FUNCTIONAL CAPACITY AND FUNCTIONAL PERFORMANCE IN PERIPHERAL ARTERIAL DISEASE: A MULTIGROUP ANALYSIS

by

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DEDICATION

To my family

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABSTRACT

Older adults with peripheral arterial disease (PAD) can experience impairments in both functional capacity (FC) and functional performance (FP). Few studies have examined the effect of PAD severity on FC and FP utilizing a latent variable model. The purpose of this secondary analysis of the National Health and Nutrition Examination Survey (NHANES) 1999 – 2002 survey cycles was to develop and test a latent variable model of FC and FP in older adults with and without PAD.

The study sample included a subpopulation of all NHANES participants from the 1999-2002 survey cycles (*N* = 21,004) over the age of 50 years (n = 3695) who had screening performed for PAD. Subjects were then separated into a 'no PAD' (n = 3317) and 'PAD' (n = 378) group for analysis. Measures included ankle-brachial index (PAD severity), maximum calf circumference, quadriceps strength (lower extremity strength), Semmes-Weinstein monofilament test (lower extremity sensory impairment), 20-foot timed walk (usual gait speed), self-reported level of physical activity, and physical function questionnaire (ability to perform routine daily tasks).

Analyses included multigroup confirmatory factor analysis (MG-CFA) of the measurement model, structural equation modeling, and indirect effect testing. The MG-CFA of the measurement model demonstrated configural, metric, and scalar invariance between the 'no PAD' and 'PAD' groups. Multigroup structural equation modeling demonstrated acceptable fit of the model to the data controlling for PAD severity, age, and gender (RMSEA 0.058, CFI 0.811, and SRMR 0.069). The fit was also acceptable after controlling for PAD severity, age, gender, and diabetes (RMSEA 0.059, CFI 0.782, and SRMR 0.069). Indirect effect testing showed FC to

mediate the relationship between PAD severity and FP in the ‘PAD’ group. These findings support the applicability of a latent variable model for evaluating the effect of PAD severity on FC and FP in older adults with PAD.

CHAPTER I

INTRODUCTION

This dissertation examines a latent variable model of functional capacity (FC) and functional performance (FP) in a group of older adults with and without peripheral arterial disease (PAD). It will identify and evaluate the relationships between PAD severity and latent variables FC and FP. It will show that past research on PAD severity and function has yielded inconclusive and inconsistent results regarding these relationships. Additionally, it will show that past research has not provided a plausible model of the processes that explain function in older adults with PAD. This dissertation will utilize a secondary data analysis of the National Health and Nutrition Examination Survey (NHANES) to test a plausible latent variable model of FC and FP in a subpopulation of the survey with no PAD and with PAD.

Prevalence of PAD

Peripheral arterial disease (PAD) affects 8-12 million people in the United States and can be found in approximately 12-35% of adults over the age of 55 years (Hirsch, et al., 2001). There is increased risk for concomitant coronary artery disease (14-90%) and cerebrovascular disease (25%) in older adults with PAD (Golomb, Dang, & Criqui, 2006). Furthermore, PAD is associated with an increased risk of death and disability from cardiovascular disease (Newman, Sutton-Tyrrell, Vogt, & Kuller, 1993). All-cause mortality is also increased (Resnick, Lindsay, McDermott, Devereaux, Jones, & Fabsitz, et al, 2004).

Global Burden of Disease

The World Health Organization (WHO) report on disability-adjusted life years provides a tangible measure of the loss of health associated with human disease (Lancet, 2012). Disability-adjusted life years (DALY) are defined as the sum of life years lost due to premature death and years lived with disability (YLD). The YLD comprises the product of the prevalence of the disease and a disability weight. These elements compare the current condition of population health to normative standards. This recent WHO report compares these metrics from the year 1990 to the year 2010.

The United States prevalence of PAD is 5-12%, and the individual impact of this disease is striking. The WHO report states that the DALY (thousands) for peripheral arterial disease in 1990 was 505 (342-748). In 2010, the DALY for PAD was 995 (703-1445), which was a 97% increase. The YLD for PAD increased 63% from 1990 to 2010. It is evident that PAD results disability and the potential for reducing a person's life span. These figures portray the real life burden of living with peripheral arterial disease.

Living with PAD: Impact on Function

The functional consequences of PAD are significant. Adults with PAD may have impairments in walking, performing daily activities, and participating in social activities (McDermott, Liu, Greenland, et al, 2004; McDermott, Greenland, Liu, et al, 2002). Specifically, impairments in sensation, strength, and gait speed contribute to decreased function as well as lower levels of physical activity. In short, PAD can affect the quality of many aspects of a person's daily life.

Organizing Framework

The functional status framework (FSF) is the organizing structure chosen to guide this study (Leidy, 1994, 1995). The FSF has been utilized to study functional performance in people with COPD (Leidy, 1995). A diagram of the framework is shown in Figure 1.1. The concepts of functional capacity and functional performance are utilized to create a model of functional status for this dissertation.

The FSF defines functional status as a comprehensive picture of a person's functioning to include all areas that contribute to health and well being including physical, psychological, social and spiritual needs. There are four specific areas of functional status according to the framework: functional capacity, reserve, performance, and capacity utilization. The focus of this study will be on functional capacity and functional performance.

Functional capacity is defined as: "one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being" (Leidy, 1994). Physical attributes of functional capacity include strength, endurance, respiratory, and cardiac capacity (Leidy, 1994). For this study, lower extremity strength, lower extremity sensory impairment, and calf circumference were used as indicators of functional capacity. These variables will be discussed further in the next section.

Functional performance is defined as: "the physical, psychological, social, occupational, and spiritual activities that people actually do in the normal course

of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being" (Leidy, 1994).

These activities are usually performed at a level that does not require or meet a person's functional capacity. Activities of daily living represent the physical component functional performance. Social activities are those that involve family and friends as well as community involvement. Spiritual activities are those that include involvement in organized religious activities such as attendance at worship services. This study used physical activity, activities of daily living, and usual gait speed as indicators of functional performance. These will be discussed further in the next section.

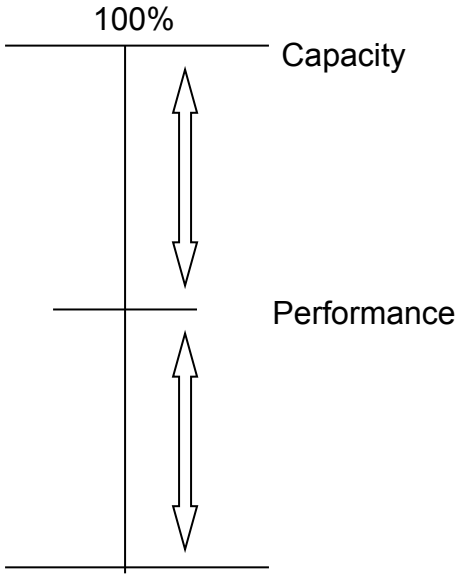


Figure 1.1. Functional status framework (Leidy, 1994)

Theoretical Model

It was determined that a multivariate model was needed to account for the complexity of the process that determines functional performance in older adults with PAD. In addition, the goal of this multivariate model is to build upon the current body of knowledge in order to provide a significant contribution to the science.

A latent variable model (Figure 1.2) was created for this study, guided by the FSF (Figure 1.1). The latent variables are functional capacity (FC) and functional performance (FP). The functional capacity indicators are lower extremity strength, calf circumference, and lower extremity sensory impairment. The functional performance indicators are physical activity, activities of daily living, and usual gait speed.

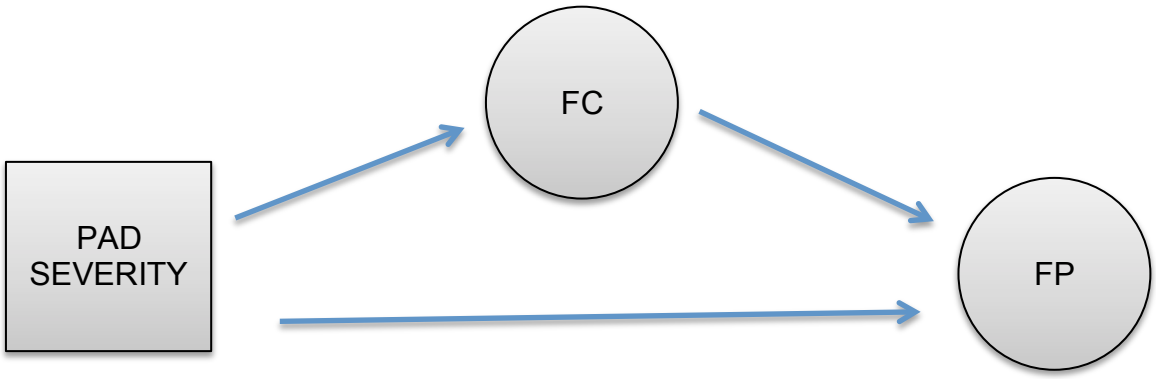


Figure 1.2. Theoretical Model

Study Significance

The severity of PAD and functional capacity can influence functional performance in older adults with PAD. The global and individual magnitude of this problem is significant as demonstrated in the data published by the WHO report (Lancet, 2012). Older adults living with PAD experience a loss in function that can affect mobility, social functioning, and ability to perform self-care and daily tasks. Research to date has provided a solid foundation to the underlying mechanisms of function in older adults with PAD, but several questions remain unanswered that will be addressed by this study.

Purpose

The purpose of this study was to determine the relationship between PAD severity, functional capacity and functional performance in older adults with PAD using a latent variable model. This model will be fit in two groups, a 'no PAD' group, and 'PAD' group, and compared. Age, gender, and diabetes were included as covariates.

Specific Aims

The specific aim with corresponding hypotheses for this study:

Specific Aim 1. Develop, test, and fit a plausible latent variable (measurement and structural) model to explain the effect of PAD severity on functional capacity (FC) and functional performance (FP) in older adults with no PAD and with PAD.

Hypothesis 1.1: The proposed latent variable model will be a good fit in both the no PAD and PAD groups

Hypothesis 1.2: Multigroup analysis will demonstrate measurement invariance of the model between the no PAD and PAD groups

Specific Aim 2. Test the full structural model to explain the effect of PAD severity, age, gender and diabetes on FC and FP in older adults with and without PAD.

Hypothesis 2.1: As PAD severity increases, FC and FP will decline

Hypothesis 2.2: As age increases, FC and FP will decline in both the no PAD and PAD groups

Hypothesis 2.3: There will be a significant difference in FC and FP controlling for age, gender, and diabetes in the no PAD and PAD groups

Specific Aim 3. Perform mediation analysis on the full structural model to determine if FC mediates the relationship between PAD severity and FP

Hypothesis 3.1: FC will mediate the relationship between PAD severity and FP in older adults with PAD

CHAPTER II

BACKGROUND AND SIGNIFICANCE

The purpose of this section is to present the existing evidence which supports the relationships between the model variables. The evidence supporting the relationships between PAD severity, FC, and FP will be discussed.

Relationship Between PAD Severity and Model Variables

Peripheral arterial disease is defined as atherosclerosis of the arterial system of the lower extremities, including the femoral, popliteal, and tibial arteries (Hirsch, Criqui, Treat-Jacobson, Regensteiner, Creager, and Olin, et al., 2001). The presence of PAD is determined by obtaining an ankle-brachial index (ABI) of the lower extremity. The ankle-brachial index is the ratio between the systolic pressure of the ankle using the posterior tibial artery or the dorsalis pedis artery (whichever is highest) and the highest systolic arm pressure. A normal ABI is greater than 0.90, and PAD is present when the ABI is 0.90 or below (Hirsch, et al., 2001). The severity of PAD is documented and categorized by the value of the ABI. As reported in previous studies, the categories of PAD disease severity by ABI are: no PAD (ABI > = 0.91 and ABI < = 1.50), mild to moderate PAD (ABI > = 0.40 and < = 0.90), and severe PAD (ABI < = 0.39). For the purpose of this study, subjects will be grouped as 'no PAD' as determined by an ABI > = 0.91, and 'PAD' as determined by an ABI < = 0.90.

PAD Disease Severity and Functional Capacity Indicators

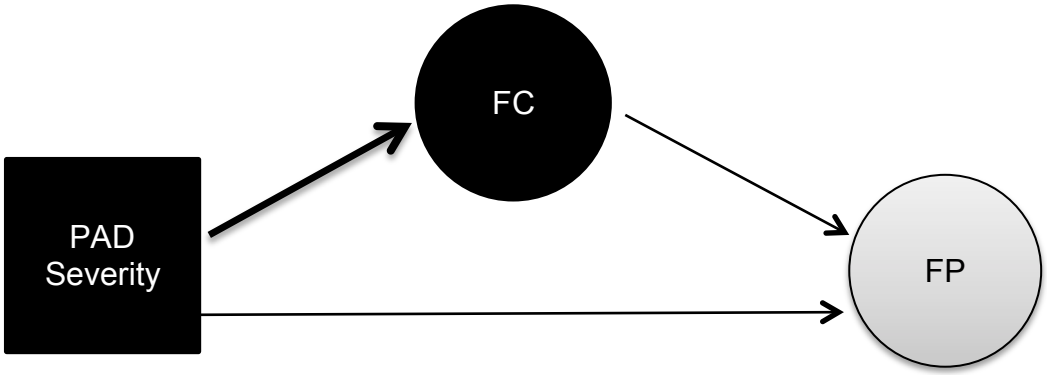


Figure 1.3 PAD Severity and Functional Capacity Indicators

Lower Extremity Strength. In older adults, PAD can result in lower extremity strength deficits (McDermott, Criqui, Greenland, Guralnik, Liu, & Pearce, et al., 2005). Known mechanisms of decreased strength in older adults with PAD include a reduction in the number of skeletal muscle fibers in the lower extremities and skeletal muscle atrophy, due to decreased perfusion to the tissues (ischemia) (McDermott, et al., 2005). Two main studies have examined the relationship between PAD disease severity and lower extremity strength.

McDermott, et al., investigated the relationship between the severity of PAD and lower extremity strength. A cross-sectional study of 269 subjects with PAD and 245 subjects without PAD was performed. The sample was 56% male and the mean age was 73 years old. The severity of PAD was measured by ABI. The categories of PAD were none (ABI 0.91 - 1.10), mild PAD (0.70 - 0.90), moderate PAD (0.50 - 0.70), and severe PAD (< = 0.50). Lower extremity strength was measured using a musculoskeletal fitness chair, which measured isometric lower extremity strength in newton-meters for knee flexion/extension

and hip flexion/extension. Results demonstrated that leg strength was significantly lower in subjects with PAD than those without PAD for hip extension (61.4 vs. 71.6 newton-meters, $p < .001$), hip flexion (54.0 vs. 61.7 newton-meters, $p < .001$) and knee flexion (29.1 vs. 35.4 newton-meters, $p < .001$). A significant relationship was found between ABI and leg strength in hip flexion/extension and knee flexion/extension.

The relationship between PAD disease severity and lower extremity strength was also evaluated in another study of 144 subjects with PAD (Atkins & Gardner, 2004). Functional performance measures of physical activity and a six-minute walk test were included as covariates. The subjects were mostly male (83.3%) with an age range of 45 to 84 years old. The presence and severity of PAD was determined by the ABI. Mild PAD was categorized by an ABI of 0.76 - 0.90, moderate PAD was categorized by an ABI of 0.51 - 0.75, and severe PAD was categorized by an ABI of 0.36 - 0.50. In this study, lower extremity strength was measured by a chair-stand test. There was a significant difference in chair-stand times between the moderate PAD group and the severe PAD group (13.49 seconds vs. 15.86 seconds, $p < .05$). The significant difference between the moderate and severe PAD groups in lower extremity strength disappeared after controlling for FP. This suggests that additional factors other than PAD disease severity may contribute to the reduced lower extremity strength in subjects with PAD.

Lower Extremity Sensory Impairment. Symptoms of peripheral neuropathy such as numbness, tingling, and foot pain can contribute to

impairments in functional capacity and functional performance (McDermott, Sufit, Nishida, Guralnik, Ferrucci, & Tian, et al., 2006). Several studies have documented the impairments of the peripheral nerves and muscles associated with PAD (McDermott, Guralnik, Albay, Bandinelli, Miniati, & Ferrucci, et al., 2004; McDermott, et al., 2006; England, Ferguson, Hiatt & Regensteiner, 1995; Weinberg, Simovic, Isner, & Ropper, 2001). However, to our knowledge no previous studies have evaluated the relationship between PAD disease severity and lower extremity sensory impairment.

Calf Circumference. Peripheral arterial disease results in the alteration of calf muscle characteristics (Mitchell, Duscha, Robbins, Redfern, Chung, & Bensimhon, et al., 2007). This includes cell death of gastrocnemius (calf) muscle and muscle fiber atrophy (Mitchell, et al., 2007; Regensteiner, Wolfel, Brass, Carry, Ringel, & Hargarten, et al., 1993). In addition, adverse metabolism in muscle, skeletal muscle capillary density, and alteration in oxygenation of calf muscle has been reported. These adverse effects are associated with muscle ischemia as a result of PAD (Regensteiner, et al., 1993). Calf muscle changes can be evaluated by measuring the calf muscle area in older adults with PAD. This has been documented in studies using a standard measure of calf circumference by measuring the calf at its largest area. Computed tomography has also been used to obtain more detailed information about the calf muscle and fat distribution in older adults with PAD (Regensteiner, et al., 1993).

In a study of calf muscle characteristics in older adults with PAD, the amount of calf muscle fiber loss, type of calf muscle fiber loss, and calf

circumference (cm^2) was measured. There was significant atrophy of both type I (slow twitch) and type II (fast twitch) fibers in calf skeletal muscle of subjects with PAD. The diameters of both types of fibers were reduced in older adults with PAD, and the authors suggested that these fiber changes likely resulted in decreased calf circumference in older adults with PAD. Indeed, calf circumference was significantly smaller in older adults with PAD compared to older adults without PAD (94.5cm^2, *SD* = 18.4 vs. 99.7 cm^2 , *SD* = 11.9, $p < .05$) (Regensteiner, et al.). In addition, there was significant reduction in calf circumference of at least 5% in the diseased legs when compared to non-diseased legs. There was also a significant correlation between PAD severity and amount of reduction in fiber area.

PAD Disease Severity and Functional Performance Indicators

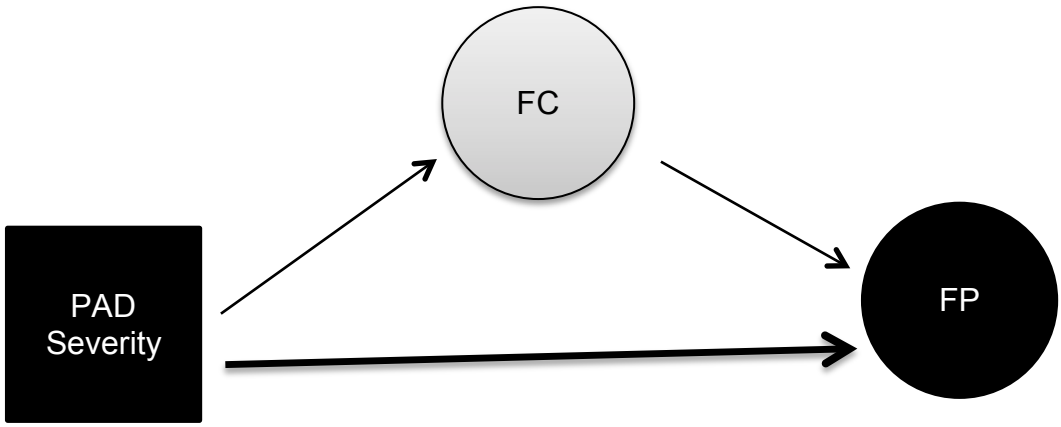


Figure 1.4 PAD Severity and Functional Performance Indicators

Peripheral arterial disease has a significant impact on a person's ability to perform FP activies (Dolan, Liu, Criqui, Greenland, Guralnik, & Chan, et al.,

2002). Several studies that have evaluated the relationship between PAD disease severity and indicators of FP will be reviewed below.

Physical Function Questionnaire (PFQ). McDermott and colleagues (McDermott, Mehta, Liu, Guralnik, Martin, & Criqui, et al., 1999) studied the relationship between PAD disease severity and indicators of FP in a group of adults aged 55 and older with PAD (n = 147). The sample was 55% male, with a mean age of 71.5 years old. The mean ABI of the group was 0.56, indicating moderate to severe PAD. The severity of PAD was measured by the ABI and the Walking Impairment Questionnaire (WIQ) measured FP. The WIQ measured walking distance, walking speed, and stair climbing ability in the community setting. Subjects were asked to report levels of difficulty associated with walking long distances, walking at different speeds, and walking up and down one to three flights of stairs. Results demonstrated that PAD disease severity as measured by ABI was an independent predictor of difficulty associated with walking distance (β= 2.73, *p*= .03) in patients with PAD and remained so even after controlling for leg symptoms, comorbidities including diabetes, and prior revascularization. These results describe the relationship between PAD disease severity and FP; more severe PAD results in worse FP.

The severity of PAD has also been shown to predict future declines in FP (McDermott, Ferrucci, Simonsick, Balfour, & Fried, et al., 2002). McDermott and colleagues (McDermott, et al., 2002) evaluated the relationship between PAD disease severity and long-term reduction in FP in a group of older adult women (n = 257). The severity of PAD was measured by ABI and divided into two

groups: ABI < 0.60 (severe PAD) and ABI 0.61 - 0.90 (moderate PAD). The mean age of the severe PAD group was 79.8 years, and the mean age of the moderate PAD group was 79.5 years. Functional performance was measured as by self-reported ability to walk a quarter mile, the number of blocks walked in the previous week, and the number of stairs climbed the previous week. Measurements were taken at baseline and followed up with subjects being retested every six months for a total of three years. Results demonstrated that women with severe PAD had a higher incidence of severe impairment in FP at the three-year follow-up. Women with severe PAD were less likely to be able to walk a quarter mile, more likely to walk less outside the home, and walked more slowly than those with less severe PAD. A lower ABI at baseline resulted in greater impairment in FP at three years.

