arterial Disease

The Healthy People 2020 is a national initiative for health promotion and disease prevention. The goal of Healthy People 2020 is to improve health by removing disparities and creating environments which promote health.

The goal of the Healthy People 2020 is to decrease the number of limb amputations in people with diabetes. In 2013, the U.S. Preventive Services Task Force (USPSTF) gave a *recommendation D*, or fair level of evidence, to screening for PAD in asymptomatic patients, proving a guideline for providers. McDermott et al. (2009) demonstrated that 19.8% of the study's patients had no exertional leg pain, 28.5% had atypical leg pain, 32.6% had classic intermittent claudication, and 19.1% had pain at rest. Asymptomatic disease may be present in up to 50% of patients with PAD (Hirsch et al., 2008). The American Heart Association (AHA) estimated that over 8 million Americans have PAD and more than 75% of these individuals do not have symptoms (USPSTF, 2013).

In an effort to prevent PAD severity and its complications, the American Diabetes Association (ADA) recommends annual screening for individuals with diabetes. The American College of Cardiology (ACC) and the American Heart Association (AHA) recommends PAD screening using a resting ABI to diagnose patients' suspected for lower extremity PAD (Rooke et al., 2011). Patients presenting with symptoms of pain or cramping during ambulation, nonhealing wounds, diabetes, and smoking should be screened (Rooke et al., 2011). However, it is often too late to screen at-risk populations when they are symptomatic, as the vascular damage has already occurred.

Fowkes et al. (2013) compared of the prevalence of peripheral artery disease (PAD) between high-income countries (HIC) and low-income or middle-income countries (LMIC). The prevalence of PAD in HIC at age 45–49 years was 5% to 28% in women and 5% to 41% in men. The prevalence of PAD in HIC in older adults 85–89 years of age was 18% to 38% in women and 18% to 83% in men. Also, smoking was an important risk factor in both HIC and LMIC, followed by diabetes, hypertension, and hypercholesterolemia.

Researchers have supported supervised exercise programs (level of evidence A) for the management of PAD (Rooke et al., 2011). Supervised exercise programs can improve arterial insufficiency thus improving oxygen delivery to the tissue and improving gait (Rooke et al., 2011). Rehabilitation programs will be beneficial for PAD management, as well as the effects of the psychological functionality of the disease. Therefore, the ability to screen high-risk patients for PAD before symptoms develop should decrease adverse PAD vascular and psychological effects. Early detection of PAD will lead to less invasive and less costly treatment modalities. Contributing factors to PAD include coronary artery disease, diabetes, smoking, hypertension, and obesity. Individually and cumulatively, these factors have a significant impact on the health of our population.

Literature Regarding Diabetes and Peripheral Artery Disease

Researchers have note reported a correlational study of glucose control and incidence PAD disease levels. Yokoyama et al., (2011) reported significant improvement in outcomes with evidence based disease management. Yokoyama et al. found incidences of composite, coronary heart disease, ischemic stroke, and peripheral artery disease (per 1000 person-years, 95% confidence interval). The study results were 8.3 (6.6–10.0), 4.4 (3.2–5.6), 3.1 (2.1–4.2), and 0.7 (0.2–1.2), respectively. Each incidence was lower in the Yokoyama et al. study compared with other cohort studies ($P < 0.01$ compared to each cohort). Significant variables predictive of the occurrence of cardiovascular events were age, duration of diabetes, HbA1c, HDL cholesterol, and urinary albumin (Yokoyama et al., 2011). Additionally, lower HbA1c levels significantly contributed to a reduced incidence of cardiovascular disease (Yokoyama et al., 2011).

The Factores de Riesgo y ENfermedad Arterial (FRENA) is a registry of stable outpatients with symptomatic coronary artery disease, cerebrovascular disease, or peripheral

artery disease to compare the incidence of subsequent myocardial infarctions, strokes or critical limb ischemia events. Camafort et al. (2011) used data from FRENA and evaluated patients with type 2 diabetes and mean HbA1c levels < 7.0% compared to those with HbA1c levels > 7.0%. Of the 974 patients with type 2 diabetes, 480 (49%) had mean HbA1c levels < 7%. Follow-up at 14 months reported 126 patients (13%) had subsequent ischemic events: myocardial infarction (*n* = 43), stroke (*n* = 29) and critical limb ischemia (*n* = 64). The incidence of subsequent ischemic events was significantly lower in patients with mean HbA1c levels of < 7.0% in those with HbA1c levels > 7.0% (Camafort et al., 2011).

Diabetes, hypertension, hypercholesterolemia, and smoking can lead to PAD and if left untreated, may lead to critical limb ischemia (Rooke et al., 2011). The U.S. Preventive Services Task Force (USPSTF) reported in 2013 that PAD based on ankle-brachial blood pressure (ABI) screening ratios occurs in between 10% to 20% of the population aged 65 years and older and 18% to 29% of patients aged 50 and older in general medical practices. The diagnosis of PAD in diabetic patients is especially challenging because of the manner in which it presents. The ability to assess severity of PAD is altered because of the clinical presentation and the limitations of diagnostic procedures (Schaper et al., 2012). Screening of high-risk populations using non - invasive technology has the potential to decrease the prevalence of PAD and provide critical information about the potential for CVD.