Physical Activity. Physical activity is an indicator of functional performance in older adults with PAD (Gardner & Clancy, 2006). It is important in the maintenance of health and function; however, daily levels of physical activity are reduced in older adults with PAD (Gardner & Clancy, 2006). The severity of PAD may affect the extent of decrease in levels of physical activity in older adults with PAD (Gardner, Killewich, Katzel, Womack, Montgomery, & Otis, 1999). Therefore, the relationship between PAD disease severity and physical activity is reviewed.

The relationship between PAD severity and physical activity was examined in a group of older adults with PAD (n = 61) (Gardner, et al.,1999). The mean age of the participants was 70 years old and the sample was mostly male

(93%). Physical activity was measured by the “Energy Expenditure Physical Activity (EEPA),” which is determined by double-labeled water and indirect calorimetry methods. The double-labeled water technique measures carbon dioxide production and oxygen uptake in urine samples. The severity of PAD was measured by ABI. Additional tests for limb perfusion included transcutaneous heating power and calf transcutaneous oxygen measurements, which measure tissue perfusion of blood flow. The results did not find a significant correlation between ABI and EEPA (r = .236, p = .072) or transcutaneous oximetry (r = .239, p = .068), but found a significant negative correlation between EEPA and transcutaneous heating power (r = -.413, p = .002). This result demonstrated that subjects with higher levels of physical activity had better calf perfusion as measured by transcutaneous heating power. It is interesting that there was no significant correlation between ABI and EEPA, which suggest that other factors may influence physical activity in older adults with PAD.

Gardner and Clancy (2006) evaluated the relationship between PAD disease severity and leisure time physical activity in a group of older adults with PAD. A group of 345 men and women with PAD (ABI < = 0.90), ranging in age from 45 to 85, were included in the study. Disease severity was measured by ABI and the subjects were divided into three categories of disease severity: mild PAD (0.70 - 0.89), moderate PAD (0.50 - 0.69), and severe PAD (< 0.50). Physical activity was measured by the Minnesota Leisure Time Physical Activity (LTPA) questionnaire, which determines the physical activity level of the person over the previous year. The LTPA also provided the duration and intensity of physical

activity. Results showed significant differences in LTPA between the three categories of disease severity (p = .030). There was also a significant difference between the groups for high intensity LTPA (p = .009) and moderate intensity LTPA (p = .016). There was no significant difference between the three groups of disease severity in low intensity LTPA. These results demonstrate that physical activity progressively declines as ABI declines and disease severity increases.

McDermott and colleagues also evaluated the relationship between PAD disease severity and physical activity in a study of 460 subjects with PAD (McDermott, Greenland, Liu, Guralnik, Celic, & Criqui, et al., 2002). The group was 59.4% male with a mean age of 71.9 years old. The severity of PAD was measured by ABI and physical activity was measured by accelerometer over a seven-day period. Subjects were categorized into groups by disease severity/ABI and included mild PAD= 0.70 - 0.90, moderate PAD= 0.50 - 0.70, and severe PAD= less than 0.50. The results demonstrated that a lower ABI was associated with lower physical activity level as measured by accelerometer over seven days for mild PAD (β= -268, p<0.001) moderate PAD (β = -341, p < .001) and severe PAD (β = -523, p < .001). After adjustment for covariates, PAD disease severity was independently associated with level of physical activity.

Usual Gait Speed. The value of utilizing usual gait speed (UGS) as an indicator of FP in older adults is well documented in the literature (Cesari, Kritchevsky, Penninx, Nicklas, Simonsick, & Newman, et al., 2005). Slower UGS is associated with subclinical cardiovascular disease (CVD) and even risk in older adults without known CVD (Hamer, Kivimaki, Lahiri, Yerramasu, Deanfield,

& Marmot, et al., 2010). Usual gait speed has been shown to be a significant predictor of disability in older adults and reported to be “nearly as good a predictor of disability as a full functional performance battery” (Guralnik, Ferrucci, Pieper, Leveille, Markides, & Ostir, et al., 2000).

In the PAD population, the relationship between the severity of PAD and usual gait speed has been evaluated, albeit with conflicting results. Seven published studies from 1998-2008 were evaluated for this review. Six out of seven of the studies reviewed had extremely small sample sizes, all with fewer than 45 subjects in the PAD group (range from 9 - 40). Also, the majority of the subjects were male. Subjects in the comparison groups without PAD were likewise small, ranging from 10 - 26 subjects. Only one of the studies reported having done a power analysis, which indicated a minimum sample size of 200 was required to achieve a power of 0.80; however, the final sample size for that study was n = 19 in the PAD group and n = 11 in the no PAD group (Scherer, Bainbridge, Hiatt, & Regensteiner, 1998).

Despite being inadequately powered, these studies drew conclusions regarding the relationship between PAD severity and UGS. It is not surprising that the results are inconsistent. Scherer, et al. (1998) evaluated UGS and other parameters of gait in older adults with and without PAD (n = 19 and n = 11, respectively). The mean ABI for the PAD group was 0.54 (*SD* = 0.22). Although they found UGS to be significantly slower in the PAD group compared to the non PAD group, they did not find a correlation between PAD severity and any gait measure, including UGS.

Several other studies found UGS to be significantly slower in patients with PAD compared to those without PAD. Crowther, Spinks, Leicht, Quigley, and Golledge (2007) studied several different components of gait in a small group of patients with (n = 28) and without PAD (n = 25). The mean age of the subjects in the PAD group was 69.9 years old (*SD* = 1.5) compared to 66.2 years old (*SD* = 1.5) in the non PAD group. The mean ABI was 0.71 (*SD* = 0.04) for the right leg and 0.73 (*SD* = 0.05) for the left leg in the PAD group. In the non PAD group, the mean ABI for both legs was 1.16 (*SD* = 0.03). Fifty percent of the subjects in the PAD group were male and 40% of the subjects in the non PAD group were male. Similar to Chen, et al. (2008), Crowther, et al., found subjects with PAD to have a significantly slower UGS than those without PAD (1.08 m/sec vs. 1.30 m/sec, $p < .001$).

McDermott, et al., (2001) evaluated alterations in gait in subjects with and without PAD. The sample size was n = 40 for the PAD group and n = 22 for the non PAD group. The mean age was 77 years old (*SD* = 7.7) in the PAD group and 71 years old (*SD* = 6.6) in the non PAD group. The mean ABI was 0.64 (*SD* = 0.19) in the PAD group and 1.08 (*SD* = 0.08) in the non PAD group. The subjects in the PAD group were 50% male and in the no PAD group 59% were male. The researchers found UGS to be significantly slower in the subjects with PAD compared to those without PAD during both the first 100 feet and last 100 feet of a six-minute walk test.

Gardner, Forrester, and Smith (2001) evaluated gait characteristics in older adults with (n = 28) and without PAD (n = 15). The mean age of the sample

for both groups was 71 years old (*SD* = 1). Mean ABI in the PAD group was 0.65 (*SD* = 0.03) compared to 1.09 (*SD* = 0.04) in the non PAD group. Ninety-three percent of subjects in both the PAD and no PAD groups were male. The results of the analysis showed that the subjects in the PAD group had 15% slower UGS than those in the non PAD group, which was a significant difference ($p < .05$).

And finally, Kuo and Yu (2008) analyzed NHANES data from the 1999-2002 cycles to evaluate the relationship of PAD severity and usual gait speed in older adults with PAD. This analysis included a subset of subjects over the age of 60 with (n = 206) and without PAD (n = 1592). The sample was 50% male in the PAD group and 48% male in the no PAD group. This study found UGS to be significantly slower in the PAD group compared to the no PAD group (0.869 m/sec vs. 0.994 m/sec, $p < .001$). However, the authors did not use survey sample weights in the analysis, which can result in biased estimates and standard errors (Johnson, Paulose-Ram, Ogden, et al., 2013).

In summary, there are several studies in the literature that have evaluated the relationship between PAD severity and UGS. Most of the studies had small sample sizes and included primarily male participants. Overall, UGS was reduced in subjects with PAD.

Functional Capacity Indicators and Functional Performance

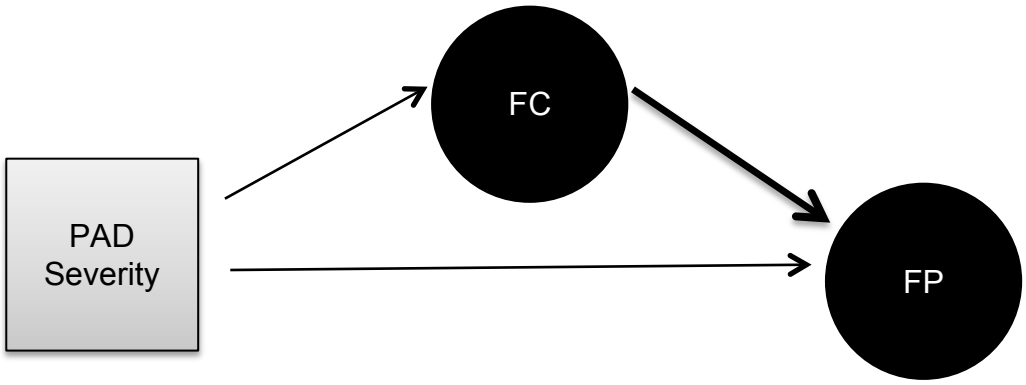


Figure 1.5 Functional Capacity Indicators and Functional Performance

Lower Extremity Strength. Lower extremity muscle strength is defined as the maximum force generated by an individual (Macaluso & de Vito, 2004). Muscle strength peaks between ages 20 - 30 and begins to decline at around age 50, with a subsequent yearly decline of 12-15% (Macaluso & de Vito, 2004; Samuel & Rowe, 2009). The ability to perform FP tasks is associated with muscle strength in older adults; reduced muscle strength results in a reduced ability to perform both upper and lower extremity FP tasks such as lifting and carrying shopping bags and getting up from a chair (Macaluso & de Vito, 2004).

Declines in lower extremity strength have been documented in older adults with PAD. Histological studies have shown ischemic changes in skeletal muscle, including muscle fiber atrophy and denervation, which contribute to muscle weakness and loss of strength (Regensteiner, Wolfel, Brass, Carry, Ringel, & Hargarten, et al., 1993). Several studies that examined the impact of loss of muscle strength on functional performance indicators such as ADLs and physical activity in persons with PAD will be reviewed.

Regensteiner, et al. (1993) characterized the effects of PAD on FC and FP. A sample of men with PAD (mean age 65 years, n = 26) and a sample of men without PAD (mean age 63 years, n = 6) were evaluated. Functional capacity indicators included muscle strength by dynamometer measures and calf muscle cross-sectional area. The functional performance outcome measure in this study was walking time on a treadmill. Histological analysis showed decreases in muscle fiber number and diameter in subjects with PAD, as well as muscle denervation, which was associated with decreased muscle strength in the limb. Gastrocnemius muscle strength was significantly decreased in PAD subjects compared with controls (30 lbs. vs. 53 lbs., $p < .05$). Muscle strength was weakly correlated with walking time on a treadmill ($r = 0.41$, $p < .05$). Calf muscle area was also significantly reduced in subjects with PAD compared to controls (94.5 cm^2 vs. 99.7 cm^2, $p < .05$). In summary, these factors were associated with FP in subjects with PAD. However, given that muscle strength was weakly correlated with walking time on a treadmill, additional FC indicators besides strength likely influence functional performance in subjects with PAD.

A cross-sectional study by McDermott, Criqui, Greenland, Guralnik, and Liu, et al. (2004) assessed the relationships between PAD and lower extremity strength and functional performance. A total of 269 subjects with PAD (mean age 73.2 years) and 245 subjects without PAD (mean age 69.5 years) were included in the study. Functional performance measures included the six-minute walk test, actual physical activity over a seven-day period as measured by accelerometer, and four-meter walking velocity.

Results showed significantly decreased lower extremity strength at all levels of testing in the PAD group compared to controls (hip extension, 61.4 newton-meters vs. 71.6 newton-meters, $p < .001$; hip flexion, 54 newton-meters vs. 61.7 newton-meters, $p < .001$; knee flexion, 29.1 newton-meters vs. 35.4 newton-meters, $p <. 001$). Six-minute walking distance was significantly lower in the PAD group compared to controls (1173 feet vs. 1402 feet, $p < .001$). The four-meter walking velocity was also significantly lower in the PAD group compared to controls (0.891 m/sec vs. 0.9330 m/sec, $p < .05$). Physical activity was lower in the PAD group than controls (864 activity units vs. 1040 activity units, $p < .01$). The severity of PAD, as indicated by ABI, was correlated with each FP outcome measure. However, after adjusting for leg strength, these correlations were decreased. Leg strength was a modest contributor in the relationship between the severity of PAD (decreased ABI) and lower extremity function as measured by four-meter walking velocity. Additionally, knee extensor strength was found to be independently associated level of physical activity. Lower extremity knee extensor strength was a significant predictor of six-minute walk distance ($\beta = 3.78$, $p < .001$), four-meter walking velocity ($\beta = .002$, $p < .001$), and seven-day physical activity level ($\beta = 5.35$, $p < = .05$).

The above studies highlight strength as an important indicator of FC of persons with PAD, as well as the effect of strength on FP measures. In summary, some of the studies demonstrated a significant relationship between lower extremity strength and FP, but others did not.

Lower Extremity Sensory Impairment. Lower extremity nerve function can be impaired in persons with PAD. This can lead to a reduction in sensation and symptoms of numbness, pain, and tingling in the feet. These symptoms may influence functional capacity and functional performance.

Early histological and structural studies have demonstrated skeletal muscle and peripheral nerve changes in subjects with PAD (Farinon, Marbini, Gemignani, Govoni, Bragaglia, & Sianesi, et al., 1984). These impairments can contribute to decreased FC and FP in older adults with PAD.

England, Ferguson, Hiatt, and Regensteiner (1995) studied the effect of peripheral neuropathy on lower extremity function in a group of older adults (mean age 66 years) with PAD (n = 16). A group of seven patients (control) and a group of nine patients (exercise intervention group) were evaluated over a period of four months. The impact of PAD on muscle strength and nerve conduction was assessed using muscle strength testing, nerve conduction studies, and electromyographic studies (EMG). Evidence of muscle denervation was found on EMG, demonstrating motor axon disease in patients with PAD. Sensory nerves were also affected, as evidenced by declines in sensory action potentials. Additionally, nerve conduction studies showed defects in both motor and sensory nerves. Ischemic damage to nerves was suspected due to the nerve conduction pattern of disruption, which demonstrated primary axonal-loss and multifocal lesions. Lower extremity muscle strength declined in the control group and remained the same in the exercise group. Nerve conduction and EMG results were decreased in the exercise group as well as the control group. This study

demonstrates that both motor and sensory nerves are affected by lower extremity ischemia in PAD. Although the sample size was very small, the study adds to the evidence of ischemia-induced nerve dysfunction based on EMG and nerve conduction studies.

Muscle and nerve impairments resulting from PAD-associated ischemia and lower extremity functioning were examined in the InCHIANTI Study (McDermott, Guralnik, Albay, Bandinelli, Miniati, & Ferrucci, 2004). The InCHIANTI Study is a cross-sectional study (n = 109) that evaluated men and women aged 60 and over that resided in surrounding communities of Florence, Italy. The purpose of the study was to determine whether PAD was associated with muscle and nerve impairment as evidenced by nerve conduction studies, muscle cross-sectional area, and lower extremity muscle power. Functional performance outcome measures included a 400-meter walk and fast four-meter walking speed. There were significant differences in all functional performance measures between the PAD and no-PAD group fast four-meter walking speed (1.28 m/s vs. 1.42 m/s, $p < .001$) and 400-meter walk (392.28 meters vs. 336.41 meters, $p < .001$). Muscle and nerve variables were also significantly different between the PAD and no-PAD group as seen in nerve conduction velocity (43.04 m/s vs. 44.16 m/s, $p < .01$) and muscle power (83.69 watts vs. 103.51 watts, $p < .001$). Muscle cross sectional area was not significantly different between the two groups. The study also evaluated the relationship between PAD severity and the functional performance measures above with and without adjustment for nerve conduction velocity. These results demonstrated that PAD severity was

significantly associated with functional performance measures such as fast walking velocity. The relationship between PAD severity and functional performance measures did not significantly change after adjustment (in separate analyses) for nerve conduction velocity or muscle cross-sectional area. This indicates that nerve conduction velocity and muscle cross-sectional area do not completely explain the relationship between PAD and functional performance. The relationship between PAD severity and functional performance was slightly attenuated when adjusting for muscle power, suggesting that muscle power may be a mediator in the relationship between PAD and functional performance.

Lower extremity nerve function was studied in a group of men and women with and without PAD (n = 770) to evaluate the association between PAD and lower extremity nerve function (McDermott, Sufit, Nishida, Guralnik, Ferrucci, & Tian, et al., 2006). Because diabetes is associated with peripheral neuropathy, the study controlled for diabetes in patients with and without PAD. Studies of nerve function included evaluation of motor and sensory nerves by nerve conduction velocity in the peroneal (motor) and sural (sensory) nerves. Results demonstrated that subjects with severe PAD (without diabetes) had worse peroneal nerve conduction velocity that those without PAD (42.6 m/s vs. 44.8 m/s, $p < .01$). Subjects with mild PAD (without diabetes) also had worse peroneal nerve conduction velocity than those without PAD (42.6 m/s vs. 44.1 m/s, $p < .01$). Subjects with diabetes and PAD had worse peroneal nerve conduction velocity (40.8 m/s vs. 43.5 m/s, $p < .05$) and lower sural nerve amplitude (3.1 μV vs. 4.8 μV, $p < .05$) than those without PAD. In summary,

subjects with PAD were reported to have worse nerve function in all areas than those without PAD. In PAD subjects with diabetes, all measures of nerve function were worse than in those with PAD and no diabetes. After controlling for diabetes, PAD was still associated with reduced peroneal nerve function. However, there was not an association between sural nerve function and PAD after controlling for diabetes. The study suggests that motor nerve function is directly affected by PAD but the impact of PAD on sensory nerve impairment remains unclear.

Gaps in Scientific Literature

The Indirect Effect of Functional Capacity. A review of the current scientific literature demonstrates a lack of evidence for mediation of the relationship between PAD severity and several individual indicators of FC. Several of the studies reviewed suggested mediating variables, in particular, the FC indicator lower extremity strength. There is some evidence to support associations between PAD and reduced lower extremity strength (McDermott, Liu, Lu, Guralnik, & Criqui, 2012) as well as lower extremity strength as a mediator between PAD severity and indicators of FP. However, the statistical methods used to evaluate strength as a mediator are unclear, incomplete, or the results are conflicting.

For example, Herman, Liu, Lu, Guralnik, Ferrucci and Criqui, et al. (2009), studied changes in lower extremity strength in older adults with PAD with a five-year follow-up. This study included a sample of 374 subjects, both men (n = 222) and women (n = 152) aged 55 and over with PAD. Lower extremity strength was

measured using isometric testing of both hip and knee flexion and extension. The main outcome measure was change in six-minute walking distance, measured annually for a mean follow-up of five years. Subjects had testing done upon entry to the study to establish baseline values and were retested annually. The primary aim of the study was to determine whether there was an association between lower extremity strength and “functional decline” in men and women with PAD. A secondary aim was to determine whether strength “was in the causal pathway” of association between PAD and decline in FP.

The authors found that lower extremity strength measures at baseline were associated with average “functional decline” in women, but not men. The reasons for this finding were unexplained, and the data for the main outcome measure for both men and women were not included in the paper. Some factors that may have contributed to this lack of finding include lack of power due to small sample size for between-group analysis, as participants were grouped by strength tertiles and had 40 - 50 subjects. Also, the authors reported missing data for the follow-up visits, but the amount or patterns of missing data were not available. Missing data was handled using multiple imputation, but the process for imputing data was not reported. Certainly, any and all of these factors can influence analysis and final results. It would be interesting to repeat this study using growth models and/or survival modeling (Muthen & Muthen, 2013).

Lower Extremity Sensory Impairment. The research studies included in this review have highlighted the role of lower extremity nerve impairment in functional performance in subjects with PAD. These studies provided evidence

for the effect of nerve impairment on functional performance in persons with PAD. However, one of the studies did not show that nerve impairment affects lower extremity function (McDermott, Guralnik, Albay, Bandinelli, Miniati, & Ferrucci, 2004), indicating that further study is required to delineate this issue. Furthermore, most of the studies focused on motor nerve dysfunction, and information on the role of sensory nerve impairment is limited. One of the studies did suggest that sensory nerve function is impaired in persons with PAD. Our study provides an opportunity to further clarify the role of sensory impairment in PAD and its influence on lower extremity function. In addition, the influence of sensory impairment on functional capacity and functional performance is not known. This gap in knowledge can be addressed in this study.

Multivariate Analysis. Research to date has provided strong evidence of bivariate relationships between PAD severity and indicators of FC and FP. However, multivariate analysis is necessary to analyze the factors that impact FP in older adults with PAD, simultaneously. This gap in the literature is also addressed by this study.

CHAPTER III:

METHODS

Research Design

The specific aims were accomplished by a secondary data analysis using a publicly available data set, the continuous National Health and Nutrition Examination Survey (NHANES), available from the data archives of the Centers for Disease Control (http://www.cdc.gov/nchs/nhanes.htm). The NHANES data sets are available in 2-year cycles and the sample for this study will be drawn from the 1999 - 2000 and 2001 - 2002 cycles. The 2003 - 2004 cycles were not included because several of the selected variables were not available for this cycle. The NHANES survey is a complex probability sample of non-institutionalized civilians of the United States population. It includes three testing components, the household interview, physical exam, and blood testing. The physical exam and blood testing were completed at the NHANES mobile examination center and the household interview was conducted at the participant's home. Demographic, socioeconomic, dietary, and health-related information was obtained during the household interview. The physical exam included medical exams, dental exams, and physiological testing (such as cardiac, pulmonary, and functional testing). A comprehensive variety of blood tests were also completed.