Evidence-Based Model

The Stetler (2001) model provides a foundation to guide research utilization for the creation of evidence-based practice (Burns & Grove, 2009). This framework can be used to support, develop, and influence practice decisions. This model supports institutional and policy makers' use of the evidence to facilitate evidence-based practice (Burns & Grove, 2009). The

Stetler model of evidence-based practice provides a framework, which allows for integration of research into practice. The model is designed to assist with critical assessments of the literature, planning and implementation of the evidence. The relevant research is linked to the problem addressed through synthesis and appraisal of the literature. This model includes the following steps: preparation, validation, comparative evaluation of the literature, translation, and evaluation. Preparation requires critical consideration of the purpose, focus and potential outcomes of the implementation (Burns & Grove, 2009). Validation involves critical appraisal of the literature to determine the strength of the evidence and to ensure significance to the practice problem. Comparative evaluation looks at the state of the evidence along with the setting to ensure research application and currency with nursing practice (Burns & Grove, 2009). The translation phase determines how the research will be applied to practice. A pilot unit should be selected to evaluate the implementation and feasibility for generalization across the institution. The evaluation phase involves data gathering through formal and informal evaluations of the evidence-based project. The Stetler model (Figure 1) was used to facilitate the literature review, validate and synthesize the current literature on PAD. There was evaluation of the literature based on currency with practice and the information garnered was used to substantiate the need for research. The Stetler model was used to implement the screening of asymptomatic patients with diabetes and hypertension. The data collected were analyzed and the results evaluated.

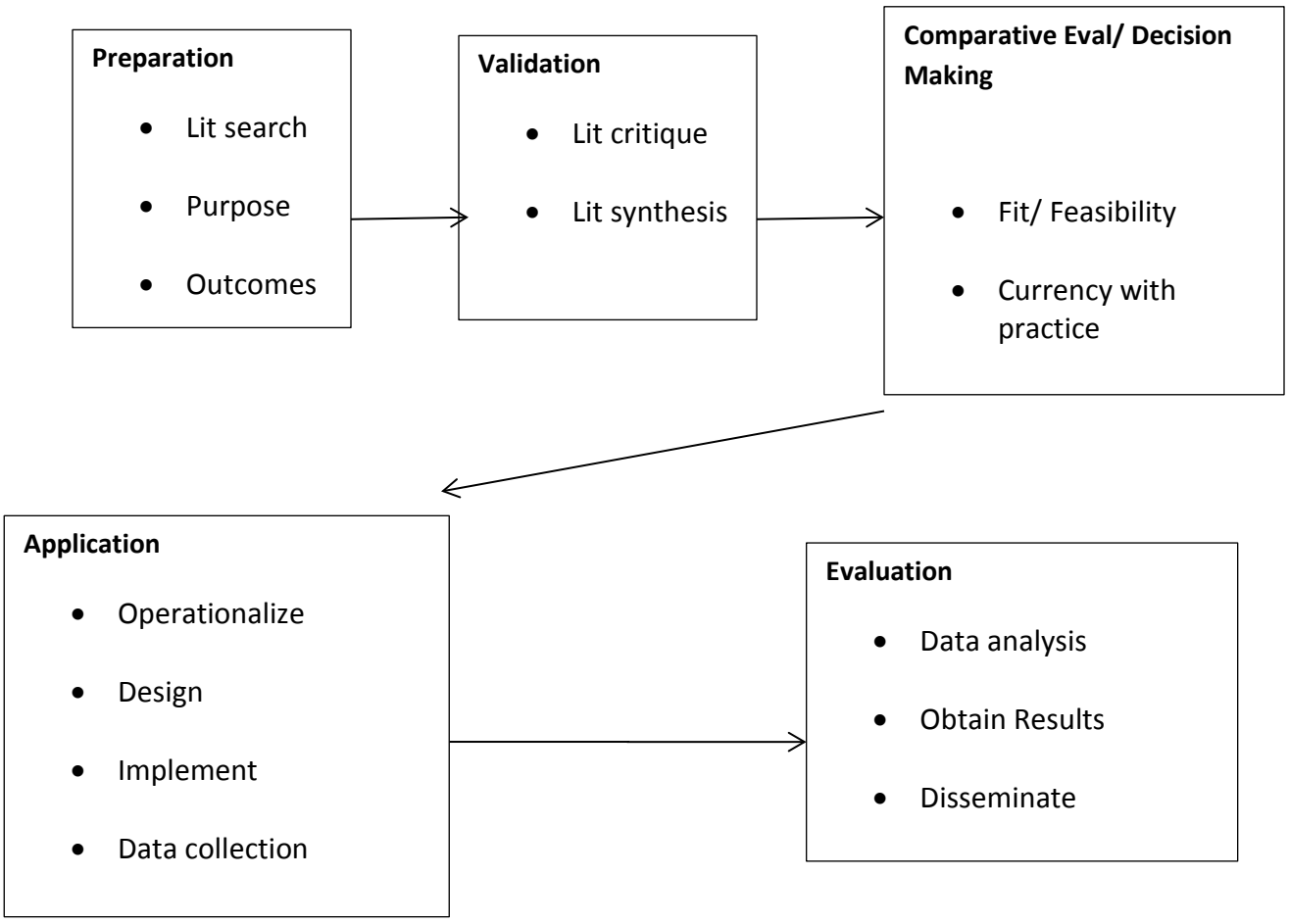

Figure 1. EBP using Stetler Model as the conceptual framework

Section 3: Methodology

Retrospective Cohort Study

The primary research method used in this project was a correlational retrospective cohort study. This correlational retrospective cohort study evaluated the impact of early screening for PAD disease outcomes along with the relationship between HbA1cs and severity of disease. A cohort study requires following one or more groups based on intervention or environmental factors over time. There are two types of cohort studies: prospective and retrospective. In a prospective study, the researcher collects baseline data from the study group in the present and outcomes data in the future (Friis & Sellers, 2009). A retrospective study requires the researcher to gather data from the past and then collect outcomes data from the past or the present (Friis & Sellers, 2009). For this study, a retrospective chart review was conducted looking for patients with diabetes, hypertension and the diagnosis of peripheral artery disease in the Corpus Christi, Texas area Christus Spohn Health System, which provided a convenience sample for the study. The Christus Spohn Health System is currently in the process of implementing PAD screening in several rural clinics as an adjunct to facilitate timely access to specialty care for this vulnerable population.

The Delivery System Reform Incentive Payment (DSRIP) project is part of the government's initiative to improve patient outcomes and the data collected for this project is available in the public domain. As part of the DSRIP initiative, clinic patients with diabetes and hypertension were screened using the PAD-IQ. This device is noninvasive and uses segmental pressure to obtain Skin Perfusion Pressure (SPP) to provide a quantitative evaluation of microcirculatory perfusion of the skin. Clinic patients with diabetes and hypertension were screened using the PAD-IQ for PAD. The device was noninvasive and used segmental pressure

to obtain SPP, which provided a quantitative evaluation of microcirculatory perfusion of the skin. The segmental volume plethysmography was used to obtain Pulse Volume Recording (PVR), which provided information about the variations in the volume of blood passing through a limb during each cardiac cycle (Vasamed SensiLase PAD-IQ, 2013). The waveform provided a pictorial view of the macro circulation. This device can be used to obtain the traditional ankle brachial index (ABI) (Vasamed SensiLase PAD-IQ, 2013). SPP was used to localize specific arteries causing limb ischemia, document limb revascularization post intervention and to assess wound healing. This population based sample was categorized according to mild, moderate and severe disease. Adequate perfusion was greater than 70 mm Hg; mild disease has SPP of 40 to 60 mm Hg, moderate disease has an SPP of 30-40 mmHg, and severe disease has an SPP of less than 30 mm Hg.

A retrospective chart review was conducted for baseline data abstraction of asymptomatic patients screened for PAD and their confidentiality was maintained by de-identification before analysis (Burns & Grove, 2009). Data abstraction was conducted to obtain the HbA1c levels in the diabetic patients through chart reviews and trended with the level of PAD indicated by the SPP pressures. Disease levels were correlated with HgA1cs for the sample.

Correlational studies provided information about the strength and direction of relationships between variables. The higher the confidence level, the higher the strength of the relationships. Analysis of the data provided clarification of theoretical concepts and possible identification of causal relationships.

Setting and Sample

The Christus Spohn Family Health Clinics (FHCs) implemented the PAD-IQ in all facilities as part of the DSRIP project. The FHC facilities provide primary care for rural and underserved communities.

All patients with the diagnosis of hypertension and diabetes were screened for PAD and included in the study (n = 149) of these patients charts were randomly selected for secondary data analysis. Diabetic and hypertensive patients that have not been screened for PAD were excluded. The secondary data analysis evaluated HbA1c and level of PAD disease looking for a correlation.

Measurement

The PAD-IQ provides information on the macro and micro circulation and allows for data storage to the cloud which can be retrieved easily for printing or sent electronically to a specialist, if one is needed (Vasamed SensiLase PAD-IQ, 2013). Macro and micro circulation were measured using PAD-IQ, as well as patient HbA1cs from chart reviews. The psychometrics of SPP were successfully demonstrated in the literature. The comparative study of the SPP, ABI and TBI to multidetector-row computed tomography (MDCT) done by Okamoto et al. in 2006 demonstrated that SPP outperformed all in the hemodialysis (HD) patient population for above knee (AK) level disease. SPP <50 mmHg was 100% sensitive for PAD detection and for below-the-knee (BK) level disease; SPP was 84.8% sensitive for PAD detection. For AK level disease, ABI < 0.9 was insensitive for PAD and of the 13 of 72 limbs with ABI result of <0.9, sensitivity for ABI detecting peripheral arterial occlusive disease (PAOD) BK was only 29.9%. Skin Perfusion Pressure was the most useful tool with respect to both sensitivity and specificity for early detection of PAD in renal population. In 2009, Bailey