Setting and Sample

Participants for the NHANES two-year cycles were selected using information from the US Census Bureau. The sampling procedure consisted of

four stages. Stage 1 was the selection of the primary sampling units, which were single counties across the US. Stage 2 was the division of the primary sampling units into segments of city blocks. Stage 3 was the random selection of households from the city blocks. Stage 4 was the random selection of individuals within the households. The average number of persons selected from each household was 1.6. (Johnson, Paulose-Ram, Ogden, et al., 2013). Sample weights were used in order to obtain an unbiased national estimate. Use of the sample weights is required for analysis of the 1999 - 2002 survey cycles in order to reflect the unequal probability of sample selection (Johnson, et al., 2013). The NHANES survey intentionally over-sampled African-American, Hispanic, low-income White Americans, and adults over the age of 60.

The sample for this analysis was drawn from the 1999 - 2000 and 2001 - 2002 NHANES survey cycles. The total survey sample was N = 21,004. The subsample of interest consisted of all surveyed persons, men and women aged 50 and older (n = 3695). The subsample was divided into two groups for the analysis, those subjects with an ankle-brachial index (ABI) of < = 0.90 (PAD group, n = 378) and those subjects with an ABI of > = 0.91 (no PAD group, n = 3317).

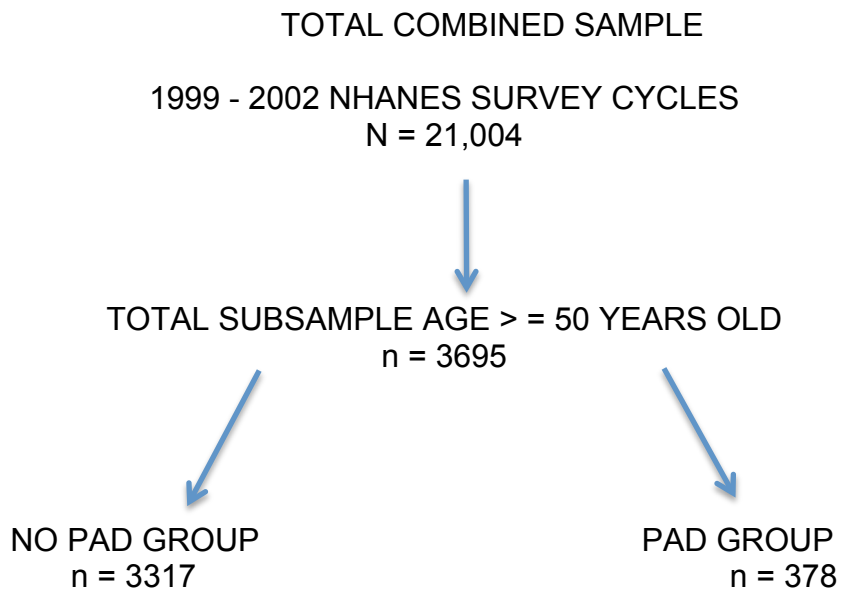


Figure 1.6 Sample Size Determination

Measures

This study is a secondary analysis of data derived from the NHANES publicly available data from cycles 1999 - 2002. The measures for the variables were limited to what were used by the NHANES investigators. Reliability and validity is reported when available.

Descriptive Measures

Demographic characteristics included age, gender, race, income, marital status, and highest level of education. Categories of race included non-Hispanic white, non-Hispanic black, Mexican-American, other Hispanic, and other racial/multi-racial. Marital status categories included never married, married, divorced, widowed, separated, and living with partner. Education categories included less than 9^{th} grade, 9 - 11^{th} grade, high school graduate/GED, some college/Associates degree, and college graduate and above. There were nine

categories of household income, ranging from zero to greater than 75,000 per year. Age-adjusted frequencies for medical conditions including hypertension, diabetes, high cholesterol, coronary artery disease, congestive heart failure, myocardial infarction, stroke, arthritis, and cancer were compared between groups.

Functional Capacity Observed Indicators

Lower Extremity Strength

Knee extensor strength was measured using the Kinetic-Communicator (Kin-Com) dynamometer (Chattecx Corp., Chattanooga, TN) on all subjects aged 50 and over. The Kin-Com dynamometer is a computer-controlled device used to evaluate dynamic strength characteristics of various joints in the body. The Kin-Com measures muscle force by providing resistance during isokinetic movement and isometric muscle contractions (Mayhew, Rothstein, Finucane & Lamb, 1994).

Muscle strength examinations were conducted at the mobile examination center. Knee extensor strength was measured in peak torque (newton-meters) of the quadriceps muscle at the speed of 60 degrees per second. A total of six muscle strength trials were obtained which included three warm-up measurements followed by three actual test measurements. The average of the three actual test measurements was used as the variable in this study. In order for the strength variable to be on a similar scale as the other variables in the study, strength was converted from newton-meters to kilograms. This was done only for input to Mplus for the confirmatory factor analysis and structural equation modeling analyses.

The reliability and test-retest reliability of the Kin-Com dynamometer has been evaluated previously in a study using controlled laboratory conditions without human subjects (Mayhew, Rothstein, Finucane & Lamb, 1994). Measurements of force, angle, and velocity of the Kin-Com device were evaluated on two different days. Intraclass correlation coefficients for between-day measurements of force, angle and velocity were above 0.99.

Lower Extremity Sensory Impairment

Lower extremity sensory impairment was evaluated by the Semmes-Weinstein Monofilament (SWM) test in subjects over 40 years of age in the mobile examination center. The SWM is performed to detect loss of sensation in the feet (Dros, Wewerinke, Bindels & van Weert, 2009). The SWM test was performed using a 5.07 monofilament with a ten-gram filament force. Slight pressure was applied in non-sequential order with the monofilament to the plantar-first metatarsal head, the plantar fifth metatarsal head, and the plantar hallux. The number of correct and incorrect responses is counted and recorded. A site was considered to be sensate if the subject responded correctly on the first attempt or had two correct responses out of three. A site was considered to be insensate if the subject responded incorrectly twice or if the subject responded incorrectly one time and another time was unable to determine a response either way. The total number of insensate areas was recorded for each foot (0 - 3). The right and left total number of insensate areas was summed to create one continuous score (0 - 6).

Monofilament testing is a commonly used screening measure and it has not been shown to be accurate for the diagnosis of peripheral neuropathy (Dros, Wewerinke, Bindels, & van Weert, 2009). However, a recent systematic review found sensitivity to range between 41 - 93% and specificity to range between 68 - 100% (Dros, Wewerinke, Bindels & van Weert, 2009). While not adequate for the diagnosis of peripheral neuropathy, the American Diabetes Association (ADA) does recommend the use of a 5.07/10 g monofilament as part of the comprehensive foot examination and risk assessment in diabetics. The ADA also recommends the monofilament test to screen for sensory loss in the feet (Boulton, Armstrong, Albert, Frykberg, Hellman, & Kirkman, et al., 2008). Predictive validity has been demonstrated using the 5.07/10 g monofilament test; an abnormal test has been reported to be a predictor for the development of foot ulceration and amputation (Godhes & Rith-Najarian, 1995; Rith-Najarian, Stolusky, & Godhes, 1992).

In the absence of a diagnosis of peripheral neuropathy by the accepted reference standard (nerve conduction study), the ADA recommends a clinical examination plus more than one test for diagnosis (Boulton, et al., 2008). Tests include vibration sensation with a tuning fork, pressure sensation with a monofilament, ankle reflexes and pinprick test (Boulton, 2008). However, the monofilament test continues to be recommended as a screening tool to assess the foot for loss of sensation.

Calf Circumference

The measure of maximum calf circumference was included in the anthropometric section of the physical exam. The anthropometric examination included several different body measurements. The exam was completed in the MEC by a trained examiner and recorder. A measuring tape was used to determine the maximum calf circumference of the right leg in centimeters.

Functional Performance Observed Indicators

Physical Function Questionnaire

Thirteen items were selected from the NHANES Physical Function Questionnaire (PFQ) (Appendix A) which was conducted as part of the household interview. The NHANES PFQ is a 19 - item scale that measures ADLs such as dressing and eating, leisure activities such as reading and watching television, and ability to perform on physical activities such as walking, stooping, and lifting. Items were scored as 1 = *no difficulty*, 2 = *some difficulty*, 3 = *much difficulty*, 4 = *unable to do,* and 9 = *don't know.*

Individual items for this study were selected based on relevancy to the research questions and non-relevant items were excluded. Items involving the upper extremity function and managing finances were removed. Thirteen items were chosen and a total score variable was created with a possible score range of 13 - 52. A high total PFQ score represents worse physical function. The reliability for the items used in the PFQ scale for this study was 0.91.

Average Level of Daily Physical Activity

Self-reported average level of daily physical activity was measured using a single question from the NHANES Physical Activity Questionnaire (PAQ). The participant was asked to select the response that most accurately reflected the level of average daily physical activity. The responses were coded as 1 = *sits most of the day and does not walk very much*, 2 = *stand or walks a lot during the day but does not have to lift or carry things very often,* 3 = *lifts light loads or climbs stairs or hills often*, and 4 = *does heavy work or carries heavy loads*. This variable was considered continuous with a higher score reflecting higher level of self-reported average daily physical activity. Participants could also answer 7 = *refused* and 9 = *don't know.* These two items were recoded as missing (-999) for the purpose of transferring into Mplus for analysis. The full PAQ used in the NHANES study was recently validated against accelerometer data collected in the 2003 - 2004 cycle in adults over the age of 18 who had been advised to increase physical activity for cholesterol control (Fan, Ham, Muppidi, & Mokdad, 2009).

Usual Gait Speed

Usual gait speed has been shown to be a predictor of physical function in older adults. In this study, usual gait speed was determined by a timed 20 - foot walk. This test was completed in the MEC as an adjunct to the muscular strength exam. A walking test track was created in the MEC and the start and end points were marked with tape. The participant was asked to walk the length of the test

track at their usual, comfortable walking speed. The walk was timed with a handheld stopwatch and measured in seconds.

Observed Endogenous Variable

PAD Severity

Peripheral arterial disease severity was determined by the value of the ankle-brachial index (ABI). All subjects included in the study had an ABI completed in the MEC portion of the NHANES health survey. The ABI is a non-invasive and efficient test commonly used to diagnose PAD. The ABI is a calculation of the highest systolic ankle pressure (posterior tibial artery and/or the dorsalis pedis artery) divided by the highest systolic brachial pressure using a Doppler and blood pressure cuffs. A normal ABI is between 1.0-1.15 and PAD is suspected when the ABI is lower than 0.90. The sensitivity and specificity for diagnosing PAD in an ABI less than 0.90 is 95% and 99%, respectively (Bernstein & Fronek, 1982). The ABI has also been shown to be reproducible and reliable, with a reported mean intraobserver and interobserver error of 8-9% (Holland-Letz, Endres, Biedermann, Mahn, Kunert, & Groh, et al., 2007).

For the purposes of this study, the lowest ABI recorded between the right and left legs was selected for use in the analysis. A new variable was created to represent this value. This variable was used to place subjects into two groups, with and without PAD. Subjects were selected for the PAD group if they had an ABI of less than or equal to 0.90. Subjects were selected for the NO PAD group if they had an ABI of greater than or equal to 0.91. A grouping variable was also created.

Study Procedures

Data Acquisition and Preparation

The 1999 - 2000 and 2001 - 2002 demographics, questionnaire, examination and laboratory data files were downloaded from the NHANES website (Johnson, 2013) in the form of SAS transport files. Files were appended to create one data set representing the
1999 - 2002 survey years. Variables of interest were merged from the individual data files to the 4-year dataset by the subject identification number. Once a complete 4-year dataset was created, key variables of interest were analyzed and recoded if indicated. To account for the complex survey design, the entire 4-year sample (N = 21,004) was retained and a subpopulation variable was created to identify all subjects > = 50 years of age. Complex sample weights for the interview and examination were retained. The variables representing cluster and stratum were provided by NHANES for the survey years 1999 - 2002, so no additional analysis was required to calculate these weights.

Data Management

All data management subsequent to the download, appending, and merging of datasets was completed in SPSS (Version 21.0 Complex Samples, IBM, 2013). A complex sample plan file was created in the SPSS complex samples package. This plan file included the cluster, strata, and subject interview and examination sampling weights. This also included creation of a subpopulation variable to identify the selected sample population of all adults

> = 50 years of age who had ABI testing done. Dummy variables were created for gender and diabetes. A grouping variable was then created for presence or absence of PAD. Subjects were placed into a 'no PAD' or 'PAD' group depending on the value of the ABI. Missing data were re-coded to -999. A complete dataset was required for input into Mplus, therefore, all character missing (blanks), numeric missing (period), 'refused', 'don't know' entries were re-coded as -999 for missing. Descriptive statistics were calculated in SPSS. Multigroup confirmatory factor analysis and structural equation modeling were run in Mplus 7.11 (Muthen & Muthen, 2013).

Power Analysis-Degrees of Freedom

Degrees of freedom were calculated in order to perform the power analysis. The number of model parameters was determined by the sum of the observed variables, estimated regression coefficients, variances, and covariances. The full SEM model had 9 observed variables, 11 regression coefficients, 3 variances and 5 covariances. The total number of model parameters was 27. Degrees of freedom were calculated using the equation below where n = the number of observed variables. Total degrees of freedom for the full SEM model was calculated as 18 (Appendix A).

Power Analysis-Sample Size

Power analysis was performed in order to determine the estimated power for the intended SEM analysis in this study. The first step in the power calculation was to calculate the design effect (DEFF) and effective sample size (ESS) for each group. The DEFF is the estimated increase in variance due to the complex

survey design. Effective sample size represents the equivalent sample size for each group had the sample been drawn from a simple random sample (West, Berglund, & Heeringa, 2008). The ESS was subsequently used in the final power calculation.

Effective sample size was obtained by dividing the actual sample size by the average DEFF for each group. To calculate the DEFF for each group, general linear model was selected from the complex samples package in SPSS. Per NHANES analytic guidelines, the MEC weight is recommended if subjects had both the interview and exam completed (Johnson, 2013). Next, a linear regression was run for each path in the hypothesized model and path-specific design effects were obtained for each group. Design effects were then entered into an excel spreadsheet and an average DEFF for each group was calculated.

The average design effect for the NO PAD group was 1.299 and 1.382 for the PAD group. The total number of actual subjects were 3317 and 378 for the no PAD and PAD groups, respectively.

The ESS were calculated as n/DEFF:

	Actual Sample Size	Average DEFF	ESS
NO PAD	3317	1.299	2553
PAD	378	1.382	273

Table 3.1 Estimated Sample Size

Next, a power analysis was conducted to determine if the ESS of each group was adequate for a desired minimum power of 0.80. A web-based utility program was used to generate syntax for the statistical program R (Preacher & Coffman, 2006). To generate the R syntax, the desired alpha level, the model degrees of freedom, desired null root mean squared error (RMSEA), and alternative RMSEA were entered. Once the R syntax for calculating power was generated, it was submitted to Rweb, a web-based R interface, which ran the R syntax and produced the desired power analysis (Preacher & Coffman, 2006). For an alpha level of .05, df = 18, desired power of .80, null RMSEA .05 and alternative RMSEA of .10, the estimated minimum sample size was calculated as n = 207. Therefore it was concluded that each separate group included in this study, had an adequate ESS to detect a power of .80 in model tests of close and not-close fit.

Data Analysis

Missing data

To examine the amount of missing data, a missing value analysis was performed in SPSS. The 6 observed latent variable indicators (lower extremity strength, lower extremity sensory impairment, calf circumference, ADL, UGS, PA) and 4 observed exogenous variables (ABI, age, gender, diabetes) were included.

In the NO PAD group (n = 3317), seven out of ten variables had less than 5% missing values. The remaining three variables, lower extremity strength, calf circumference, and PFQ items, had 23.8%, 24%, and 27% missing values, respectively. In the PAD group (n = 378), eight out of ten variables had less than 10% missing values. The remaining two variables, lower extremity strength and calf circumference, had 36% and 32% missing values, respectively. Table 3.1 summarizes the reasons for missing data on the strength variable for the PAD group and table 3.2 for the no PAD group. The reasons for missing data are listed by general and specific exclusion criteria for participation in the exam. In both groups, the calf circumference variable missing data were recorded as "could not obtain" by NHANES. Examination protocols for body measures stated that inability to obtain measures was due to inability or refusal to remove clothing, bone deformities, body size or measures that exceeded the maximum possible measurement due to instrument limitations. No subjects in this subsample had right or left lower extremity amputations.

Little's Missing Completely at Random (MCAR) test (Little, 1988) was performed to determine if the data was MCAR. This output was obtained by checking the expectation-minimization box in the missing value analysis in SPSS. The chi-square statistic and significance level were included in the output. For both the PAD and NO PAD groups, Little's MCAR test was significant, which indicated that the data were *not* MCAR (Little, 1988). Therefore, the missing data were determined to be *missing at random*.

Missing Data Handling

The options considered for handling the MAR data included multiple imputation or full-information maximum likelihood (FIML) estimation. Full-information maximum likelihood estimation uses all available data for estimation, while multiple imputation replaces missing values. Multiple imputation was attempted using Mplus. The imputation procedure was successful, and five separate, imputed datasets were created which contained the model and auxiliary variables (SEQN, age, gender, survey weights, etc.). Running the imputed datasets was also attempted using Mplus (TYPE = IMPUTATION), but analysis was abandoned after inability to combine the TYPE = IMPUTATION and TYPE = COMPLEX with multigroup analysis.

Simulation studies have shown that in data MAR, FIML produces efficient, unbiased parameter estimates and standard errors (Enders & Bandalos, 2009; Larsen, 2011). It has been shown to perform superiorly compared to alternative methods such as pairwise deletion (Enders & Bandalos, 2009) and multiple imputation (Larsen, 2011). Full-information maximum likelihood with observed

information is the default in Mplus for TYPE = COMPLEX using the MLR estimator. Therefore, this was the option used to handle the MAR data in this analysis.

Evaluation of Assumptions

The Maximum Likelihood (ML) estimator is commonly used in SEM analyses and often the default for many statistical programs including Mplus (Muthén & Muthén, 2013). Certain assumptions are present with the use of the ML estimator (Hoyle, 2012). These include the assumption of multivariate normality, independence of observations, and no missing values. It is also assumed that the endogenous variables have no measurement error.

Multivariate Normality

Multivariate normality is an assumption of the data in SEM analysis (Hoyle, 2012). To test the six observed variables (strength, calf circumference, sensory impairment, usual gait speed, physical activity, PFQ) for multivariate normality, the multivariate normality test command was utilized in Stata13 (Stata, 2013). The results included the Doornik-Hansen Omnibus test for multivariate normality (Doornik & Hansen, 2008), the Henze-Zirkler test (Henze & Zirkler, 1990), and Mardia's tests for skewness and kurtosis (Mardia, 1970). The results showed that *p*-values were significant at $p < .000$ for all tests, therefore indicating that multivariate normality was *not* present in the observed variables

Solution for Violation of Normality Assumption

In Mplus, the default estimator for CFA and SEM is Maximum Likelihood (ML), which assumes multivariate normality (Muthén & Muthén, 2013). Ignoring

the normality assumption would lead to inaccurate model fit statistics and biased standard errors. Therefore, an alternative solution for handling the continuous, non-normal data with missing values was selected.

The decision was made *not* to transform the data prior to input and analysis in Mplus. Instead, the Maximum Likelihood Robust (MLR) estimator was selected. The MLR estimator is the default in Mplus analysis for complex survey sample (TYPE = COMPLEX). It has been shown to provide unbiased estimates and standard errors in a sample with missing values, and less biased estimates and standard errors in samples that have both missing values and non-normal data distributions (Yuan, Wallentin, & Bentler, 2012). Given the presence of non-normally distributed data with missing values, it was the estimator of choice for this study.

Model Specification

Model Identification

The hypothesized measurement model was evaluated for identification in several ways. First, the “three indicator” rule of thumb was applied. This rule states that in order for a latent variable model to be identified, latent variables must have a minimum of three indicators. The hypothesized model in this study has a minimum of three indicators per latent variable. Second, in order for a model to be identified, the degrees of freedom must be greater than or equal to zero. The total degrees of freedom for the hypothesized model were 18. Third, the latent variables must be assigned a scale. In the hypothesized model, this was achieved by fixing the path coefficient of one latent variable indicator

(reference variable) to 1.0. The latent variable scale then is based on the shared variance of the reference variable. And lastly, the model was recursive. This was evident by unidirectional paths without feedback loops. All criteria for identification were met and the hypothesized model was considered identified.

Disturbances

The disturbances, or the residuals of the exogenous (observed) variables, were allowed to covary in this model. Theoretical foundation supports a covariance between the disturbances of the latent variable indicators. The latent variable disturbances were also allowed to covary in the model.

Modification Indices

Modification indices with a value of 10 or greater are reported as the default in Mplus (Muthén & Muthén, 2013). Modification indices were requested in the output command of the input syntax (modindices (all)). Modification indices were considered if adding the parameter made conceptual sense, and if there would be a substantial change in the chi-square by adding it.

Model Fit Indices

The model fit indices that were selected for both the measurement and structural models included the root mean squared error of approximation (RMSEA), the comparative fit index (CFI), and the standardized root mean square residual (SRMR). The RMSEA is a measure of model badness-of-fit (Hoyle, 2012) with the lower bound value of zero indicating improved model fit. The RMSEA value between 0 and 0.05 is commonly accepted as the model having a “close fit” (Hoyle, 2012). Some references report the RMSEA to be as

high as 0.08 for an “acceptable” fit, with any value greater than 0.08 to be considered “unacceptable” model fit. The RMSEA confidence intervals (CI) describe the precision of the estimate and a narrow CI is desired. The CFI is considered a measure of model “goodness of fit”, with the possible range between zero and one. The higher the CFI, the better the model fit with the cutoff criterion of an acceptable CFI of > 0.90, with a preferred CFI of > 0.95 (Bentler, 1990). The SRMR is a measure of model “badness-of-fit” with a minimum value above zero, with the cutoff criterion of < 0.08. Both the RMSEA and SRMR are sensitive to small sample sizes, while the CFI is not. These three model fit indices reflect the current “gold standard” in model fit index reporting (Hoyle, 2012).

Model Testing

Multigroup Confirmatory Factor Analysis

To assess the validity of the measurement model (Figure 3.2), confirmatory factor analysis (CFA) was performed to test for measurement invariance between the two groups. This analysis was completed before proceeding with analysis of the hypothesized full structural equation model. First, pre-analysis decisions will be discussed followed by the specific CFA steps.