and Schechter conducted a validation study assessing wound healing prediction accuracy rate and PAD detection. Wound healing prediction accuracy rates were SPP/PVR 93.2% (82/88) while TCOM/ABI was 63.9% (23/36). Peripheral artery disease detection using SPP/PVR 96.2% (50/52) and TCOM/ABI 61.5% (32/52). Importantly, ABI was unable to be obtained bilaterally in 22% (22/100) of the sample population. The SPP has been used successfully to assess the severity of limb ischemia and for the prediction of wound healing more accurately than can other noninvasive measurements.

The National Glycohemoglobin Standardization Program (NGSP) has been standardizing HbA1c instrument screening certification worldwide. To obtain a NGSP certification, manufacturers have to meet the criteria of a 95% confidence level (Saudek et al., 2013). In 2000, Rohlfing et al, demonstrated a sensitivity (83.4%) and specificity (84.4%) for detecting undiagnosed diabetes at a HBA1c cutoff of 1 SD above the normal mean of 7 (Rohlfing et al., 2000). The sensitivity and specificity of A1C ≥6.5% for detection of prevalent diabetes were 47 and 98%, respectively against a single fasting glucose ≥126 mg/dl (Selvin, Steffes, Gregg, Brancati, & Coresh, 2013). Selvin et al. (2013) repeated the testing 3 years later and the sensitivity improved to 67% and specificity remained high at 97% (Selvin et al., 2013). Glycohemoglobin has been successfully used to screen for diabetes.

Data Collection Tool and Data Analysis

Data Collection Tool and Procedure

1. A list of clinic patients with the diagnosis of hypertension and type I or II diabetes was obtained from the selected study health center.
2. A sample of patients' charts from clinics was selected for the sample size of n=100 using a random number generator.
3. Charts were reviewed for documentation of HbA1c and peripheral flow.
4. Patients who did not meet the criteria of HbA1c and SPP were discarded and others were selected from which the subject was removed.

5. Data were collected using a data collection tool (Appendix B).
6. Data were analyzed using SPSS for descriptive and inferential statistics (Appendix A).

Data collected were analyzed based on age, sex, the level of disease, and were then compared to HbA1c levels for correlations. Data analysis was conducted using SPSS for descriptive and inferential statistics. The relationships between the variables was explored using Pearson correlation coefficient to assess the degree and direction of connection between the variables (Terry, 2012).

Protection of Human Subjects

Approval for this study was obtained on May 15th, 2014 from the institutional review board (IRB) for the Christus Health System and the study number assigned was 2014-008 (Appendix D). Permission to use the DSRIP data was obtained on May 15th, 2014 as part of the IRB approval. The potential participants' charts were obtained through data mining of clinic patients' personal health information (PHI) with the diagnosis of diabetes and hypertension. The HIPAA Privacy Rule was used since the data collected was de-identified; and this rule only applied to individually identifiable health information. Because the data collected were de-identified, the data was not considered to be personal health information (PHI) and could be used or disclosed without a signed authorization or an approved waiver of authorization. All personal health information (PHI) was maintained according to electronic documentation and confidentiality policies of the Christus Spohn Health System. Security within the electronic documentation system was restricted to the principal investigator. All personal health information was coded with the study participant's assigned study identification number and stored on an encrypted thumb drive locked in the office of the principal investigator.

The objective of this project was to evaluate the relationship between level of PAD and HbA1c using secondary data obtained from the charts of patients within the clinic setting with the diagnosis of diabetes and hypertension. The correlational study looked at the relationships among variables. It provided a quantifiable methodology to analyze variables and add to the literature and knowledge of PAD. This study provided a scientific foundation for early management and treatment of PAD. The intended outcome of this study is to lead to improved PAD recognition, early intervention and the use of effective preventive methods. Critical limb ischemia could be delayed and or prevented through effective screening methodologies. The quality of life of this vulnerable population will be improved through early access to specialty care. The cost of advanced PAD will be decreased and it can lead to the prevention of cardiovascular disease.

Section 4: Findings, Discussion, Results and Implications

Findings and Results

Of the 200 charts reviewed, 149 were selected based on the criteria of patients with diabetes and hypertension that had been screened for peripheral vascular disease using the PADIQ device. There were 53 male participants or 35.6% of the sample and 96 female participants or 64.4%. More than half of the sample was between the ages of 31-60 years of age (79.9%). See Table 2.

Table 2
Frequencies and Percentage for Dependent Variable

		n	%
Age Group	30 or less	7	4.7
	31-60	119	79.9
	60 or greater	23	15.4
Gender	Male	53	35.6
	Female	96	64.4
HBA1c	7 or less	48	32
	7.1 to 10	74	49.6
	10 or greater	27	18.1

Table 3 shows the descriptive statistics for levels of PAD among study participants. The sample n=149 was assigned a level of disease from 1-4 based on SPP. The participants with no disease were given a minimum score of 1(SPP > 70mm Hg). Mild disease was given a score of 2 (SPP 40-60 mm Hg), Moderate disease was given a score of 3 and Severe disease was given a score of 4(<30 mm Hg). Left leg PAD has a mean of m = 1.42, with a SD = .80. Right leg PAD has a mean of m= 1.35 with a SD of .68.

Table 3
Mean and Standard Deviation for Peripheral Artery Disease (PAD)

	N	*M*	*SD*	*Min*	*Max*
Levels of PAD	149			1	4
Lt leg	149	1.42	.80	1	4
RT Leg	149	1.35	.68	1	4

As seen in Table 4, left PAD mild disease was *n* =26 or 17.4%. Moderate disease *n* =8 or 5.4% and severe disease n=7 or 4.7%. Right PAD mild disease was n=26 or 17.4%. Moderate disease n=10 or 6.7% and severe disease n=2 or 1.3%.

Table 4
Frequency and Percentage of PAD

PAD levels	*n LT Pad*	*% LT PAD*	*n RT PAD*	*% RT PAD*
1	108	72.5	111	74.5
2	26	17.4	26	17.4
3	8	5.4	10	6.7
4	7	4.7	2	1.3

Descriptive statistics as listed in Table 5 shows a mean age of 51.5 years with the standard deviation of 10.3 sample size n=149. The mean HGA1c is 8.3 with a *SD* of 2.15. Left PAD has a mean of *m* =1.42, with a *SD* = .80. Right PAD has a mean of *m* = 1.35 with a *SD* of .68.

Table 5

Descriptive Statistics

	Mean	**STD Deviation**	***N***	**Sex**
Age	51.51	10.30	149	M: 53 F: 96
HbA1c	8.3	2.15	149	
LT PAD	1.42	.80	149	
RT PAD	1.35	.68	149	

A Pearson's correlation was run to determine the relationship between 149 patients' HbA1c and level of PAD (see Table 2). There was a significant relationship between HbA1c and LT PAD (r =.21, p=.009). There was no relationship between HbA1c and RT PAD (r =.01, n =149, p =.90). There was a significant relationship between HbA1c and age (r =.34, p =.00).

Correlations

Table 6

Correlations

		Age	HbA1c	LT PAD	RT PAD
Age	Pearson Correlation		-.336**	-.018	.092
	Sig. (2-tailed)		.000	.826	.265
	N	149	149	149	149
HbA1c	Pearson Correlation	-.336**		.212**	.010
	Sig. (2-tailed)	.000		.009	.900
	N	149	149	149	149
LT PAD	Pearson Correlation	-.018	.212**		-.013
	Sig. (2-tailed)	.826	.009		.880
	N	149	149	149	149
RT PAD	Pearson Correlation	.092	.010	-.013	1
	Sig. (2-tailed)	.265	.900	.880	
	N	149	149	149	149

** Correlation is significant at the 0.01 level (2-tailed).

Summary of findings

These findings support the importance of tight glycemic control, as well as early screening for PAD in high-risk populations. Project findings added to the literature and knowledge about PAD and the significance of early screening in the prevention of cardiovascular events (CVD).

Discussion of findings in the context of the literature

Findings have added to the literature about the importance of tight glycemic control in the prevention of peripheral artery disease.

Routine screening for peripheral artery disease has been supported by the findings. Ultimately, these findings demonstrate that cardiovascular disease (CVD) prevention will be improved because of the link between PAD and CVD.

Interpretation of Findings, and Implications for Evidence-Based Practice Policy

Policies could be developed using the findings from this study and others which supported the need for early screening of high risk populations such as patients with diabetes, hypertension and hypercholesterolemia. Policies regarding the population disparities could be supported by this study and others.

Practice

These studies could become the foundation for new practice guidelines to screen for PAD as a mechanism for the decrease in cardiovascular disease. There findings could be used to develop further studies about early screening for PAD in the diabetic population. Also, early screening of high risk populations would be developed.

Research

The Stetler model (2001) was used as the conceptual framework for this evidence-based project. The framework facilitated the research question and literature review. The data was analyzed using this frame work. The results demonstrated that there was significance between HbA1c and PAD. These results highlight the importance of glycemic control in an effort to prevent diabetic complications. The significant strides made in the risk reduction of PAD and CVD through the behavior modification efforts of lessened tobacco use, a less sedentary lifestyle

and obesity will be applied to facilitate health promotion and decrease disease progression. Early recognition of PAD will provide opportunities for early interventions such glycemic control, blood pressure control and exercise to slow and decrease progression. A decrease in disease progression will ultimately lead to:

- Improved limb salvage
- Decrease in the number of limb amputations
- Decrease in the psychological effects of PAD
- Decrease in the medical and surgical cost of interventions
- Improved CVD prevention

Results of this study can be used to further support other research into early screening for PAD, ultimately leading to a change in the current practice of only screening patients that are symptomatic. The success of asymptomatic screening would lead to a practice change which, ultimately, will improve patient care and clinical outcomes. The main strength of this project is its innovative focus - a comparison of the values of glucose control and severity of peripheral artery disease (PAD). Screening of asymptomatic patients is not supported in the literature; however, early PAD identification will positively impact the prevalence and incidence of severe cardiovascular disease. Early screening will have a significant impact by providing information about the severity of PAD allowing for the initiation of therapy to improve outcomes, save limbs and lives.