Mplus Version 7.11 was the software choice for all CFA and SEM analyses (Muthén & Muthén, 2013). The dataset prepared in SPSS was saved as a raw data file without variable names in the form of a comma separated file (.csv). The order of the variable names was recorded for the CFA input file code created to run the analysis. The data file was specified in Mplus along with the

names of the variables in order they appear in the corresponding dataset (.csv file). The cluster, strata, and sample weights were also included. The type of the analysis was TYPE = COMPLEX, and Maximum Likelihood Robust (MLR) estimator was selected.

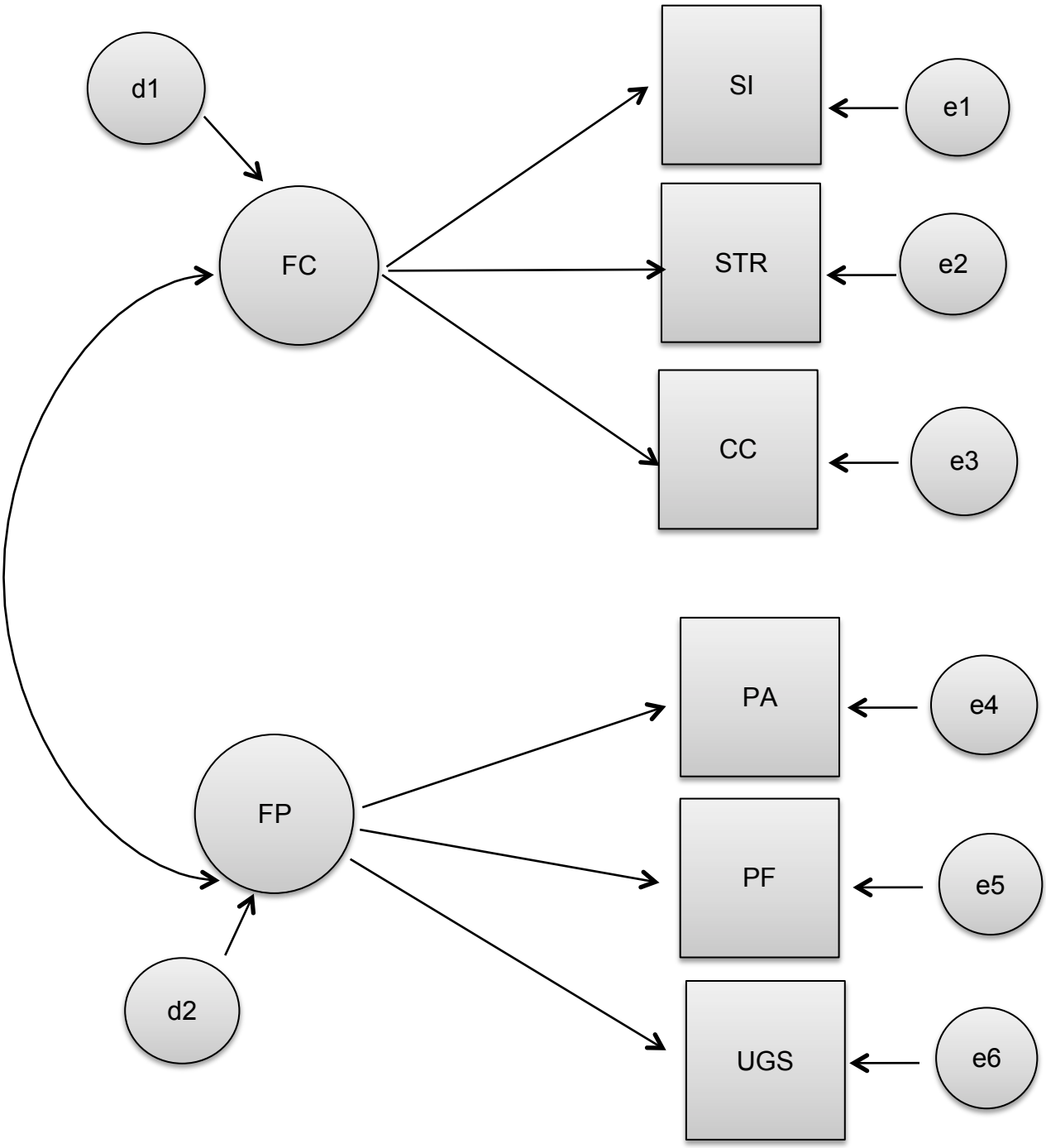


Figure 3.2 Measurement Model
FC= Functional Capacity, FP= Functional Performance, SI= Sensory Impairment, STR= LE Strength, CC= Calf circumference, PA= Physical activity, PF= Physical Function, UGS= Usual Gait Speed, d1, d2= Latent variable errors, e1-e6= Latent variable indicator errors

Measurement Model Invariance

To test for measurement invariance between the two groups, a series of stepwise models were tested, with the level of measurement invariance increasing with each step (Muthén & Muthén, 2013). First, the measurement model fit was evaluated in each group separately. Then, parameter constraints were imposed on the model in a stepwise fashion to test for configural invariance, metric invariance, and scalar invariance. Lastly, the groups were tested for invariance of factor variances, error variances, and latent variable means. Factor score determinacy was requested for both groups to determine the quality of the factor scores.

Configural invariance is determined by testing for equality of the measurement model between the two groups. To test for configural invariance, the measurement model fit was estimated in each group separately, then between the groups. This was achieved by allowing all model parameters to be freely estimated while fixing both factor means to zero. Metric invariance was determined by testing for equality of the factor loadings between groups. To test for metric invariance, all factor loadings were constrained to equality in both groups. Scalar invariance tested for invariance in the intercepts between groups. To test for scalar invariance, the intercepts were held to equality in both groups. To test for strict factorial invariance, equality constraints were placed on the factor variances in both groups. Strict factorial invariance allows factor means and covariances to be freely estimated.

Chi-square Difference Testing

In order to compare the model B (metric) with model A (configural) and model C (scalar) with model B and model A, the Satorra-Bentler scaled chi-square difference test for nested models was performed (Satorra & Bentler, 1999). This is different than the Satorra-Bentler scaled chi-square test (Satorra & Bentler, 1994), which cannot be used for nested models because the chi-square difference would not lead to a chi-square difference statistic (Satorra, 1999). Instead, in the case of nested models, a chi-square difference test for the Satorra-Bentler scaled chi-square was calculated manually using a recommended formula (Muthen & Muthen, 2013; Satorra-Bentler, 1999):

Multigroup Analysis: Latent Variable Means and Intercepts

Parallel Slopes

To determine between-group differences in latent variable intercepts while controlling for the exogenous variables, a parallel slopes model was tested. The factor loadings of age, gender, diabetes, and ABI were constrained to equality for both groups. Since the no PAD group had the latent variable intercepts set to zero, the between-group difference for latent variable intercept was estimated.

Non-Parallel Slopes

To determine between-group differences in latent variable means with the effect of different values of the exogenous variables on the latent variable, a non-parallel slopes model was tested. Equality constraints were released and the effect of age, gender, and ABI on functional capacity and functional performance was allowed to vary.

The equality constraint on gender was released for both functional capacity and functional performance. Both ABI and age remained constrained to equality between groups. Gender was coded as a dummy variable with 0 = female and 1 = male. The model was estimated and the coefficients were entered into the non-parallel slopes regression model:

$$\text{regression model } Y = b0 + b1\ D1 + b2\ X1 + b3\ (D1 * X1)$$

Testing for Indirect Effects in Latent Variable Model

After demonstrating configural, metric, and scalar invariance between the groups, the full structural equation model was tested (Figure 3.3). The path of interest was the causal path from the exposure variable PAD severity to functional performance. To test the hypothesis that the functional capacity mediates the relationship between the exposure variable ABI and functional performance, estimates were first obtained from mediation analysis using the MODEL INDIRECT command in Mplus 7.2 (Muthen & Muthen, 2014). After estimates and standard errors were calculated, they were entered into the Monte Carlo (MC) online utility for calculating the 95% CI (Selig & Preacher, 2008). The MC 95% CI was considered to be significant if the CI did not contain the value of zero (MacKinnon, Lockwood, & Williams, 2004).

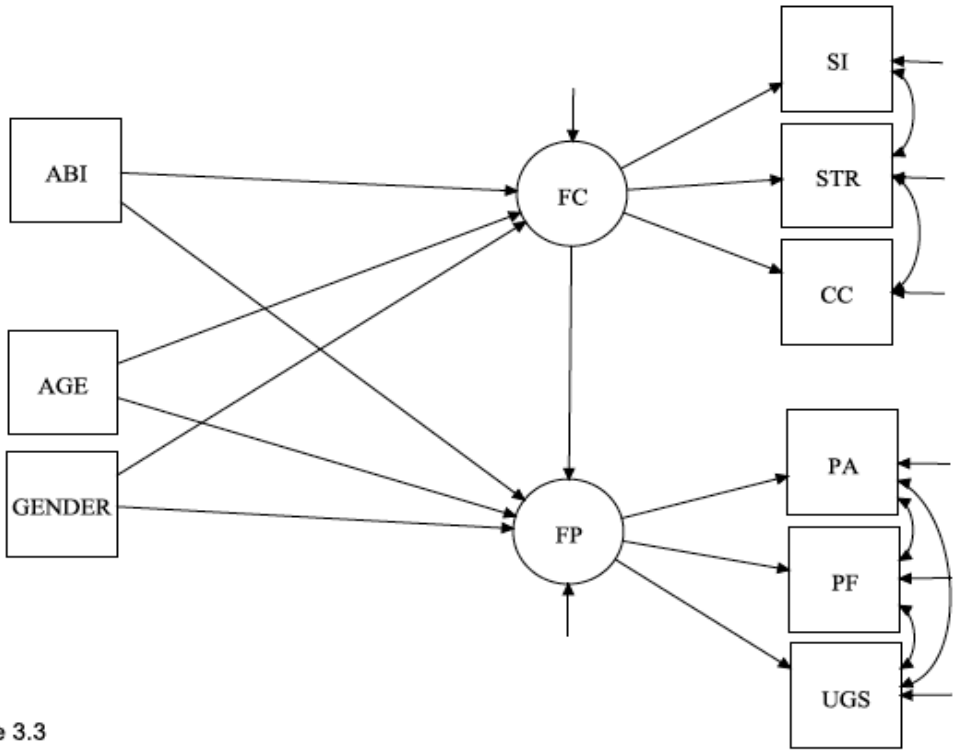


Figure 3.3
Full Structural Equation Model
(ABI= ankle-brachial index, SI= sensory impairment, STR= strength, CC= calf circumference, PA= level of physical activity, PF= physical function, UGS= usual gait speed)

Metric of Latent Variables

The reference-group method was the default in Mplus 7.11 as the method to identify the metric of the latent variables. This default assigned the first group (in this study the no PAD group) as the reference group and the latent variable means were set to zero and the latent variable variance fixed to one. The loadings and intercepts of the factor indicators were set to equality across the two groups. This allowed for the difference in the latent variable means between groups to be estimated.

Differences in Latent Variable Means

In order to compare the difference in latent variable means between the no PAD and PAD groups the ALIGNMENT METHOD was used (Muthen &

Muthen, 2013). The Mplus default sets the latent variable means to zero in the reference group (the no PAD group) and are free to be estimated in the PAD group. This allows the difference in the latent variable means to be compared across groups.

Equivalent Models

The possibility of equivalent models was investigated as part of this dissertation. Equivalent models differ in the relationships between model variables that result in identical predicted covariance matrices and fit indices as the proposed model (Hoyle, 2012). Hershberger (2006) has proposed a method called “the replacement rule” to evaluate for equivalent models. To implement the replacement rule, the full structural model is separated into blocks called preceding blocks, focal blocks, and succeeding blocks. The full structural model is annotated according to the replacement rule in Figure 3.4 below. The possible equivalent model tested for this study is shown in Figure 3.5. Using the replacement rule, the direction of the path from FC to FP was reversed. The Mplus code was changed to reflect this and the model was analyzed again to determine if the change in the path direction resulted in identical estimated covariance matrices and identical fit indices.

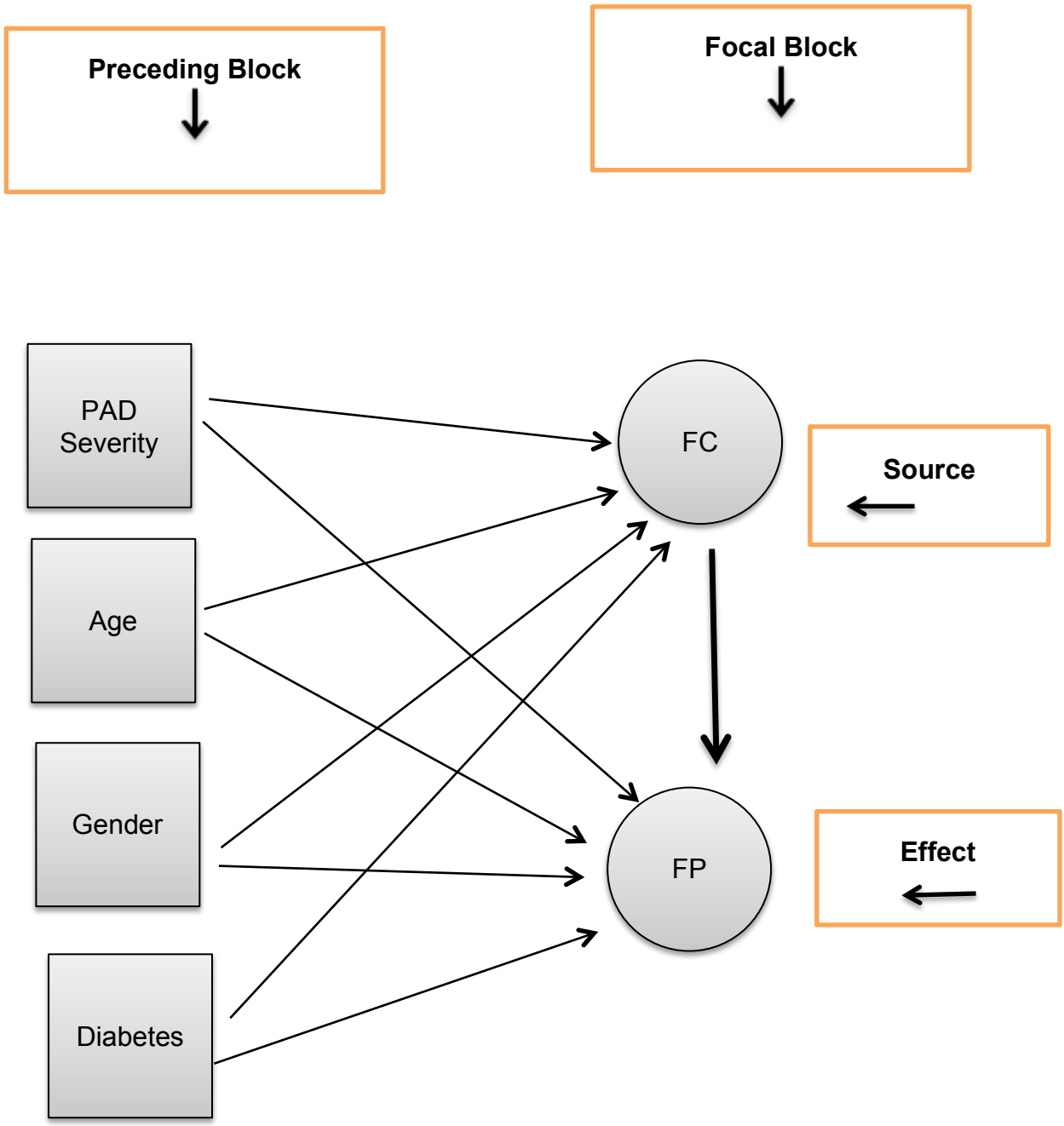


Figure 3.4 Test for equivalent models, hypothesized model (Hershberger, 2006)

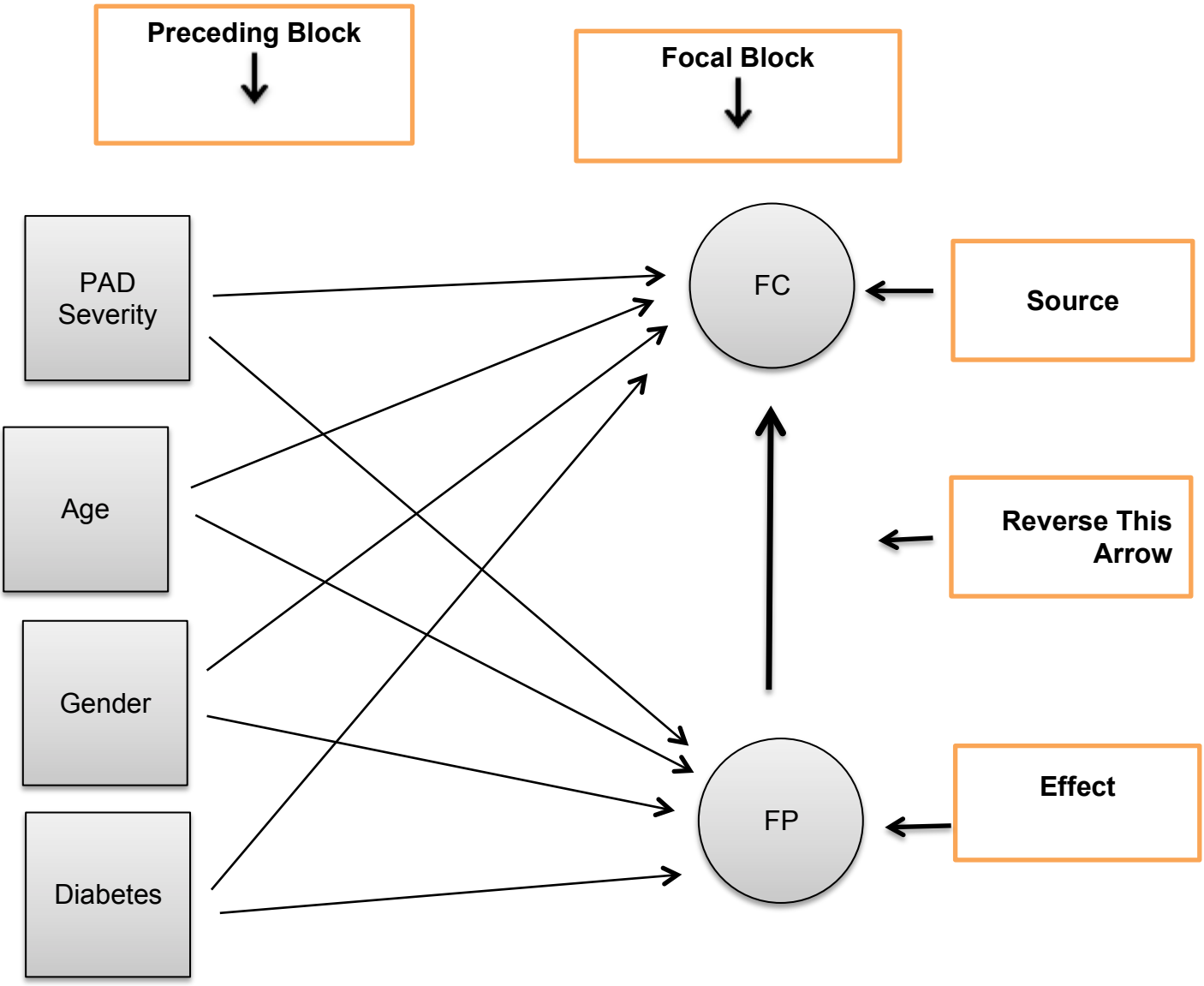


Figure 3.5 Test for equivalent model, alternative model (Hershberger, 2006)

CHAPTER IV

Results

Sample Characteristics

Demographic characteristics of the study sample are summarized for each group in Table 4.1. The age of the study subsample ranged from 50 - 85 years old. The mean age in the no PAD group was 62.41 (*SE* = 0.190) and the mean age in the PAD group was 70.53 (*SE* = 0.834). Subjects were significantly older in the PAD group ($p < .0001$). The majority of the subjects in both groups were female. In the no PAD group (n = 3317), 47% of the sample was male and 52% of the sample was female. In the PAD group (n = 378), 44% of the sample was male and 56% of the sample was female.

The majority of the sample for both groups was Caucasian (no PAD group 79.5%, PAD group 79.8%) and most of the subjects were married (no PAD group 68%, PAD group 53%, $p < .0001$). In the PAD group, a significantly larger percentage of the sample had less than a 9^{th} grade education than those in the no PAD group (15.2% vs. 9.2%, $p = .037$). Most of the subjects in the no PAD group had a high school degree or above (75.7%), with 25.2% having a college degree or higher. Conversely, only 66% of the subjects in the PAD group had a high school degree or above, with only 15.2% of the sample having a college degree or higher, which was a significant difference ($p = .0067$) between the two groups. Most of the sample for both groups reported an income level of below $44,000 (52.4% no PAD vs. 72.7% in the PAD group). There was a significant

difference between the two groups for an income level greater than $75,000 (no PAD 24.6% vs. PAD 10.3%, p = .0003).

Age-adjusted frequencies of medical conditions listed by group in Table 4.2. Crude, unadjusted frequencies are found in Table 4.3. For age 50 - 59 years old, subjects with no PAD had a lower rate of hypertension (34.39% vs. 51.35%), high cholesterol (43.40% vs. 62.48%), diabetes (8.0% vs. 15.78%) coronary artery disease (4.51% vs. 18.38%), congestive heart failure (2.44% vs. 4.55%) history of myocardial infarction (3.88% vs. 4.22%), angina (3.88% vs. 16.15%), and stroke (1.84% vs. 6.21%). Diabetic subjects in the no PAD group took more oral medication for blood glucose control than those with PAD (75.58% vs. 39.03%). Subjects in the no PAD group were less likely to use insulin for treating diabetes than those with PAD (1.08% vs. 6.18%). Subjects with no PAD had a lower rate of obesity, defined as a BMI between 30 - 39, (27.05% vs. 32.86%) but a higher rate of morbid obesity, defined as a BMI > = 40, (4.92% vs. 1.88%) than those with PAD.