This project involved secondary data analysis looking for correlations between the two variables of glycos-hemoglobin (HbA1c) and PAD. The relationships discovered could add to the literature and provide a foundation for more research in this field. Secondary data analysis

relies on the data available from the original EBP, which is screening patients with diabetes and hypertension for PAD. Limitations of the plan included sample size may not be large enough for statistical significance. Ideally, this project should be a longitudinal one, so that the full value of early screening can be obtained. Baseline assessments of PAD and HbA1c should be obtained and the participants followed over time to see the full impact of screening and early intervention.

Project strengths and limitations

Strengths. The strength of the project was its unique look at peripheral arterial disease and correlation with glycos-hemoglobin (HBA1c). This perspective has not been studied previously and it will add important viewpoints and results to the literature on this subject.

Analysis of Self

As a practitioner

My nursing focus has always been a clinical or practical one. Research that can be applied to practice for improved clinical outcomes has been a passion of mine. The DNP prepared leader or practitioner will gain skills that enables them to communicate effectively on behalf of the patient and the clinician at the bedside. A doctorate that supports practice can bridge the gap between scientific research and the application of the evidence to the care of patients for improved outcomes. There needs to be a foundation for practice, and nurses that are PHD, DNS or DNSc prepared gain the knowledge to drive research which facilitates the credibility of nursing science. It is highly beneficial to create a foundation for the nursing profession. Doctoral nurses acquire additional knowledge to drive research which facilitates the credibility of nursing practice.

The DNP will allow for the continuation of my passion for nursing; knowledge is a powerful tool that can be used to increase my credibility as a clinical expert. As we move forward with Obamacare and the Affordable Care Act, we will need to effectively manage patients with a focus on quality and fiscal responsibility. The DNP practitioner role positions advanced practice nurses (APNs) to assist in alleviating the burden of managing complex patients with many core morbidities. DNP-prepared nurses, have many opportunities to utilize an enhanced skill set which includes clinical expert, teacher, patient advocate and nurse executive. A DNP provides the foundation to go out in the world and make a difference in healthcare outcomes.

This project in future professional development

Peripheral artery disease prevention has a global impact. The literature does not support the screening of asymptomatic patients for PAD; however, as I discuss my project and I share the literature, I have begun to have many insights during moments with my peers. I foresee this project continuing past my DNP and my becoming an advocate for the prevention of PAD and campaigning to save limbs. This project has had many barriers and I have had to use leadership, as well as communication skills, to navigate for a solution. The organizational IRB process forced me to persevere in order to obtain approval.

Currently, less than 1% of all nurses in America have a doctoral degree and when I reflect on that statistic, I am excited and humble to discover that I am one of the few. The responsibility of a doctorate is an important one for healthcare policy and outcomes. There are many opportunities available for my skill set and I will continually evaluate and ensure these

skills are being used to collaborate and advocate for constantly improving nursing and patient outcomes.

Ethics is very important to me academically and personally. Ethics are a part of my value system and it is essential that I maintain the ethical standards and value system with which I was raised. The DNP essential competencies provide us with a foundation to impact healthcare on many levels. The science of nursing practice is advanced by looking at the scientific underpinnings for practice (AACN, 2006). Walden students have the vision and the mission to advance their chosen profession and work towards improving the environment in which we work and live. Our acquired skills will be used to manage the challenges of society.

According to the AACN, healthcare systems will be improved through leadership and quality initiatives; the DNP prepared Walden graduate will have the necessary tools to create and shape future health policies. Patient care will be advanced using improved technology. Clinical outcomes will be improved through the use of evidenced-based practice. DNPs have the skill set to advocate for better patient outcomes through interprofessional collaborations (AACN, 2006). Health care policies and health care performed will be transformed and thus lead to a healthier population.

The AACN essentials and Walden's vision for its students will be utilized in my practice as I advocate for better health for patients. My passion is prevention and I will use my honed skills to advocate for health care policies that focus on disease prevention. While in the DNP program, my leadership skills will be further developed and I will use them to advance nursing professionally through population education and the education of future nursing students.

Summary and Conclusion

Peripheral artery disease has significant correlations with other cardiovascular events and early recognition has the potential to impact health care clinically by providing opportunities for early interventions, such as behavior modifications and cardiac rehabilitation. Furthermore, less invasive interventions such as angioplasty will be available to prevent critical limb ischemia (CLI) and limb amputations. The benefits of early recognition of these diseases will contribute to improving clinical outcomes through the creation of opportunities for aggressive management of the risk factors leading to this disease.

The direct health care cost of PAD is between $164 and $290 billion dollars per year and the ability to decrease these cost will free up funds that will become available for other health care areas (SAGE, 2010),.

Section 5: Scholarly Product

Project Summary and Evaluation Report

Peripheral artery disease (PAD) affects 8 to 10 million Americans and it is expected to increase as the population ages and chronic diseases continue to rise (Hirsch, Hartman, Town & Virnig, 2008). Peripheral artery disease is defined as atherosclerosis of the abdominal aorta, iliac, and lower-extremity arteries (Olin & Sealove, 2010). According to the Sage Group (2010), the direct cost of PAD in the United States is estimated to be between $164 and $290 billion. The U.S. Preventive Services Taskforce (USPSTF) defines PAD as a manifestation of systemic atherosclerosis that has demonstrated a significant correlation with other atherosclerotic, cardiovascular diseases (CVD) and cardiac related events (USPSTF, 2013). A high percentage of the PAD population is undiagnosed before a serious cardiovascular event; therefore, the ability to screen and diagnose this disease could have a dramatic impact on the efforts to decrease cardiovascular disease. Individuals with PAD have a three to five times increased risk of CVD mortality when compared to people that do not have PAD (Criqui et al., 1992).

Additionally, the consistent correlation between PAD and future CVD events has influenced the American Heart Association (AHA) and the National Cholesterol Education Program (NCEP) to establish recommendations for intensive atherosclerotic risk factor reduction for PAD and CVD patients (NCEP, 1993). Early identification of patients with PAD has the potential to impact CVD and, in doing so, to create opportunities for aggressive management of the risk factors leading to this disease. Common disease and lifestyle factors have been directly linked to PAD and CVD; therefore, health promotion has been focused on risk reduction (AHA, 2013).

Significant strides have been made in the risk reduction of this disease through modification of health behaviors such as tobacco use, sedentary lifestyle and obesity. Disease management of hypertension, diabetes and hyperlipidemia has proven to have significant impact on atherosclerosis (Olin & Sealove, 2010). Secondary prevention involves screening for diseases before they have had an impact on the individual. Screening high-risk patients with diabetes and hypertension who are asymptomatic for PAD is an example of secondary prevention. The ultimate goal of prevention is to impact the prevalence and incidence of disease.

Method

The primary research method used in this project was a correlational retrospective cohort study. This correlational retrospective cohort study evaluated the impact of early screening for PAD disease outcomes along with the relationship between HbA1cs and severity of disease. The Delivery System Reform Incentive Payment (DSRIP) project is part of the government's initiative to improve patient outcomes and the data collected for this project is available in the public domain. As part of the DSRIP initiative, clinic patients with diabetes and hypertension were screened using the PAD-IQ. This device is noninvasive and uses segmental pressure to obtain Skin Perfusion Pressure (SPP) to provide a quantitative evaluation of microcirculatory perfusion of the skin. All patients with the diagnosis of hypertension and diabetes were screened for PAD and included in the study (n = 149) of these patients charts were randomly selected for secondary data analysis. Diabetic and hypertensive patients that have not been screened for PAD were excluded. The secondary data analysis evaluated HbA1c and level of PAD disease looking for a correlation.

Data collected was analyzed based on age, sex, and for the level of disease and compared to HbA1c levels for correlations. Data analysis was conducted using SPSS for descriptive and inferential statistics.

Results

Two hundred charts were reviewed and n=149 were selected based on the criteria of patients with diabetes and hypertension that had been screened for peripheral vascular disease using the PADIQ device. Male patients were 53 and female were 96, with an age range of 24 to 85. Descriptive statistics listed in Table 2 shows a mean age of 51.5 with the standard deviation (SD)of 10.3 sample size n=149. The mean HGA1c is 8.3 with a *SD* of 2.15. Left PAD has a mean of m=1.42, with a SD = .80. Right PAD has a mean of m= 1.35 with a SD of .68.

A Pearson's correlation was run to determine the relationship between 149 patients' HbA1c and level of peripheral artery disease (PAD) as shown in Table 3. There was a significant relationship between HbA1c and LT PAD (r=.21, p=.009). There was no relationship between HbA1c and RT PAD (r=.01, n=149, p=.90). There was a significant relationship between HbA1c and age (r=.34, p=.00).

Discussion

The results demonstrated that there was significance between HbA1c and PAD. These results highlight the importance of glycemic control in an effort to prevent diabetic complications. The significant strides made in the risk reduction of PAD and CVD through the behavior modification efforts of lessened tobacco usage, decreased sedentary lifestyles and obesity will be applied to facilitate health promotion and decrease disease progression. Early recognition of PAD will provide opportunities for early interventions such glycemic control, blood pressure control and exercise to slow and decrease progression. A decrease in disease progression will ultimately lead to:

- Improved limb salvage Improved CVD prevention
- Decrease in the number of limb amputations

- Decrease in the psychological effects of PAD
- Decrease in the medical and surgical cost of interventions
- Improved CVD prevention

Results of this study can be used to further support other research into early screening for PAD, ultimately leading to a change in the current practice of only screening patients that are symptomatic. The success of asymptomatic screening would lead to a practice change, which, ultimately, will improve patient care and clinical outcomes. The main strength of this project is its innovative focus - a comparison of the values of glucose control and severity of peripheral artery disease (PAD). Screening of asymptomatic patients is not supported in the literature; however, early PAD identification will positively impact the prevalence and incidence of severe cardiovascular disease. Early screening will have a significant impact by providing information about the severity of PAD allowing for the initiation of therapy to improve outcomes and save limbs and lives.