For ages 60 and over, those with no PAD had a lower rate of hypertension (47.57% vs. 65.28%) high cholesterol (48.64% vs. 59.81%), diabetes (12.97% vs. 20.57%) congestive heart failure (6.23% vs.15.85%), stroke (7.09% vs.11.22%) and emphysema (5.95% vs. 9.74%). Angina was higher in the no PAD group than those with PAD (14.74% vs. 9.60%) and the rate of coronary artery disease was about the same for the no PAD and PAD groups (12.81% vs. 12.68%).

Descriptive Analysis of Observed Exogenous Variable

Ankle-Brachial Index (ABI)

The ABI ranged from 0.91 - 1.66 in the no PAD group and from 0.23 - 0.90 in the PAD group. A lower ABI value indicates more severe PAD. Subjects aged 50 - 59 without PAD had a mean ABI of 1.13 (*SE* = 0.004) compared to 0.80 (*SE* = 0.020) in the PAD group. Subjects aged 60 and over without PAD had a mean ABI of 1.11 (*SE* = 0.003) compared to 0.76 (*SE* = 0.013) in the PAD group. There was a significant difference in ABI between the non-PAD and PAD groups after age-adjustment (Age 50 - 59 *p = .0001, Aged 60+ p = .0001).* Subjects with PAD had significantly lower ABIs regardless of age.

Descriptive Analyses of Observed FC and FP Indicators

Table 4.5 is an item analysis for the ADL questionnaire, summarizing the mean and standard errors for each group. Table 4.6 summarizes the age-adjusted mean and standard error (*SE*) for each observed factor indicator for FC and FP by group.

Functional Capacity Observed Indicators

Lower Extremity Strength

Strength scores ranged from 46 - 696.80 newton-meters in the no PAD group, and 87.80 - 494.20 newton-meters in the PAD group. The mean score for lower extremity strength in subjects aged 50 - 59 without PAD was 324.20 (*SE* = 3.60) compared to 264.23 (*SE* =13.05) in the PAD group. For subjects aged 60 and over without PAD, the mean score for strength was 259.72 (*SE* = 4.78) compared to 219.89 (*SE* = 5.04) in the PAD group. Differences in lower extremity

strength scores between the no PAD and PAD groups were significant for subjects aged 50-59 and age 60 and over (*Age 50 - 59 p = .0001, Age 60+ p = .0001*). Subjects with PAD had significantly lower scores for lower extremity strength than those without PAD even after controlling for age.

Calf Circumference

Calf circumference (cm) ranged from 18 - 61.60 cm in the no PAD group and 23.30 - 56.30 cm in the PAD group. Mean calf circumference (cm) in subjects aged 50 - 59 without PAD was 38.89 (*SE* = 0.160) and 37.07 (*SE* = 0.856) in those with PAD. In subjects over age 60 without PAD, the mean calf circumference (cm) was 37.55 (*SE* = 0.118) compared to 36.04 (*SE* = 0.247) in the PAD group. Calf circumference was significantly smaller in the PAD group than the non-PAD group, controlling for age (*Age 50 - 59 p = .0367, Age 60+ p = .0001*).

Lower Extremity Sensory Impairment

The lower extremity sensory impairment score ranged from 0 - 6 in both groups. A higher score indicates increased sensory impairment. The mean lower extremity sensory impairment score for subjects aged 50-59 without PAD was 1.41 (*SE*= .177) and 3.28 (*SE*=1.01) in the PAD group. In subjects over age 60 without PAD, the mean score was 4.03 (*SE*= .324) compared to 4.62 (*SE*= .934) in the PAD group. Controlling for age, there was no significant difference (*Age 50-59 p=0.0683, Age 60+ p=0.5507)* in sensory impairment in older adults with or without PAD.

Functional Performance Observed Indicators

Usual Gait Speed

Usual gait speed scores ranged from 1.64 - 61.20 seconds in the no PAD group and 3.94 - 50.60 seconds in the PAD group. The mean usual gait speed score in subjects aged 50 - 59 without PAD was 5.61 (*SE* = 0.052) seconds and 6.45 (*SE* = .400) seconds in the PAD group. In subjects over age 60, the mean score in the no PAD group was 6.74 (*SE* = 0.081) seconds and 8.13 (*SE* = 0.254) seconds. The difference in usual gait speed between no PAD and PAD groups was significant (*Age 50 - 59 p = .0374, Age 60+ p = .0001*) even after controlling for age.

Physical Activity

The self-reported, average daily level of physical activity score ranged from one to four in both groups. A higher value represents a higher physical activity level. The mean score for the average daily level of physical activity for subjects aged 50 - 59 without PAD was 1.98 (*SE* = 0.035) compared to 2.14 (*SE* = 0.142) in the PAD group. For subjects aged 60 and over without PAD, the mean score was 1.97 (*SE* = 0.022) compared to 1.76 (*SE* = 0.041) for those subjects with PAD. There was a significant difference between the no PAD and PAD groups over age 60 (*p* = .0001), but there was no significant difference between groups for age 50 - 59 (*p* = .2741).

Physical Function Questionnaire (PFQ)

The individual total scores on the PFQ ranged from 13 - 52 for both groups. A higher score indicates worse function. The mean PFQ score for

subjects aged 50 - 59 in the no PAD group was 18.83 (*SE* = 0.440) compared to 24.30 (*SE* = 1.92) in the PAD group. In subjects aged 60 and over, the mean physical function score in the no PAD group was 15.80 (*SE* = 0.132) compared to 18.24 (*SE* = 0.350) in the no PAD group. There was a significant difference in physical function between the two groups, for ages 50 - 59 (p = .0001) and over the age of 60 (p = .0001).

Multigroup Confirmatory Factor Analysis

Testing for Measurement Invariance

A multigroup analysis was performed in order to test the measurement model (Figure 3.2) for measurement invariance between the two groups (no PAD vs. PAD). A summary of these results is found in Table 4.7. The model was tested for three different degrees of measurement invariance: configural, metric, and scalar.

Configural Invariance. The model was tested for configural invariance (model A) across the no PAD and the PAD groups. The factor means for functional capacity and functional performance were set to zero and the rest of the model was free to be estimated. The chi-square test of model fit yielded a chi-square value of 37.430 with 16 degrees of freedom. The RMSEA was 0.027, 90% CI [0.016 - 0.038], the CFI was 0.956, and the SRMR was 0.025. All values of each fit statistic indicated a good fit of the model to the data (Cheung & Rensvold, 2002).

Metric Invariance. Next, the model was tested for metric invariance (model B) across the no PAD and PAD groups. The factor loadings were held

equal across groups and the intercepts were free to be estimated. The chi-square test of model fit yielded a chi-square value of 38.928 with 20 degrees of freedom. The RMSEA was 0.023, 90% CI [0.012, 0.033], the CFI was 0.961, and the SRMR was 0.028. All fit statistic values indicated a good fit of the model to the data (Cheung & Rensvold, 2002).

Scalar Invariance. Next, the model was tested for scalar invariance (model C) across the no PAD and PAD groups. The factor loadings and intercepts were held equal across groups and the residuals were free to be estimated. The chi-square test of model fit yielded a chi-square value of 42.374 with 24 degrees of freedom. The RMSEA was 0.020, 90% CI [0.010, 0.030], the CFI was 0.962, and the SRMR was 0.029. All fit statistics indicated a good fit of the model to the data (Cheung & Rensvold, 2002).

Chi-Square Difference Testing. Results of the measurement invariance testing and chi-square difference testing are summarized in Table 4.7. Model B (metric) model was compared to Model A (configural) model and the chi-square difference statistic was 3.007 with four degrees of freedom and a *p*-value of .556. For Model C (scalar) compared to Model B, the chi-square difference statistic was 2.8155 with 4 degrees of freedom and a *p*-value of .589. Lastly, Model C was compared to Model A, and the chi-square difference statistic was 5.870 with 8 degrees of freedom and a *p*-value of .662. All three *p*-values were non-significant, which failed to reject the null hypothesis of no measurement invariance. This finding supports measurement invariance for the configural, metric, and scalar models between the no PAD and PAD groups. The results

were replicated using the MODEL=CONFIGURAL METRIC SCALAR command in Mplus 7.11 and found to be in agreement.

Model Testing

Latent Variable Model Indirect Effect Analysis

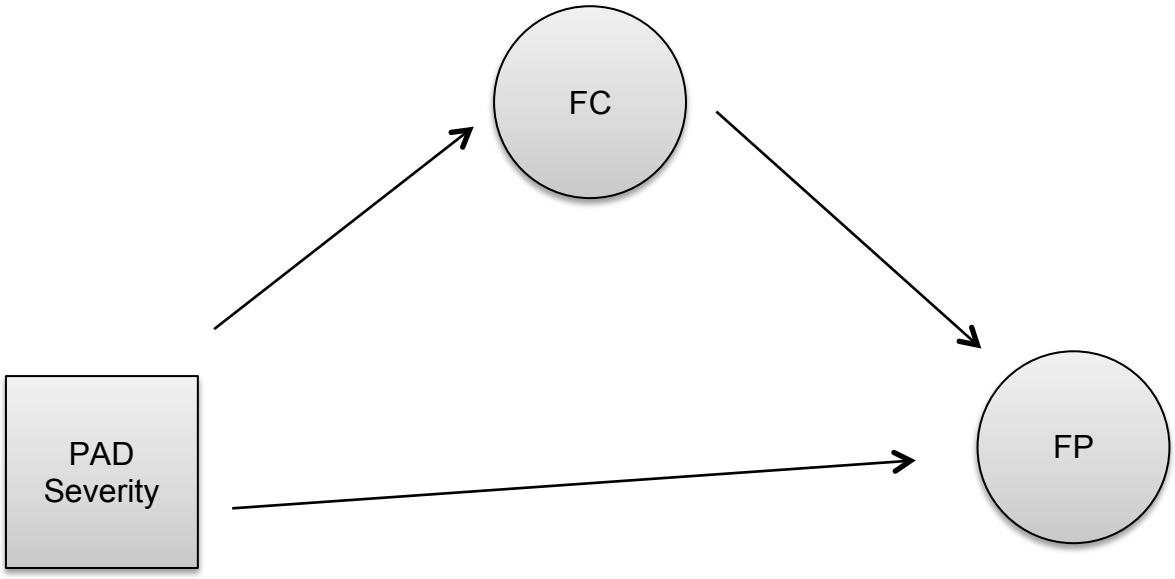
Testing for indirect effects was performed in order to determine if the latent variable functional capacity is a mediator between the exposure variable PAD severity (ABI) and the latent variable functional performance. The mediation analysis with indirect effects based on counterfactuals (causal inference) was performed using Mplus version 7.2 (Muthen & Muthen, 2014).

Standardized and unstandardized results are summarized in Figures 4.1 and 4.2. In the no PAD group, single path estimates and standard errors were calculated for the latent variable model. The exogenous variables age, gender, and diabetes were included in the analysis. The total direct effect between ABI and FP was not significant with a standardized estimate of -0.286 (*SE* = 0.191), *p* = .135. The total indirect effect between ABI and FP had a standardized estimate of 0.249 (*SE* = 0.174), *p* = 0.154.

In the PAD group, the standardized estimate for the total direct effect between ABI and FP was -1.202 (*SE* = 0.471), which was significant (*p* = .011). The standardized estimate for the indirect effect from ABI to FP through FC was also significant at -1.983 (*SE* = 0.924), *p* = 0.032. The MC 95% CI [0.1769, 0.480] was significant as it did not include zero.

Figure 4.1
PAD Group
Indirect Effect Analysis

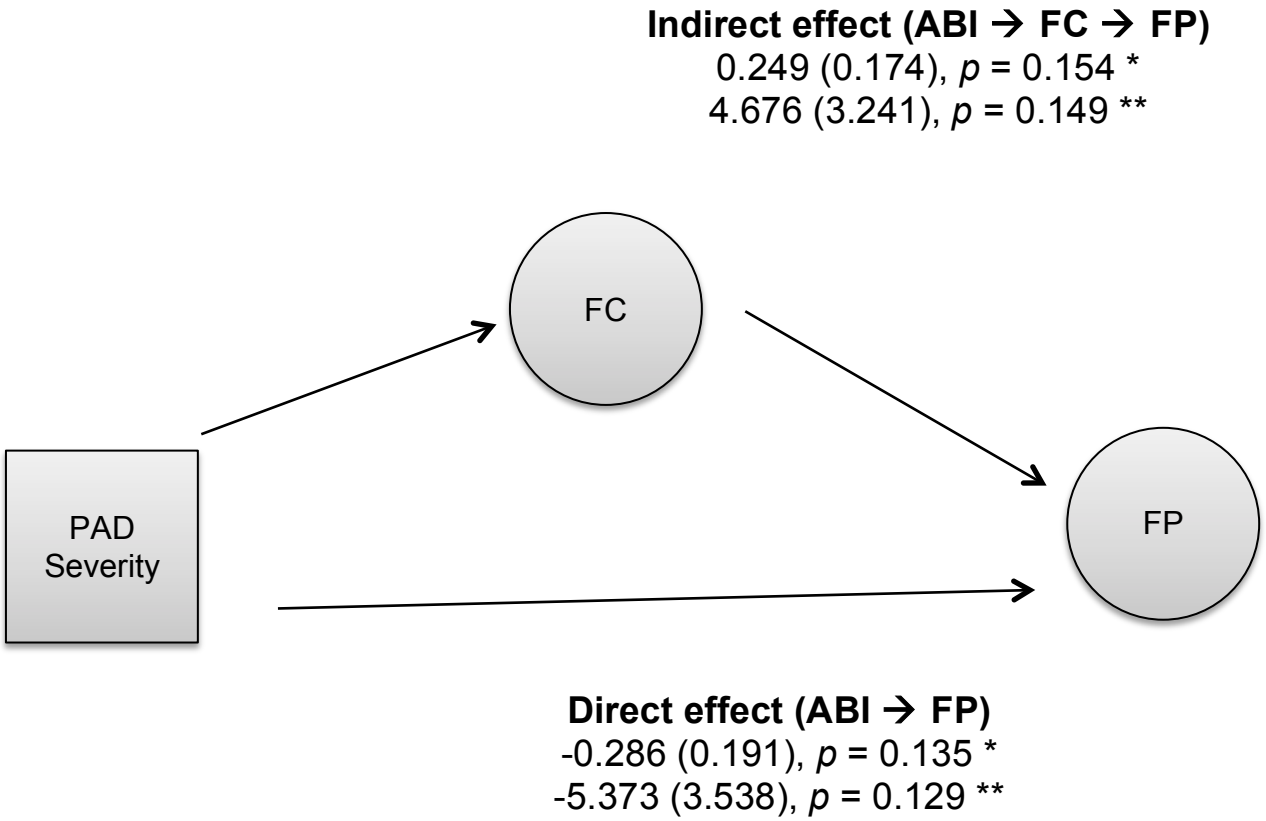
Indirect effect (ABI → FC → FP)
-1.983 (0.924), *p* = *0.032* *
25.678 (12.328), *p* = 0.037 **



Direct effect (ABI → FP)
-1.202 (0.471), *p* = 0.011 *
-31.132 (12.815), *p* = 0.015 **

*Standardized estimates
**Unstandardized estimates

Figure 4.2
No PAD group
Indirect effect analysis



*Standardized estimates
**Unstandardized estimates

Multigroup Analysis: Comparison of Latent Variable Means

MGA: Parallel Slopes

To determine between-group differences in latent variable means while controlling for the exogenous variables, a parallel slopes model was tested. Please refer to the methods section for specific steps. For functional capacity, the between group mean difference was -0.506 (*SE* = 0.246), *p* = .258, and for

functional performance it was 1.141 (*SE* = 0.448), *p* = .011. In summary, there was no significant between-group difference in functional capacity mean after controlling for age, gender, and diabetes. There was a significant between-group difference in functional performance after controlling for age, gender, and diabetes. The model fit was acceptable with an RMSEA of 0.058, CFI 0.811, and SRMR of 0.069.

MGA: Non-parallel Slopes

To determine between-group differences in latent variable means with the effect of different values of the exogenous variables on the latent variable, a non-parallel slopes model was tested. Please refer to the methods section for specific steps. The effect of age, gender, and severity of PAD were tested.

Age. The effect of age on between-group differences in latent variable means is summarized in Table 4.9. In both groups, functional capacity decreases with increasing age. The difference in the functional capacity means between the two groups also decreases with increasing age. The biggest difference appears to be at age 50, with the PAD group having worse functional capacity. In both groups functional capacity declines as age increases.

In both groups, functional performance mean scores became higher with increasing age, representing a decline or worsening of performance. However, the PAD group had larger increases in functional performance mean scores than did the no PAD group by age 80. This reflects a worsening of functional performance decline with increasing age in the PAD group compared to the no PAD group.

ABI. This analysis was performed to determine the relationship between severity of PAD as determined by the ABI and the functional capacity and performance values. The results are summarized in Table 4.8. Functional capacity scores increased with higher ABI values. The biggest increase in the functional capacity score (from 5.609 to 9.706) was seen as the ABI increased from 0.20 (severe PAD) to 0.50 (moderate PAD).

Functional performance scores increased, representing worse function, as ABI values decreased (low ABI values represents more severe PAD). The biggest decline in functional performance occurred from the 0.50 (moderate PAD) to the 0.20 (severe PAD) ABI. Both functional capacity and functional performance worsened with more severe PAD.

Gender. The results for gender are summarized in Table 4.11. For functional capacity, the male and female differences were larger in the no PAD group. The differences in the no PAD and PAD groups were larger among males than females. Lastly, males had a higher functional capacity than females in both groups. For functional performance, males also had a higher functional performance than the females in both groups.

Test for Equivalent Models

As described in the methods section, the replacement rule (Hershberger, 2006) was used to test for a possible equivalent model. One possible equivalent model was tested and is shown in Figure 3.5. The direction of the arrow connecting the FC and FP paths was reversed and analyzed in Mplus. Covariance matrices from the original model analysis (Figure 3.4) and the

possible equivalent model (Figure 3.5) were saved into separate files and compared. Results showed the estimated covariance matrices ***were not*** identical. The fit indices were also compared and ***were*** found to be identical. According to MacCallum, Wegener, Uchino, & Fabrigar (1993), identical fit indices can occur by chance even if the two models do not have identical covariance matrices. This appears to have occurred with this analysis, although the two models were found to have identical fit indices, the covariance matrices were not identical, therefore, the model tested in Figure 3.5 cannot be considered an equivalent model. It is acknowledged that other equivalent models could potentially exist, but additional investigation is beyond the scope of this dissertation.

CHAPTER V

DISCUSSION

Key Study Findings

The study of function in older adults with PAD has lacked the integration of a formal theoretical framework. Many studies have included evidence supporting bivariate relationships between salient variables, but formal investigation of a multivariate model has not been done. In fact, studies that have been guided by a theoretical framework in the PAD literature have largely focused on psychosocial constructs such as social-cognitive theory and self-efficacy. There has been little study of the mechanisms that connect PAD severity and functional capacity and performance in older adults with PAD.

In this study, a multivariate, latent variable model of functional capacity and performance was developed and tested in older adults with and without PAD. The measurement model was tested for measurement invariance between the two groups, and configural, metric, and scalar invariance was demonstrated. Fit statistics for the measurement model showed good fit of the model to the data. Multigroup full structural equation modeling demonstrated a good fit of the model to the data as well. Indirect effect analysis of the latent variable model showed functional capacity to mediate the effect between PAD severity and functional performance in the PAD group only. Multigroup alignment analysis facilitated the estimation of between group differences in latent variable means. There was no significant difference in latent variable means between the PAD

and no PAD groups for functional capacity, however, there was a significant difference in means for functional performance.

Review and Discussion of the Main Conclusions of the Study

Sample characteristics

The demographic characteristics of the study sample are consistent with previous studies. Given that the presence of even mild PAD is a marker for cardiovascular disease, increased prevalence of cardiovascular risk factors are expected in the PAD group. Many studies have demonstrated the presence of increased cardiovascular risk factors in older adults with PAD (Reis, Michos, von Muhlen, & Miller, 2008, Collins, Petersen, Suarez-Almazor, & Ashton, 2003).

The finding that African-Americans in the sample were more likely to have PAD compared to no PAD is also a finding documented in the literature. This disparity is also present in the treatment of African-Americans with PAD. For example, African-American patients are more likely to undergo lower extremity amputation for treatment of PAD than whites (Huber, Wang, Wheeler, Cuddeback, Dame, & Ozaki, et al., 1999). The disparity is alarming: African-Americans in the Medicare population from 2003 - 2005 had a four-times higher rate of amputation for PAD than whites (Fisher, Goodman, Chandra, Bronner, & Brownlee, 2008).

The finding of lower education level and income level in subjects with PAD is supported by previous literature. Low socioeconomic status as partially defined by income and education level is also associated with the presence and severity of PAD (Feinglass, Kaushik, Handel, Kosifas, Martin, & Pearce, 2000). According

to one study, the odds of having a lower extremity amputation were significantly increased if you were African-American, had a low-income, were over the age of 64, and had diabetes or other cardiovascular comorbidities (Feinglass, et al., 2000).

Subjects with PAD were less likely to be obese (BMI 30 - 39) or morbidly obese (BMI > 40) than those without PAD. Body mass index (BMI) was significantly greater in the no PAD group. This finding is consistent with other studies that have not found a significant association between BMI and PAD prevalence, or, have found an inverse relationship (Ix, Allison, Denenberg, Cushman, & Criqui, 2008). Instead, Ix, et al., (2008), found a greater association between waist to hip ratio risk of future cardiovascular events than BMI in older adults with PAD. The lack of association between BMI could be explained by the general poor health and loss of muscle mass in older adults with PAD.

Individual Latent Variable Indicators

Functional Capacity Indicators

Lower extremity strength. Reductions in lower extremity strength occur with the normal ageing process (Samuel & Rowe, 2009). The results of this study showed that lower extremity strength is significantly reduced in older adults with PAD compared to those in the no PAD group. This significant difference in lower extremity strength between the two groups was also present after age adjustment. This finding is expected and consistent with previous studies. For example, Scott-Okafor, et al., (2001) compared lower extremity strength in a PAD and no PAD group and found the PAD group to have significantly decreased

lower extremity strength compared to the no PAD group. And in 2008, McDermott, et al., studied lower extremity strength in older adults with PAD as measured by knee extensor strength. Subjects with PAD had significantly decreased lower extremity strength compared to subjects without PAD.