This study involved secondary data analysis looking for correlations between the two variables of glycos-hemoglobin (HbA1c) and PAD. The relationships discovered could add to the literature and provide a foundation for more research in this field. Secondary data analysis relies on the data available from the original EBP, which is screening patients with diabetes and hypertension for PAD. Limitations of the plan included sample size may not be large enough for statistical significance. Ideally, this project should be a longitudinal one, so that the full value of early screening can be obtained. Baseline assessments of PAD and HbA1c should be obtained and the participants followed over time to see the full impact of screening and early intervention.

Summary

Peripheral artery disease (PAD) has significant correlations with other cardiovascular events and early recognition has the potential to impact health care clinically by providing opportunities for early interventions, such as behavior modifications and cardiac rehabilitation. Furthermore, less invasive interventions such as angioplasty will be available to prevent critical limb ischemia (CLI) and limb amputations. The benefits of early recognition of these diseases will contribute to improving clinical outcomes through the creation of opportunities for aggressive management of the risk factors leading to this disease.

The quality of life of this vulnerable population will be improved through early access to specialty care.

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Appendix A

Data Collection Tool

Study ID	SEX	SPP	HbA1c	Lt PAD	RT PAD

Appendix B

Study Timeline

Table 7
Study Timeline

Date	Activity
August 2014 – December 2014	IRB Approval, Notify providers of study
January 2015 – March2015	Collect data
March 2015– April 2015	Comprise statistical analysis
September – 2015	Complete capstone project

Appendix C

Permission to Conduct Study

CHRISTUS Health

Date: 15-MAY-2014

To: Cheryl Gordon

Re: **IRB Protocol # 2014-008 "Peripheral Artery Disease Screening"**

This letter is to inform you that CHRISTUS Health IRB acknowledges receipt of the above research project and its addenda and has made the determination that the proposed research is exempt from all 45 CFR part 46 requirements under 45CFR 46.101(b); Exemption Category **_4_**.

Exempt status does not lessen the ethical obligations to human participants (or their data) as articulated in disciplinary codes of professional conduct and in the Belmont Report (See: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). It means that you, as the Principal Investigator, assumes responsibility for the protection of human participants and ensures that the research is being conducted with integrity and within acceptable ethical standards.

You are also expected to ensure that you and all individuals performing the research have successfully completed the IRB training required of all persons conducting human subjects' research within a CHRISTUS facility (See CHRISTUS Health Clinical Policy 3.200: Research and Institutional Review Boards).

The study is not subject to continuing review requirements and does not have an expiration date. It is very important, however, that you close-out your project when it is complete or if you leave the institution. Close-out forms can be obtained by contacting the IRB Office.

If you have any questions, please feel free to contact the CHRISTUS Health IRB at 469-282-2577.

**********NOTE**********

If any changes are made to the research design, study population, or data collection tool, IRB re-evaluation is REQUIRED as changes may affect exempt status.

Sincerely,

Thomas Diller, M.D., MMM
CHRISTUS Health IRB Chair

Cc: Charles Volk, M.D.
Sheryln Wachtel, Ph.D.

CHRISTUS Health Research Office
919 Hidden Ridge
Irving, TX 75038
469-282-2686

Appendix D

IRB Certificate

Dear Ms. Gordon,

This email is to notify you that the Institutional Review Board (IRB) confirms that your study entitled, "Peripheral Artery Disease Screening," meets Walden University's ethical standards. Our records indicate that you will be analyzing data provided to you by Christus Spohn as collected under its oversight. Since this study will serve as a Walden doctoral capstone, the Walden IRB will oversee your capstone data analysis and results reporting. The IRB approval number for this study is 12-03-14-0393878.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the documents that have been submitted to IRB@waldenu.edu as of this date. This includes maintaining your current status with the university and the oversight relationship is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB materials, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden
website: http://academicguides.waldenu.edu/researchcenter/orec

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Please note that this letter indicates that the IRB has confirmed your study meets Walden University's ethical standards. You may not begin the doctoral study analysis

Walden IRB Approval, continued

phase of your doctoral study, however, until you have received the **Notification of Approval to Conduct Research** e-mail. Once you have received this notification by email, you may begin your study's data analysis.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Sincerely,
Libby Munson
Research Ethics Support Specialist
Office of Research Ethics and Compliance
Email: irb@waldenu.edu
Fax: 626-605-0472
Phone: 612-312-1283

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