Calf circumference. The measure of maximum calf circumference was significantly smaller in the PAD group compared to the no PAD group. This difference remained significant after adjustment for age. This finding is expected for several reasons. First, older adults with PAD have higher prevalence of hypertension, high cholesterol, diabetes, and heart disease, in addition to several other medical comorbidities. This indicates that overall health is worse than those without PAD. Older adults in poor health are less likely to engage in physical activity, have worse lower extremity strength, and therefore, less muscle mass. This is supported by histologic studies that have demonstrated increased cell death in the calf muscle, reduced numbers of Type I and Type II calf muscle fibers, and reduced cross-sectional fiber area in subjects with PAD (Mitchell, Duscha, Robbins, Redfern, Chung, Bensimhon, & Kraus, et al, 2007; Askew, Green, Walker, Kerr, Green, Williams, & Febbraio, 2005). Decreased calf perfusion in subjects with PAD and decreased numbers of capillaries in muscle fibers has also been documented (Askew, et al., 2005). The significantly smaller maximum calf circumference in the PAD group is likely a combination of histological changes that occur as a result of PAD as well as deconditioning and muscle loss due to as a result of disuse.

Lower extremity sensory impairment. The results of this study showed that there was a significant difference in degree of sensory impairment between the PAD and no PAD groups. After adjustment for age, there was no significance between the two groups with regards to degree of sensory impairment. Comparing our results to the literature is difficult given that few studies evaluated for sensory impairment using monofilament testing. One study (McDermott, Criqui, Greenland, Guralnik, Liu, Pearce, & Taylor, et al., 2004) mentioned monofilament testing in the methods section of the paper, but no results were documented. However, impairment of sensory nerves in older adults with PAD has been studied using other methods of diagnosis, including quantitative sensory testing (QST), thermal testing, and mechanical testing (Lang, Schober, Rolke, Wagner, Offenbacher, & Treede, et al., 2006). This study showed significant differences in degree of sensory impairment between subjects with both moderate and severe PAD and a group without PAD, even after controlling for diabetes.

The significant difference between the two groups disappeared after controlling for age indicating that monofilament testing may not be sensitive enough to differentiate between normal age-related changes in sensation and pathologic impairment due to PAD.

Functional Performance Indicators

Usual gait speed. The usual gait speed as measured by the 20-foot walk, was significantly slower in the PAD group compared to the no PAD group. This difference remained after adjustment for age. This finding is similar to other

studies that have evaluated usual gait speed in older adults with PAD. Scherer, Bainbridge, Hiatt, & Regensteiner, 1998) reported significantly slower usual gait speeds in older adults with PAD compared to a control group without PAD. Similarly, Crowther, Spinks, Leicht, Quigley, & Golledge (2007) found usual gait speed to be significantly slower in subjects with PAD compared to a control group without PAD. The slower usual gait speed may be due to changes in gait patterns such the adaptation of a shuffling gait in older adults with PAD (Crowther, et al., 2007). Alterations in movement at the hip and ankle joints have also been demonstrated (Chen, Pipinos, Johanning, Radovic, Huisinga, Myers, & Stergiou, 2008). Pain in the lower extremities present in a large percentage of patients with PAD, is presumed to aggravate and exacerbate impairments in gait.

Physical function. Physical function as measured by a 13-item questionnaire, was significantly higher in the PAD group compared to the no PAD group indicating a decreased ability to perform day-to-day functional tasks. This difference remained significant after age adjustment. This is expected and similar to findings reported previously in the literature. Izquierdo-Porrera, Gardner, Bradham, Montgomery, Sorkin, & Powell, et al., (2005) found subjects with PAD to report perceived decreased ability to perform daily functional tasks.

Physical activity. Average level of self-reported physical activity was significantly lower in the PAD group compared to the no PAD group. After adjustment for age subjects aged

50 - 59 with PAD had a significantly higher level of physical activity compared to those without PAD group. This finding may be due to a small sample size in the

PAD group (n = 36) aged 50 - 59. However, subjects over the age of 60 with PAD had a significantly lower level of physical activity compared to the no PAD group.

This finding is similar to other studies of physical activity in older adults with PAD. Gardner & Clancy (2006) studied self-reported leisure-time physical activity in a group of older adults with PAD. This study found that subjects with a higher mean ABI and less severe PAD had higher levels of mean leisure-time physical activity compared to subjects with a lower ABI and more severe PAD. Gardner, Montgomery, Scott, Afaq, & Blevins (2007) assessed level of daily physical activity over seven days in a group of older adults with PAD compared to a group without PAD with a step activity monitor. Subjects with PAD had significantly lower levels of physical activity than the group without PAD, which remained significant after adjustment for age and other covariates.

Summary of Latent Variable Indicators Descriptive Statistics

Functional capacity indicators. Older adults with PAD had significantly decreased lower extremity strength and smaller maximum calf circumference measures than the group without PAD. These findings are expected and consistent to previous studies.

Functional performance indicators. Older adults with PAD had significantly slower usual gait speed than those without PAD. The mean usual gait speed was 0.77 m/s in the PAD group. A commonly reported cutoff indicating high risk for health-related outcomes is gait speed less than 1 m/s (Cesari, Kritchevsky, Penninx, Nicklas, Simonsick, & Newman, et al., 2005). The level of

physical activity and ability to perform ADLs was also significantly lower in the PAD group compared to the no PAD group. This is also expected and consistent with previous studies.

Latent Variable Model

The main purpose of this dissertation was to create and develop a latent variable model of functional capacity and functional performance in older adults with PAD. The relationship between PAD severity, FC, and FP was also of primary interest in this study.

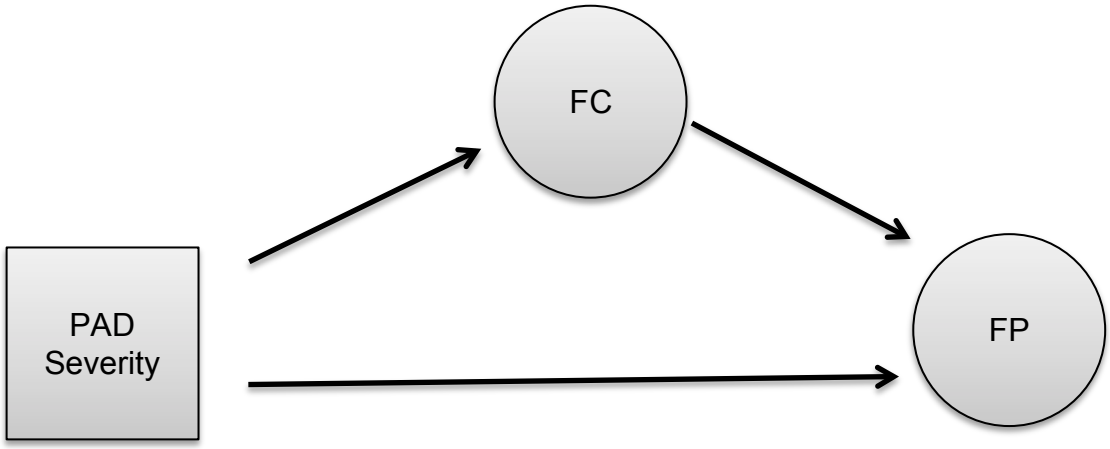


Figure 5.1 Latent Variable Model

Model Testing

Multigroup Analysis: Measurement Model

Multigroup analysis was performed in order to determine if the proposed measurement model of FC and FP could be used to compare the PAD and no PAD groups. The model was tested in each group separately first and showed good fit for both. Next, the proposed model was tested for measurement invariance between the two groups. The analysis demonstrated configural, metric, and scalar invariance between the two groups. This means that the

relationships of the observed latent variable indicators to the latent variable are the same between the two groups. The two groups can still have different means and variances, but the inference after demonstrating measurement invariance is that the differences will be through the common latent variable (Millsap & Olivera, 2012). Demonstrating invariance of the measurement model between the two groups allowed for meaningful group comparisons of the full structural model to be made.

Full SEM Analysis

Model Fit

Multigroup analysis was performed on the full structural model and the detailed results are found in Chapter 4. The salient results will be discussed next.

Latent Variable Means

One of the more substantively interesting results yielded from this study is that the analysis provided an avenue for obtaining the difference between latent variable means. The FC mean was smaller in the PAD group compared to the no PAD group, but not significantly smaller. This could be due to the indicator measures, especially for calf circumference and lower extremity sensory impairment. The FP mean was significantly smaller in the PAD group compared to the no PAD group. It is expected that the group without PAD would have a higher FP than the group with PAD. This analysis allows quantification of latent variables FC and FP, which has not been evaluated in the literature at the time of this dissertation.

Indirect Effect Analysis

The indirect effect analysis enabled testing of the hypothesis that functional capacity mediates the relationship between the exposure variable PAD severity and functional performance. It did show that there is a significant direct effect between PAD severity and functional performance as well as a significant indirect effect through functional capacity. As discussed in the results section, there is both a direct and indirect effect of PAD severity on functional performance. From a clinical perspective, this allows for two possible areas of intervention to increase functional performance in older adults with PAD. If there is a direct effect of the severity of PAD on functional performance, then interventions to increase lower extremity blood flow should increase functional performance. Past research has shown that angioplasty or bypass surgery alone does not result in long-term increases in functional performance. There is a significant indirect effect as well through functional capacity. Again, past interventions that solely focused on strength or endurance training did not result in long term improvements in FP either. Perhaps a coordinated intervention to improve blood flow followed by long term strength and endurance training to increase capacity is the answer for long term improvements in functional performance. Longitudinal studies are the best avenue for testing the efficacy of such an intervention.

Equivalent Models

The possibility of equivalent models was investigated as part of this dissertation. It is worth noting that that the existence of alternative or equivalent

models in SEM analysis is recognized as fairly common. One large review study evaluated 79 published SEM reports over a 20-year period from 1984 - 2004 (Henley, Shook, & Peterson, 2006). This review study reported that 75% of the models reviewed had at least one equivalent model as evaluated by the replacement rule. It is acknowledged that the analysis for this study was not a comprehensive search potential equivalent models, and therefore, such models may still exist.

Study Limitations

There are several limitations to this study. First, this study was a secondary analysis and therefore limited by the measures available in the dataset. For example, a better measure of functional capacity would strengthen this research. Similarly, the Semmes-Weinstein monofilament test is useful for sensory impairment screening, but not for motor nerve impairment or diagnosis of peripheral neuropathy. And lastly, physical activity was self-reported and measured by questionnaire in this study. A physical activity monitor used to measure physical activity was not included in the NHANES survey cycles used in this study (1999-2002).

The second limitation relates to sources of specification error. These include possible omitted variables, measurement error, and reverse causation. *Omitted variables*. There is a high likelihood of omitted variables in the hypothesized model. It is acknowledged that omitted variables can result in biased parameter estimates and standard errors (Tomarken & Waller, 2005).

Future studies can include sensitivity analyses to determine the effect of the omitted variable(s) on the model.

Measurement error. Measurement error in the causal variable (PAD severity measured by ABI) can result in biased estimates of its effect. Even though the sensitivity and specificity of the ABI are both greater than 90%, even small amounts of measurement error can result in biased estimates. One way the effect of this measurement error is reduced is by the use of multiple indicators for each latent variable.

Reverse causation. The possibility of reverse causation is also a mechanism for specification error. Reverse causation was not formally tested in this study and can be done in future studies. Theoretically, the idea of reverse causation in this model does not make sense. The hypothesized causal effect in this study is that PAD severity has a causal effect on functional capacity and functional performance in older adults with PAD. Reverse causation indicates that functional capacity and functional performance have a causal effect on the severity of PAD. While this was not tested, it does not make conceptual sense. Additionally, if both causal directions are specified the model would have a feedback loop and would not be identified.

Third, analysis of lower order model components (path coefficients and variance explained) was not a specific aim of this study and therefore not included in the analysis and interpretation of the data. Future studies can focus on a study of the lower order model components and predicting variance

explained using appropriate methodology if indicated (Hayduk, Cummings, Boadu, Pazderka-Robinson, & Boulianne, 2007).

A fourth limitation of the study involves the degree of PAD severity in the study sample (PAD group, n=378). The mean ABI of the PAD group was 0.76 (range 0.23-0.89). This mean ABI value represents mild-moderate PAD. An ABI of less than 0.50 would indicate severe PAD. Overall, 262 subjects fell into the mild-moderate PAD group, and 116 fell into the severe PAD group. There were not enough subjects in the severe PAD group for adequate power to run a multigroup analysis. Instead, two groups were created, PAD and no PAD. Future studies should evaluate the model in subjects with mild to moderate and severe PAD to capture the effect of all levels of PAD severity on functional capacity and functional performance.

Significance of Study Findings

The most significant contribution of this research is the application of multivariate, latent variable modeling to the study of function in older adults with PAD. The attempt to identify indicators of functional capacity and functional performance and thereby providing definition, measurement, and substantive value to them has not been done before. This research should be viewed as a stepping-stone for future research and evaluation of the complex problem of function in older adults with PAD.

While the contributions of this study are largely methodological, there is applicability to nursing practice now. Specifically, this study provides confirmation that in older adults with PAD, the effect of PAD severity on functional

performance is mediated through functional capacity. The inference is that interventions should focus on increasing capacity in order to increase performance. Given that there is both a direct and indirect effect, a study combining both an intervention to improve blood flow followed by a long-term strength and endurance program is the answer to sustained improvements in functional performance.

The mean usual gait speed in the PAD group suggests high risk for future disability, even with a mean ABI of 0.76, or mild to moderate PAD. Interventions to increase functional capacity in older adults with mild to moderate PAD can likely improve functional performance and perhaps even prevent or prolong future disability.

Future Study and Next Steps

Further study is needed to replicate the findings of this study. Next steps should include further refinement of the model and testing in other samples. Refinement of the model should include more definitive measures of functional capacity as well as better measures for sensory impairment and physical activity. The role of lower extremity pain in this process also needs to be delineated.

As discussed in the limitation section, groups were divided into a PAD group and no PAD group. Future studies should further break down the PAD group to differentiate between mild, moderate, and severe PAD in order to extract differences in the model and latent variable interactions. And finally, a longitudinal study of the effect of PAD severity on functional capacity and functional performance should be conducted in order to see changes over time.

To determine if increases in functional capacity result in functional performance increases, an intervention study should be conducted. Aggressive, early intervention is of particular interest given that older adults with mild-moderate PAD are at high risk for future disability.

Table 3.2.

Missing data for No PAD group, Strength variable

Reason for Missing Value	n (%)
General Exclusions:	
Safety exclusion	250 (7.5)
SP refusal	49 (1.5)
No time	17 (0.5)
Physical limitation	248 (7.5)
Communication problem	9 (0.3)
Equipment failure	51 (1.5)
SP ill/emergency	19 (0.6)
Interrupted	1 (0.1)
Came late/left early	144 (4.3)
Other	64 (1.9)
Excluded for:	
Chest/Abdomen surgery last 3 weeks	18 (0.5)
Myocardial infarction	8 (0.2)
Told by Dr had brain aneurysm or stroke	144 (4.3)
Severe neck or back pain	101 (3.0)
Difficulty bending/straightening right knee	62 (1.9)
Had right knee or right hip replacement	64 (1.9)
Total Missing Values	1249 (37)

SP=sample person

Table 3.3.

Missing data for PAD group, strength variable

Reason for Missing Value	n (%)
General Exclusions:	
Safety exclusion	32 (8.5)
SP refusal	5 (1.3)
No time	3 (0.8)
Physical limitation	30 (7.9)
Equipment failure	3 (0.8)
SP ill/emergency	1 (0.3)
Came late/left early	11 (2.9)
Other	5 (1.3)
Excluded for:	
Chest/Abdomen surgery last 3 weeks	1 (0.3)
Myocardial infarction	1 (0.3)
Told by Dr had brain aneurysm or stroke	14 (3.7)
Severe neck or back pain	13 (3.4)
Difficulty bending/straightening right knee	9 (2.4)
Had right knee or right hip replacement	9 (2.4)
Total Missing Values	137 (36)

SP=sample person

Table 4.1.

Unadjusted demographic characteristics of sample by group

	No PAD Group (n=3317)		PAD Group (n=378)		*p-value*
Age (years)	62.41	(.190)	70.53	(.834)	<0.0001
Gender					
Male (n, %)	1689	(47.1)	190	(44.0)	
Female (n, %)	1628	(52.9)	188	(56.0)	
Body Mass Index	28.38	(.173)	27.34	(.348)	0.0078
Systolic blood pressure (mm/Hg)	132.86	(.849)	144.84	(2.322)	<0.0001
Diastolic blood pressure (mm/Hg)	72.79	(.617)	66.78	(1.166)	<0.0001
60-second heart rate	69.99	(.387)	72.53	(1.085)	0.0286
Ethnicity (n, %)					
Non-Hispanic white	1864	(79.5)	216	(79.8)	0.7663
Non-Hispanic black	523	(7.6)	90	(13)	<0.0001
Mexican American	680	(3.5)	56	(2.6)	0.0106
Other Hispanic	151	(5.4)	13	(3.8)	0.3877
Other racial/multi-racial	99	(3.9)	3	(0.8)	0.0216
Marital Status (n, %)					
Never Married	126	(3.6)	11	(2.9)	0.4699
Married	202	(68)	186	(53.3)	<0.0001

Divorced	328 (11.4)	35 (12.8)	0.7655
Widowed	506 (12.9)	115 (28.0)	<0.0001
Separated	96 (2.0)	11 (2.1)	0.9861
Living with Partner	64 (2.1)	2 (0.8)	0.0814
Education (n, %)			
Less than 9th grade	668 (9.2)	94 (15.2)	0.0370
9 -11th grade	556 (15)	78 (18.9)	0.0687
High school grad/GED	734 (25.2)	95 (30.7)	0.2072
Some college/ Associates	719 (25.3)	59 (20.1)	0.0075
College grad or above	633 (25.2)	50 (15.2)	0.0067
Income (n, %)			
0-4,999	32 (0.8)	10 (1.7)	0.0077
5,000-9,999	214 (5.6)	43 (11.0)	0.0005
10,000-14,999	334 (8.4)	49 (15.4)	0.0970
15,000-19,999	244 (6.8)	40 (9.8)	0.0333
20,000-24,999	245 (7.1)	26 (8.6)	0.7989
25,000-34,999	384 (12.4)	60 (18.3)	0.0187
35,000-44,999	292 (10.0)	26 (7.9)	0.2430
45,000-54,999	234 (9.7)	22 (7.1)	0.4303
55,000-64,999	179 (7.4)	11 (5.1)	0.0511
65,000-75,000	143 (5.9)	7 (2.8)	0.0309
75,000 and over	517 24.6)	32 (10.3)	0.0003

Table 4.2.
Medical comorbidities by group, age-adjusted

	No PAD Group %, SE	PAD Group %, SE	No PAD Group %, SE	PAD Group %, SE
	Age 50-59	Age 50-59	Age 60+	Age 60+
Hypertension	34.39 (1.99)	51.35 (11.38)	47.57 (1.24)	65.28 (2.49)
High Cholesterol	43.40 (1.64)	62.48 (12.49)	48.64 (1.27)	59.81 (3.23)
Diabetes	8.00 (.849)	15.78 (9.38)	12.97 (.780)	20.57 (2.64)
Taking Oral medication	75.58 (5.57)	39.03 (9.43)	71.01 (2.63)	60.40 (7.10)
Taking Insulin	1.08 (0.30)	6.18 (4.70)	3.81 (0.60)	10.71 (2.73)
Coronary Artery Disease	4.51 (.681)	18.38 (8.30)	12.81 (1.53)	12.68 (4.55)
Congestive Heart Failure	2.44 (.610)	4.55 (2.54)	6.23 (1.10)	15.85 (4.85)
Myocardial Infarction	3.88 (.752)	4.22 (2.41)	11.64 (1.31)	12.87 (4.95)
Angina	3.88 (.726)	16.15 (7.90)	14.74 (1.95)	9.60 (3.99)
Stroke	1.84 (.470)	6.21 (4.16)	7.09 (1.32)	11.22 (4.39)
Emphysema	2.37 (.539)	1.19 (1.20)	5.95 (1.27)	9.74 (4.67)
Arthritis				
-Osteoarthritis	54.95 (5.18)	46.57 (21.96)	68.63 (3.00)	53.59 (9.36)
Cancer	8.96 (.924)	9.19 (6.19)	20.45 (.918)	19.75 (3.12)
Liver disease	5.06 (.735)	6.67 (4.75)	3.18 (.622)	2.65 (.701)
Current Cigarette Smoker	65.41 (1.75)	60.47 (11.58)	60.15 (1.41)	53.25 (2.84)
Smoked minimum 100 cigarettes	56.64 (1.64)	82.85 (7.86)	51.55 (1.63)	67.70 (3.31)

Obesity, BMI >=30, <=39	27.05 (1.61)	32.86 (10.42)	27.55 (1.21)	22.64 (2.42)
Morbid Obesity, BMI >40	4.92 (0.91)	1.88 (1.89)	2.79 (0.41)	3.52 (1.20)

Table 4.3.
Medical comorbidities by group, unadjusted

	No PAD Group (n=3317) Frequency (%, SE)	PAD Group (n=378) Frequency (%, SE)	*p*
Hypertension	1468 (41.3)	230 (62.5)	*p*<0.0001
High Cholesterol	1278 (45.9)	164 (59.4)	p=0.0210
Diabetes	466 (10.4)	84 (19.3)	*p*<0.0001
Taking Oral medication	342 (72.6)	57 (57.4)	p=0.3293
Taking Insulin	102 (2.5)	33 (10)	*p*<0.0001
Coronary Artery Disease	243 (7.3)	49 (14.5)	p=0.0001
Congestive Heart Failure	140 (3.4)	37 (9.3)	*p*<0.0001
Myocardial Infarction	225 (6.3)	52 (13.7)	*p*<0.0001
Angina	213 (6.4)	29 (9.5)	p=0.4058
Stroke	150 (3.7)	41 (10.4)	*p*<0.0001
Emphysema	107 (3.7)	24 (7)	p=0.0029
Osteoarthritis	325 (31.6)	51 (44.1)	p=0.0856
Rheumatoid Arthritis	413 (56.3)	44 (49.1)	p=0.1477
Current Cigarette Smoker	497 (30.6)	90 (35.2)	p=0.0353
Smoked minimum 100 cigarettes	1750 (53.9)	257 (70.3)	*p*<0.0001
Obesity, BMI >=30, <=39	909 (27.3)	77 (24.5)	p=0.0099
Morbid Obesity, BMI >40	112 (3.8)	11 (3.2)	p=0.8185
Cancer	471 (15)	67 (17.9)	p=0.0789

Table 4.4.
Physical Function Questionnaire Item Means, Standard Error

PFQ Item (all items 1-4 scale)	No PAD Group (n=3317)	PAD Group (n=378)	*p*
	Mean (SE)	*Mean (SE)*	
Difficulty walking 2 or 3 blocks	1.41 (.022)	1.93 (.085)	<0.0001
Difficulty walking up 10 steps	1.73 (.031)	2.08 (.065)	<0.0001
Difficulty stooping, crouching, kneeling	1.38 (.025)	1.62 (.052)	0.0006
Difficulty lifting and carrying 10 pounds	1.30 (.021)	1.56 (.059)	<0.0001
Difficulty performing household chores	1.34 (.020)	1.59 (.060)	<0.0001
Difficulty preparing own meals	1.12 (.011)	1.25 (.048)	0.0002
Difficulty walking between rooms on same floor	1.08 (.008)	1.17 (.031)	0.0002
Difficulty standing up from armless chair	1.26 (.017)	1.48 (.037)	0.0001
Getting in and out of bed difficulty	1.19 (.014)	1.23 (.033)	0.3092
Difficulty dressing yourself	1.13 (.010)	1.21 (.044)	0.0108
Difficulty going to movies or events	1.25 (.018)	1.44 (.051)	0.0002
Difficulty attending social event	1.20 (.018)	1.31 (.043)	0.0298
Difficulty doing leisure activities at home	1.08 (.009)	1.11 (.024)	0.2419

Note: All items scored range 1-4 (1=no difficulty, 2=some difficulty, 3=much difficulty, 4=not able to do)

Table 4.5.
Age-adjusted factor indicator means, standard errors by group

	No PAD	PAD	No PAD	PAD	*p* (Age 50-59, Age 60+
	Age 50-59		Age 60+		
	No PAD Group Mean, SE	PAD Group Mean, SE	No PAD Group Mean, SE	PAD Group Mean, SE	
Functional Capacity Indicators					
Lower Extremity Strength (Newton-Meters)	324.20 (3.60)	264.23 (13.05)	259.72 (4.78)	219.89 (5.04)	*p*=0.0001, *p*=0.0001
Lower Extremity Sensory Impairment	1.41 (.177)	3.28 (1.01)	4.03 (.324)	4.62 (.934)	*p*=0.0683, *p*=0.5507
Calf Circumference (cm^2)	38.89 (.160)	37.07 (.856)	37.55 (.118)	36.04 (.247)	*p*=0.0367, *p*=0.0001
Functional Performance Indicators					
Usual Gait Speed (seconds)	5.61 (.052)	6.45 (.400)	6.74 (.081)	8.13 (.254)	*p*=0.0374, *p*=0.0001
Daily level of physical activity	1.98 (.035)	2.14 (.142)	1.97 (.022)	1.76 (.041)	*p*=0.2741, *p*=0.0001
Physical Function	18.83 (.440)	24.30 (1.92)	15.80 (.132)	18.24 (.350)	*p*=0.0057, *p*=0.0001
Exogenous Variable					
Ankle-Brachial Index	1.13 (.004)	0.80 (.020)	1.11 (.003)	0.76 (.013)	*p*=0.0001, *p*=0.0001

Table 4.6.
Multigroup CFA: Model Invariance Testing

Model	Nested MLR Chi-square (df)	Comparison MLR Chi-square (df)	Scaling Correction Factor (nested, comparison)	RMSEA [90% CI]	CFI	SRMR	Diff test Scaling Correction Factor (Cd)	TRd (df)	*p*
A	-	37.430	1.4447	0.027 [.016-.038]	0.956	0.025	-	-	-
B	-	38.928	1.5360	0.023 [.012-.033]	0.961	0.028	-	-	-
C	-	42.374	1.4980	0.020 [.010-.030]	0.962	0.029	-	-	-
B vs. A	38.928	37.430	1.5360 1.4447	-	-	-	1.902	3.0077 (4)	0.556
C vs. B	42.374	38.928	1.4980 1.5360	-	-	-	1.308	2.8155 (4)	0.589
C vs. A	42.374	37.430	1.4980 1.4447	-	-	-	1.603	5.870 (8)	0.662

Model A=configural invariance, Model B=metric invariance, Model C=scalar invariance

Table 4.7.
Expected differences in FC and FP given PAD severity

	ABI						
	0	0.20 (Severe)	0.50	0.70 (Mild-Mod)	0.90 (Mild)	0.91 (Normal)	1.0
	Intercept						
Functional Capacity							
No PAD Group	-	-	-	-	-	16.205	17.808
PAD Group	2.878	5.609	9.706	12.437	15.168	-	-
	Intercept						
Functional Performance							
No PAD Group	-	-	-	-	-	-1.940	-2.132
PAD Group	3.697	2.5096	0.728	-0.458	-1.646	-	-

*ABI factor loading FC= 13.656, FP= -5.937, Calculation FC, no PAD group= 0 + 17.808*ABI, PAD group= 2.878 +13.6565*ABI, Calculation FP, No PAD= 0 + -2.132*ABI, PAD= 3.697 + -5.937*ABI*

Table 4.8.
Effect of age on mean intercept differences for FC and FP

Age	**0**	**50**	**60**	**70**	**80**
Functional Capacity (FC)	Factor Loading (FL)				
No PAD Group	-0.454	-22.70	-27.24	-31.78	-36.32
PAD Group	-0.231	-28.475	-30.785	-33.095	-35.095
Functional Performance (FP)					
No PAD Group	0.070	3.5	4.2	4.9	5.6
PAD Group	0.114	-11.225	-10.085	-8.945	-7.805

*Calculations for FC, no PAD group= 0 + FL*age, PAD group= -16.925 + FL*age, for FP, no PAD group= 0 + FL*age, PAD group= -2.354 + FL*age*

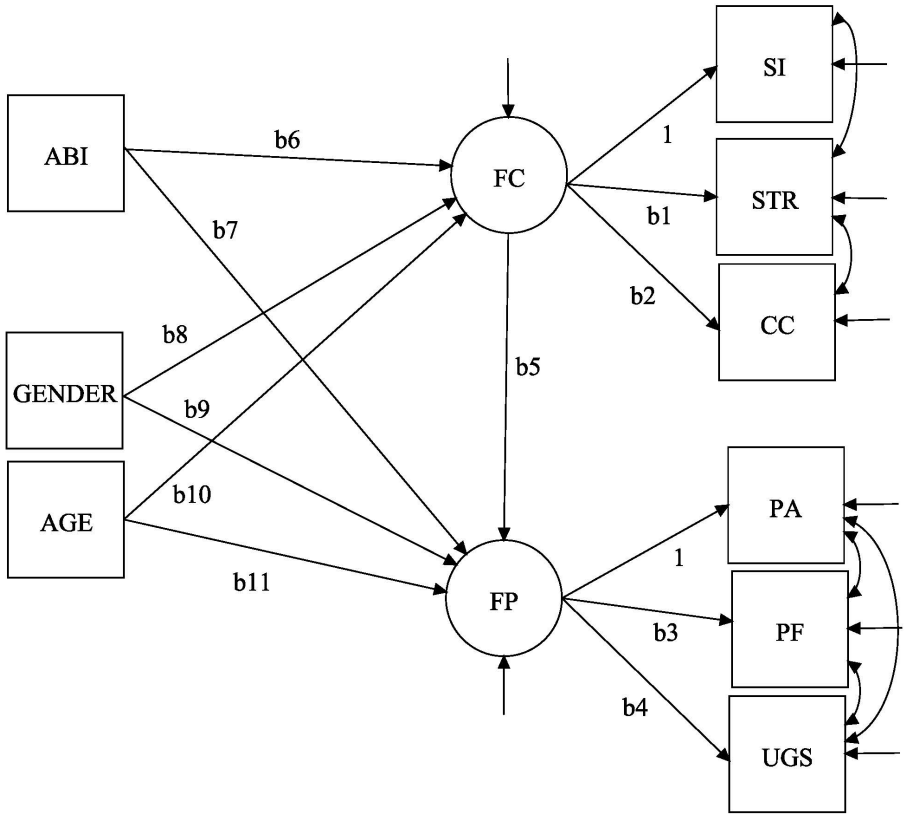
Table 4.9.
Effect of gender on FC and FP scores

	Female	Male
Functional Capacity		
No PAD Group	0	9.904
PAD Group	0.188	4.795
Functional Performance		
No PAD Group	0	-0.362
PAD Group	0.782	-0.453

No PAD Group equation: FC = 0 +9.904 (male) –coef (age) + coef (abi) = 9.904, PAD Group equation: FC = 0.188 + 4.795 (male) –coef (age) + coef (abi)= 4.983
No PAD-PAD difference, males: 9.904 – 4.983= 4.921

No PAD Group equation: FP = 0+ -0.362 (male) –coef (age) + coef (abi) = -0.362
PAD Group equation: FP = 0.782 + -0.453 (male) - coef (age) + coef (abi) = -0.329
The No PAD-PAD group difference, males: -0.362 - -0.329 = -0.03

APPENDIX A
DEGREES OF FREEDOM CALCULATION



(ABI= ankle-brachial index, SI= sensory impairment, STR= strength, CC= calf circumference, PA= level of PA, PF= physical function, UGS= usual gait speed)

Calculation of degrees of freedom

Model Parameters:
Regression coefficients= 11
Covariances= 5
Error variances= 8
Variances=3
Total= 27

n=observed variables
n(n+1)/2- # parameters

9(9+1)/2 - 27
90/2 - 27=
45 - 27= 18

df= 18

Model Parameter Equation

SI = FC*1 + e1
STR= FC*b1 + e2
CC= FC*b2 + e3

PA= FP*1 + e4
PF= FP*b3 + e5
UGS= FP*b4 + e6

FP= FC*b5 + d2

APPENDIX B

PHYSICAL FUNCTION QUESTIONNAIRE

BOX 1A

CHECK ITEM PFQ.001:
IF AGE OF SP IS >= 20, GO TO PFQ.048
OTHERWISE, CONTINUE WITH BOX 1B.

BOX 1B

CHECK ITEM PFQ.002:
IF SP <= 4, CONTINUE.
OTHERWISE, GO TO PFQ.020.

PFQ.010 The next set of questions is about limitations caused by any long-term physical, mental or emotional problem or illness. Please do not include temporary conditions, such as a cold.

Is {SP} limited in the kind or amount of play activities {he/she} can do because of a physical, mental or emotional problem?

YES	1	
NO	2	(PFQ.020)
REFUSED	7	(PFQ.020)
DON'T KNOW	9	(PFQ.020)

PFQ.015 Is {SP} able to take part **at all** in the usual kinds of play activities done by most children {his/her} age?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

PFQ.020 {Do you/Does SP} have an impairment or health problem that limits {your/his/her} ability to {crawl, walk or play} {walk, run or play} {walk or run}?

CAPI INSTRUCTION:
IF CHILD'S AGE = 1-4, DISPLAY "CRAWL, WALK OR PLAY". IF CHILD'S AGE = 5-15, DISPLAY "WALK, RUN OR PLAY". IF SP'S AGE = 16-19, DISPLAY "WALK OR RUN".

YES	1	
NO	2	(BOX 1BB)
REFUSED	7	(BOX 1BB)
DON'T KNOW	9	(BOX 1BB)

PFQ.030 Is this an impairment or health problem that has lasted, or is expected to last **12 months or longer**?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

BOX 1BB

CHECK ITEM PFQ.035:
IF SP AGE <= 15, CONTINUE.
OTHERWISE, GO TO END OF SECTION.

PFQ.040 Does {SP} receive Special Education or Early Intervention Services?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

BOX 1C

CHECK ITEM PFQ.045:
GO TO END OF SECTION.

PFQ.048 The next set of questions is about limitations caused by any long-term physical, mental or emotional problem or illness. Please do not include temporary conditions, such as a cold [or pregnancy].

Does a physical, mental or emotional problem **now** keep {you/SP} from working at a job or business?

YES	1	
NO	2	(PFQ.056)
REFUSED	7	(PFQ.056)
DON'T KNOW	9	(PFQ.056)

PFQ.050 {Are you/Is SP} limited in the kind **or** amount of work {you/s/he} can do because of a physical, mental or emotional problem?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

PFQ.055 Because of a health problem, {do you/does SP} have difficulty walking **without** using any **special equipment**?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

PFQ.056 {Are you/Is SP} **limited in any way** because of difficulty remembering or because {you/s/he} experience{s} periods of confusion?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

BOX 1D

CHECK ITEM PFQ.058:
IF 'YES' (CODE 1) IN PFQ.048, PFQ.050, PFQ.055, OR PFQ.056, GO TO PFQ.060.
OTHERWISE, CONTINUE.

PFQ.059 {Are you/Is SP} **limited in any way** in any activity because of a physical, mental or emotional problem?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

BOX 1E

CHECK ITEM PFQ.059A:
IF SP AGE IS <=59 AND 'NO' (CODE 2) ENTERED IN PFQ.048, PFQ.056 **AND** PFQ.059, GO TO PFQ.090.
OTHERWISE, CONTINUE.

PFQ.060 The next questions ask about difficulties {you/SP} may have doing certain activities because of a health problem. By "health problem" we mean any long-term physical, mental or emotional problem or illness {not including pregnancy}.

By {yourself/himself/herself} and without using any special equipment, how much difficulty {do you/does SP} have . . .

HAND CARD PFQ1
DO NOT INCLUDE TEMPORARY CONDITIONS LIKE PREGNANCY OR BROKEN LIMBS.

CAPI INSTRUCTION:
IF PFQ.055 = '1' (YES), DO NOT DISPLAY 'B' OR 'C'.
IF SP FEMALE, DISPLAY 'NOT INCLUDING PREGNANCY'.

RESPONSES: NO DIFFICULTY = 1, SOME DIFFICULTY = 2, MUCH DIFFICULTY = 3, UNABLE TO DO = 4, REFUSED = 7, DON'T KNOW = 9.

a. **managing {your/his/her} money [such as keeping track of {your/his/her} expenses or paying bills]**? ____

b. **walking for a quarter of a mile [that is about 2 or 3 blocks]**? ____

c. **walking up 10 steps without resting**? ____

d. **stooping, crouching, or kneeling**? ____

e. **lifting or carrying something as heavy as 10 pounds [like a sack of potatoes or rice]**? ____

f. **doing chores around the house [like vacuuming, sweeping, dusting, or straightening up]**? ____

g. **preparing {your/his/her} own meals**? ____

h. **walking from one room to another on the same level**? ____

i. **standing up from an armless straight chair**? ____

j. **getting in or out of bed**? ____

k. **eating, like holding a fork, cutting food or drinking from a glass**? ____

l. **dressing {yourself/himself/herself}, including tying shoes, working zippers, and doing buttons**? ____

m. **standing or being on {your/his/her} feet for about 2 hours**? ____

n. **sitting for about 2 hours**? ____

o. **reaching up over {your/his/her} head**? ____

p. **using {your/his/her} fingers to grasp or handle small objects**? ____

q. **going out to things like shopping, movies, or sporting events**? ____

r. **participating in social activities [visiting friends, attending clubs or meetings or going to parties]**? ____

s. **doing things to relax at home or for leisure [reading, watching TV, sewing, listening to music]**? ____

BOX 1F

CHECK ITEM PFQ.066:
IF 'SOME DIFFICULTY' (CODE 2), 'MUCH DIFFICULTY' (CODE 3), OR 'UNABLE TO DO' (CODE 4) IN PFQ.060 A THROUGH S, CONTINUE.
OTHERWISE, GO TO PFQ.090.

PFQ.067 What condition or health problem causes {you/SP} to have difficulty with or need help with {NAME OF UP TO 3 ACTIVITIES/these activities}?

HAND CARD PFQ2
ENTER ALL THAT APPLY UP TO 5 BUT DO NOT PROBE.
DO NOT ENTER 'OLD AGE' AS CONDITION -- IF OLD AGE IS REPORTED, PROBE FOR ANY **OTHER** CONDITION.

CAPI INSTRUCTION:
IF THE TOTAL NUMBER OF ITEMS CODED 'SOME DIFFICULTY' (CODE 2), 'MUCH DIFFICULTY' (CODE 3), OR 'UNABLE TO DO' (CODE 4) IN PFQ.060 A THROUGH S <=3, DISPLAY EACH ITEM NAME IN THE TEXT OF QUESTION. IF MORE THAN 3 ITEMS ARE CODED IN THIS MANNER DISPLAY "THESE ACTIVITIES" IN THE TEXT OF QUESTION.

ARTHRITIS/RHEUMATISM	10
BACK OR NECK PROBLEM	11
BIRTH DEFECT	12
CANCER	13
DEPRESSION/ANXIETY/EMOTIONAL PROBLEM	14
OTHER **DEVELOPMENTAL** PROBLEM (SUCH AS CEREBRAL PALSY)	15
DIABETES	16
FRACTURES, BONE/JOINT INJURY	17
HEARING PROBLEM	18
HEART PROBLEM	19
HYPERTENSION/HIGH BLOOD PRESSURE	20
LUNG/BREATHING PROBLEM	21
MENTAL RETARDATION	22
OTHER INJURY	23
SENILITY	24
STROKE PROBLEM	25
VISION/PROBLEM SEEING	26
WEIGHT PROBLEM	27
OTHER IMPAIRMENT/PROBLEM	28
REFUSED	77
DON'T KNOW	99

BOX 2

CHECK ITEM PFQ.068:
IF CODE 10-11 OR 13-28 IN PFQ.067, CONTINUE WITH LOOP 1.
OTHERWISE, GO TO PFQ.090.

LOOP 1:
ASK QUESTION PFQ.069 FOR EACH CONDITION MENTIONED IN PFQ.067 (CONDITION: 10-11 OR 13-28).

PFQ.069 How long have you had {CONDITION 10-11 or 13-28}?

CAPI INSTRUCTION:
IF CODE 28 IN PFQ.067, THE FILL SHOULD BE {THE OTHER CONDITION YOU MENTIONED}.

|___|___|___|
ENTER NUMBER (OF DAYS, WEEKS, MONTHS OR YEARS)

SINCE BIRTH	666
REFUSED	777
DON'T KNOW	999

ENTER UNIT

DAYS	1
WEEKS	2
MONTHS	3
YEARS	4
REFUSED	7
DON'T KNOW	9

BOX 3

END LOOP 1:
CYCLE ON NEXT CONDITION.
IF NO NEXT CONDITION, GO TO PFQ.090.

PFQ.090 {Do you/Does SP} now have any health problem that requires {you/him/her} to use special equipment, such as a cane, a wheelchair, a special bed, or a special telephone?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

PFQ.100 {Do you/Does SP} usually use any special eating utensils?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

PFQ.110 {Do you/Does SP} usually use any aids or devices to help {you/him/her} dress [such as button hooks, zipper pulls, long-handled shoe horn, etc.]?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

Questionnaire: Family
Target Group: ■ Head of CPS Family (Non-SP)
■ Head of CPS Family Spouse (Non-SP)

APPENDIX C

DEMOGRAPHIC QUESTIONNAIRE

BOX 1A

RULES FOR ADMINISTERING THE DEMOGRAPHIC AND OCCUPATION SECTION OF THE FAMILY QUESTIONNAIRE:

1. FOR THE PURPOSE OF ADMINISTERING THIS SECTION A SEPARATE "FAMILY" IS DEFINED AS THE 'NHANES FAMILY' AS DESCRIBED BELOW:

   GROUP 1

■ ■EITHER AN INDIVIDUAL HOUSEHOLDER OR PRIMARY FAMILY.

   ■ RELATED SUBFAMILY.

   ■ SECONDARY INDIVIDUALS WHO ARE RELATED TO ANYONE ABOVE AS A PARTNER.

   GROUP 2

   ■ UNRELATED SUBFAMILIES.

   ■ SECONDARY INDIVIDUALS WHO ARE RELATED TO THEM AS A PARTNER.

   GROUP 3

   ■ SECONDARY INDIVIDUALS WHO ARE NOT RELATED TO ANY INDIVIDUALS ABOVE.

   NOTE: FOSTER CHILDREN SHOULD BE CONSIDERED PART OF THE FOSTER PARENT'S FAMILY.

2. USING THE DEFINITION IN (1), ADMINISTER THE SECTION ONCE TO EACH GROUP (NHANES FAMILY) IF THERE IS AT LEAST 1 SP IN THE GROUP.

3. QUESTIONS SHOULD BE LOOPED THROUGH SEPARATELY FOR EACH CPS FAMILY WITHIN THE GROUP: HOUSEHOLDER, PRIMARY FAMILY, RELATED SUBFAMILY, UNRELATED SUBFAMILY AND SECONDARY INDIVIDUAL.

BOX 1

LOOP 1:
ASK DMQ.110 - DMQ.140 AS APPROPRIATE FOR NON-SP HEAD OF CPS FAMILY AND NON-SP SPOUSE (RELATIONSHIP OF "MARRIED" IN THE SCREENER) OF HEAD OF CPS FAMILY.

- FIRST ASK DMQ.110, 130, AND 140 FOR NON-SP HEAD OF CPS FAMILY.
- NEXT, ASK DMQ.140 FOR NON-SP SPOUSE OF HEAD OF CPS FAMILY.
- EACH TARGET PERSON SHOULD BE ASKED THIS SECTION ONCE.
- IF NO NON-SP HEAD OF CPS FAMILY AND NON-SP SPOUSE, GO TO END OF SECTION.

DMQ.110 In what country {were you/was NON-SP Head} born?

_____
ENTER COUNTRY NAME

REFUSED 7
DON'T KNOW 9

CAPI INSTRUCTION:
FOLLOW THE BASIC FORMAT FOR DIETARY SUPPLEMENT LOOKUP. ONLY ALLOW ENTRY OF 1 COUNTRY. COUNTRY LOOKUP IN SP AND FAMILY QUESTIONNAIRES SHOULD WORK EXACTLY THE SAME.

DMQ.115 PRESS BACKSPACE KEY TO START THE LOOKUP.
SELECT COUNTRY FROM CAPI COUNTRY LIST.
IF COUNTRY **NOT** ON LIST --
PRESS BACKSPACE KEY TO DELETE ENTRY
THEN TYPE '**' AND SELECT '** COUNTRY NOT ON LIST'.
PRESS ENTER TO ACCEPT SELECTION.

CAPI INSTRUCTION:
DISPLAY FIPS COUNTRY LIST. INTERVIEWER SHOULD ONLY BE ABLE TO SELECT 1 COUNTRY FROM THE LIST OR USE THE '**' OPTION TO ACCEPT THE ENTRY THEY KEYED. REFUSED AND DON'T KNOW OPTIONS SHOULD BE AVAILABLE TO THE INTERVIEWER AS THE F6 AND F5 KEYS.

BOX 2

CHECK ITEM DMQ.120:
IF ANY CODE OTHER THAN 'UNITED STATES', SKIP TO DMQ.140.

DMQ.130 In what state {were you/was NON-SP HEAD} born?

ENTER 2 LETTER STATE ABBREVIATION TO START THE LOOKUP.
SELECT STATE FROM CAPI STATE LIST.
PRESS ENTER TO ACCEPT SELECTION.

CAPI INSTRUCTION:
DISPLAY FIPS STATE LIST. INTERVIEWER SHOULD ONLY BE ABLE TO SELECT 1 STATE FROM THE LIST. DON'T KNOW AND REFUSED SHOULD BE VALID OPTIONS. THE STATE LOOKUP IN THE SP AND FAMILY QUESTIONNAIRES SHOULD WORK EXACTLY THE SAME.

DMQ.140 What is the **highest** grade or level of school {you have/NON-SP HEAD/NON-SP SPOUSE has} **completed** or the **highest degree** {you have/he/she has} **received**?

ENTER HIGHEST LEVEL OF SCHOOL.

NEVER ATTENDED/KINDERGARTEN ONLY	0
1ST GRADE	1
2ND GRADE	2
3RD GRADE	3
4TH GRADE	4
5TH GRADE	5
6TH GRADE	6
7TH GRADE	7
8TH GRADE	8
9TH GRADE	9
10TH GRADE	10
11TH GRADE	11
12TH GRADE, NO DIPLOMA	12
HIGH SCHOOL GRADUATE	13
GED OR EQUIVALENT	14
SOME COLLEGE, NO DEGREE	15
ASSOCIATE DEGREE: OCCUPATIONAL, TECHNICAL, OR VOCATIONAL PROGRAM	16
ASSOCIATE DEGREE: ACADEMIC PROGRAM	17
BACHELOR'S DEGREE (EXAMPLE: BA, AB, BS, BBA)	18
MASTER'S DEGREE (EXAMPLE: MA, MS, MEng, MEd, MBA)	19
PROFESSIONAL SCHOOL DEGREE (EXAMPLE: MD, DDS, DVM, JD)	20
DOCTORAL DEGREE (EXAMPLE: PhD, EdD)	21
REFUSED	77
DON'T KNOW	99

BOX 3

END LOOP 1:
- ASK DMQ.110-140 FOR NEXT TARGET PERSON (NON-SP HEAD)
  ASK DMQ.140 FOR NEXT TARGET PERSON (NON-SP SPOUSE – RELATIONSHIP OF "MARRIED" IN THE SCREENER).

IF NO NEXT PERSON, GO TO BOX 4.

BOX 4

LOOP 2:
ASK OCQ.150 - OCQ.380 FOR NON-SP HEAD IF AGE >= 16 AND NON-SP SPOUSE (RELATIONSHIP OF 'MARRIED' IN THE SCREENER) OF HEAD IF NON-SP SPOUSE AGE >= 16.

OCQ.150 The next questions are about {your/NON-SP HEAD'S/NON-SP SPOUSE'S} current job or business. Which of the following {were you/was} {NON-SP HEAD/NON-SP SPOUSE} doing **last week** . . .

working at a job or business, ...	1	(OCQ.220)
with a job or business but not at work, ...	2	
looking for work, or	3	
not working at a job or business?	4	(OCQ.380)
REFUSED	7	
DON'T KNOW	9	

OCQ.160 Did {you/NON-SP HEAD/NON-SP SPOUSE} do **any** work at a job or business at all **last week** (include unpaid work in a family farm or business)?

YES	1	
NO	2	
REFUSED	7	(OCQ.380)
DON'T KNOW	9	(OCQ.380)

BOX 5

CHECK ITEM DMQ.170:
IF OCQ.150 IS CODED '2', CONTINUE.
OTHERWISE, GO TO BOX 7.

OCQ.220 For whom did {you/NON-SP HEAD/NON-SP SPOUSE} work at {your/his/her} main job or business? (What is the name of the company, business, organization or employer?)

IF MORE THAN 1 JOB, PROBE FOR **MAIN** JOB.

_____
ENTER NAME OF EMPLOYER

REFUSED	7
DON'T KNOW	9

OCQ.230 What kind of business or industry is this? (For example: TV and radio management, retail shoe store, state labor department, farm.)

_____
ENTER NAME OF BUSINESS, JOB OR INDUSTRY

REFUSED	7
DON'T KNOW	9

OCQ.240 What kind of work {were/was} {you/NON-SP HEAD/NON-SP SPOUSE} doing? (For example: farming, mail clerk, computer specialist.)

_____
ENTER NAME OF OCCUPATION

REFUSED	7
DON'T KNOW	9

OCQ.250 What {were/was} {your/NON-SP HEAD'S/NON-SP SPOUSE'S} most important activities on this job or business? (For example: sells cars, keeps account books, operates printing press.)

_____
ENTER NAME OF DUTIES

REFUSED 7
DON'T KNOW 9

OCQ.260 Looking at the card, which of these **best** describes this job or work situation?

ASK IF NOT CLEAR

HAND CARD DMQ1

AN EMPLOYEE OF A **PRIVATE** COMPANY, BUSINESS, OR INDIVIDUAL FOR WAGES, SALARY, OR COMMISSION 1
A **FEDERAL** GOVERNMENT EMPLOYEE . 2
A **STATE** GOVERNMENT EMPLOYEE . . . 3
A **LOCAL** GOVERNMENT EMPLOYEE . . . 4
SELF-EMPLOYED IN **OWN** BUSINESS, PROFESSIONAL PRACTICE OR FARM . 5
WORKING **WITHOUT PAY** IN FAMILY BUSINESS OR FARM 6
REFUSED 7
DON'T KNOW 9

BOX 6

CHECK ITEM DMQ.270:
GO TO BOX 7.

OCQ.380 What is the **main** reason {you/NON-SP HEAD/NON-SP SPOUSE} did not work **last week**?

TAKING CARE OF HOUSE OR FAMILY . . 1
GOING TO SCHOOL 2
RETIRED 3
UNABLE TO WORK FOR HEALTH REASONS 4
ON LAYOFF 5
DISABLED 6
OTHER 7
REFUSED 77
DON'T KNOW 99

BOX 7

END LOOP 2:
ASK OCQ.150 - OCQ.380 FOR NEXT TARGET PERSON (NON-SP HEAD OR NON-SP SPOUSE - RELATIONSHIP OF "MARRIED" IN THE SCREENER).
IF NO NEXT PERSON, GO TO END OF SECTION.

APPENDIX D

MEDICAL CONDITION QUESTIONNAIRE

MCQ.010 Has a doctor or other health professional **ever** told {you/SP} that {you have/s/he/SP has} asthma?

CAPI INSTRUCTION:
IF SP AGE >= 12, DISPLAY SP NAME AND "S/HE":
IF SP AGE < 12, DISPLAY "YOU" AND SP NAME.

YES	1	
NO	2	(MCQ.053)
REFUSED	7	(MCQ.053)
DON'T KNOW	9	(MCQ.053)

BOX 1

CHECK ITEM MCQ.015:
IF SP'S AGE <= 19, CONTINUE.
OTHERWISE, GO TO MCQ.040.

MCQ.020 How old {were you/was SP} when {you were/s/he was} **first** told {he/she} had asthma?

IF LESS THAN 1 YEAR, ENTER 1

CAPI INSTRUCTION:
IF SP AGE >= 16, DISPLAY "WERE YOU" AND "YOU WERE".
IF SP AGE = 12-15, DISPLAY "WAS {SP}" AND "S/HE WAS".
IF SP AGE < 12, DISPLAY "WAS {SP}" AND "YOU WERE".

|___|___|___|
ENTER AGE IN YEARS

REFUSED	777
DON'T KNOW	999

MCQ.030 {Do you/Does SP} still have asthma?

YES	1	
NO	2	(MCQ.053)
REFUSED	7	(MCQ.053)
DON'T KNOW	9	(MCQ.053)

MCQ.040 During the **past 12 months**, {have you/has SP} had an episode of asthma or an asthma attack?

YES	1	
NO	2	(MCQ.053)
REFUSED	7	(MCQ.053)

DON'T KNOW 9 (MCQ.053)

MCQ.050 [During the **past 12 months**], {have you/has SP} had to visit an emergency room or urgent care center because of asthma?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

MCQ.053 During the **past 3 months**, {have you/has SP} been on treatment for anemia, sometimes called "tired blood" or "low blood"? [Include diet, iron pills, iron shots, transfusions as treatment.]

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

BOX 2

CHECK ITEM MCQ.055:
IF SP AGE < 2, GO TO MCQ.114.
IF SP AGE 2-3, GO TO MCQ.080.
IF SP AGE 4-19, CONTINUE.
IF SP AGE >= 20, GO TO MCQ.092.

MCQ.060 Has a doctor or health professional **ever** told {you/SP} that {you/s/he/SP} had attention deficit disorder?

CAPI INSTRUCTION:
IF SP AGE >= 16, DISPLAY "YOU" AND "YOU".
IF SP AGE = 12-15, DISPLAY SP NAME AND "S/HE".
IF SP AGE < 12, DISPLAY "YOU" AND SP NAME.

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

MCQ.080 Has a doctor or health professional **ever** told {you/SP} that {you were/s/he/SP was} overweight?

CAPI INSTRUCTION:
IF SP AGE >= 16, DISPLAY "YOU" AND "YOU WERE".
IF SP AGE = 12-15, DISPLAY SP NAME AND "S/HE".
IF SP AGE < 12, DISPLAY "YOU" AND SP NAME.

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

BOX 2A

CHECK ITEM MCQ.081:
IF SP'S AGE = 4-15, CONTINUE.
IF SP AGE >= 16, GO TO MCQ.090.
OTHERWISE, GO TO MCQ.114.

MCQ.083 Has a representative from a school or a health professional **ever** told {you/SP} that {s/he/SP} had a learning disability?

CAPI INSTRUCTION:
IF SP AGE >= 12, DISPLAY SP NAME AND "S/HE".
IF SP AGE < 12, DISPLAY "YOU" AND SP NAME.

YES	1	
NO	2	
REFUSED	7	
DON'T KNOW	9	

BOX 3

CHECK ITEM MCQ.085:
IF SP'S AGE >= 6, CONTINUE.
OTHERWISE, GO TO MCQ.114.

MCQ.090 {Have you/Has SP} **ever** had chickenpox?

YES	1	
NO	2	
REFUSED	7	
DON'T KNOW	9	

MCQ.092 {Have you/Has SP} **ever** received a blood transfusion?

YES	1	
NO	2	(BOX 4)
REFUSED	7	(BOX 4)
DON'T KNOW	9	(BOX 4)

MCQ.093 In what year did {you/SP} receive {your/his/her} **first** transfusion?

|___|___|___|___|
ENTER 4-DIGIT YEAR

BOX 4

CHECK ITEM MCQ.095:
IF SP'S AGE = 8-15, CONTINUE
IF SP'S AGE >= 20, GO TO MCQ.140.
OTHERWISE, GO TO MCQ.120.

MCQ.100 Has a doctor or health professional **ever** told {SP} that {s/he} had hypertension, also called high blood pressure?

YES	1	
NO	2	(MCQ.120)
REFUSED	7	(MCQ.120)
DON'T KNOW	9	(MCQ.120)

MCQ.110 Because of {SP's} high blood pressure [hypertension], is {he/she} currently taking medicine?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

BOX 5

CHECK ITEM MCQ.112:
IF SP'S AGE >= 6, GO TO MCQ.120
OTHERWISE, CONTINUE

MCQ.114 Has {SP} **ever** been tested for lead poisoning?

YES	1	
NO	2	(MCQ.120)
REFUSED	7	(MCQ.120)
DON'T KNOW	9	(MCQ.120)

MCQ.117 How long has it been since {SP} was tested?

IF LESS THAN 1 MONTH, ENTER 1 MONTH

|___|___|
ENTER NUMBER (OF MONTHS OR YEARS)

REFUSED	77
DON'T KNOW	99

ENTER UNIT

MONTHS	1
YEARS	2
REFUSED	7
DON'T KNOW	9

MCQ.120 During the **past 12 months**, {have you/has SP} had . . .

CAPI INSTRUCTIONS:
DISPLAY ITEMS A AND B IF SP AGE <= 3.
DISPLAY ALL ITEMS (A, B, C AND D) IF SP AGE = 4-15.
DISPLAY ITEMS A AND C IF SP AGE >= 16.

RESPONSES: YES = 1, NO = 2, REFUSED = 7, DON'T KNOW = 9.

a. hay fever? ____
b. 3 or more ear infections? ____
c. frequent or severe headaches, including migraines? ____
d. stuttering or stammering? ____

BOX 6

CHECK ITEM MCQ.135:
IF SP'S AGE >= 2, CONTINUE.
OTHERWISE, GO TO END OF SECTION.

MCQ.140 {Do you/Does SP} have trouble seeing, even when wearing glasses or contact lenses, if {you/he/she} wear{s} them?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

BOX 7

CHECK ITEM MCQ.145:
IF SP'S AGE 6-19, CONTINUE.
IF SP'S AGE >= 20, GO TO MCQ.160.
OTHERWISE, GO TO END OF SECTION.

BOX 7A

CHECK ITEM MCQ.146:
IF SP AGE 8-11 AND SP IS FEMALE, CONTINUE.
OTHERWISE, GO TO MCQ.150.

MCQ.147 Have {SP's} periods or menstrual cycles started yet?

YES 1
NO 2 (MCQ.150)
REFUSED 7 (MCQ.150)
DON'T KNOW 9 (MCQ.150)

MCQ.148 How old was {SP} when her periods or menstrual cycles started?

|___|___|
ENTER AGE IN YEARS

REFUSED 7
DON'T KNOW 9

MCQ.150 During the **past 12 months**, that is, since {DISPLAY CURRENT MONTH} of {DISPLAY LAST YEAR}, about how many days did {you/SP} miss school because of an illness or injury?

IF NONE, ENTER 0

|___|___|___|
ENTER NUMBER OF DAYS

DID NOT GO TO SCHOOL 666
REFUSED 777
DON'T KNOW 999

BOX 8

CHECK ITEM MCQ.155:
IF SP AGE >= 16, GO TO MCQ.245.
OTHERWISE, GO TO END OF SECTION.

MCQ.160 Has a doctor or other health professional **ever** told {you/SP} that {you/s/he} . . . CAPI INSTRUCTION: TEXT OF QUESTION SHOULD BE OPTIONAL AFTER FIRST ITEM IS READ.	MCQ.170 {Do you/Does SP} still . . . ?	MCQ.180 How old {were you/was SP} when {you were/s/he was} **first** told {you/s/he} . . .	MCQ.190 Which type of arthritis was it?
a. **had arthritis**? YES . . . . . 1 NO . . . . . 2 (b) REFUSED . . . . . 7 (b) DON'T KNOW . . 9 (b)		had arthritis? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	RHEUMATOID ARTHRITIS . . . . . 1 OSTEOARTHRITIS . . . . . 2 OTHER . . . . . 3 REFUSED . . . . . 7 DON'T KNOW 9
b. **had congestive heart failure**? YES . . . . . 1 NO . . . . . 2 (c) REFUSED . . . . . 7 (c) DON'T KNOW . . 9 (c)		had congestive heart failure? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
c. **had coronary heart disease**? YES . . . . . 1 NO . . . . . 2 (d) REFUSED . . . . . 7 (d) DON'T KNOW . . 9 (d)		had coronary heart disease? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
d. **had angina, also called angina pectoris**? YES . . . . . 1 NO . . . . . 2 (e) REFUSED . . . . . 7 (e) DON'T KNOW . . 9 (e)		had angina, also called agina pectoris? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
e. **had a heart attack (also called myocardial infarction)**? YES . . . . . 1 NO . . . . . 2 (f) REFUSED . . . . . 7 (f) DON'T KNOW . . 9 (f)		had a heart attack (also called myocardial infarction)? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	

f. **had a stroke**? YES . . . . . 1 NO . . . . . 2 (g) REFUSED . . . . . 7 (g) DON'T KNOW . . 9 (g)		had a stroke? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
g. **had emphysema**? YES . . . . . 1 NO . . . . . 2 (h) REFUSED . . . . . 7 (h) DON'T KNOW . . 9 (h)		had emphysema? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
h. **had a goiter**? YES . . . . . 1 NO . . . . . 2 (i) REFUSED . . . . . 7 (i) DON'T KNOW . . 9 (i)	have a goiter? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	had a goiter? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
i. **had another thyroid disease**? YES . . . . . 1 NO . . . . . 2 (j) REFUSED . . . . . 7 (j) DON'T KNOW . . 9 (j)	have another thyroid disease? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	had another thyroid disease? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
j. **was overweight**? YES . . . . . 1 NO . . . . . 2 (k) REFUSED . . . . . 7 (k) DON'T KNOW . . 9 (k)			
k. **had chronic bronchitis**? YES . . . . . 1 NO . . . . . 2 (m) REFUSED . . . . . 7 (m) DON'T KNOW . . 9 (m)	have chronic bronchitis? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	had chronic bronchitis? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	
l. **had any kind of liver condition**? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	have this liver condition? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	had this liver condition? |___|___|___| ENTER AGE IN YEARS REFUSED . . . . . 777 DON'T KNOW 999	

MCQ.200 {Have you/Has SP} **ever** been told by a doctor or other health professional that {you/s/he} had an ulcer, this could be a stomach, duodenal or peptic ulcer?

YES	1	
NO	2	(MCQ.220)
REFUSED	7	(MCQ.220)
DON'T KNOW	9	(MCQ.220)

MCQ.210 During the **past 12 months** {have you/has SP} had an ulcer?

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

MCQ.220 {Have you/Has SP} **ever** been told by a doctor or other health professional that {you/s/he} had cancer or a malignancy of any kind?

YES	1	
NO	2	(MCQ.245)
REFUSED	7	(MCQ.245)
DON'T KNOW	9	(MCQ.245)

MCQ.230 What kind of cancer was it?

ENTER UP TO 3 KINDS. IF RESPONDENT OFFERS MORE THAN 3, ENTER 66 AS THE 4TH RESPONSE.

CAPI INSTRUCTIONS:
ALLOW UP TO 3 ENTRIES.
ALLOW 'MORE THAN 3 KINDS (CODE 66) ONLY AS 4TH ENTRY.

( ) ( ) ( ) ( )

BLADDER 10	LEUKEMIA 21	SKIN (NON-MELANOMA) 32
BLOOD 11	LIVER 22	SKIN (DON'T KNOW WHAT KIND) 33
BONE 12	LUNG 23	SOFT TISSUE (MUSCLE OR FAT) 34
BRAIN 13	LYMPHOMA/HODGKINS' DISEASE 24	STOMACH 35
BREAST 14	MELANOMA 25	TESTIS (TESTICULAR) 36
CERVIX (CERVICAL) 15	MOUTH/TONGUE/LIP 26	THYROID 37
COLON 16	NERVOUS SYSTEM 27	UTERUS (UTERINE) 38
ESOPHAGUS (ESOPHAGEAL) 17	OVARY (OVARIAN) 28	OTHER 39
GALLBLADDER 18	PANCREAS (PANCREATIC) 29	MORE THAN 3 KINDS 66
KIDNEY 19	PROSTATE 30	REFUSED 77
LARYNX/WINDPIPE 20	RECTUM (RECTAL) 31	DON'T KNOW 99

BOX 9

LOOP 1:
ASK MCQ.240 FOR EACH TYPE OF CANCER (CODES 10-39 AND CODE 99) ENTERED IN MCQ.230.

MCQ.240 How old {were you/was SP} when {TYPE OF CANCER/cancer} was **first** diagnosed?

CAPI INSTRUCTIONS:
DISPLAY TYPE OF CANCER (CODE 10-39) ENTERED IN MCQ.230.
DISPLAY "CANCER " IF DON'T KNOW ENTERED IN MCQ.230.

|___|___|___|
ENTER AGE IN YEARS

REFUSED 777
DON'T KNOW 999

BOX 9A

END LOOP 1:
ASK MCQ.240 FOR NEXT TYPE OF CANCER (CODES 10-39 AND CODE 99) ENTERED IN MCQ.230.
IF NO NEXT TYPE, CONTINUE WITH MCQ.245.

MCQ.245 During the **past 12 months**, that is since {DISPLAY CURRENT MONTH} of last year, about how many days did {you/SP} miss work at a job or business because of an illness or injury {do not include maternity leave}?

CAPI INSTRUCTION:
DISPLAY "DO NOT INCLUDE MATERNITY LEAVE" ONLY IF SP IS FEMALE.

|___|___|___|
ENTER NUMBER OF DAYS

DOES NOT WORK 666
REFUSED 777
DON'T KNOW 999

BOX 10

CHECK ITEM MCQ.247:
IF SP AGE >= 20, CONTINUE.
OTHERWISE, GO TO END OF SECTION.

MCQ.250 Including living and deceased, **were any of {SP's/ your} biological** that is, blood **relatives** including grandparents, parents, brothers, sisters **ever told by a health professional that they had** . . . CAPI INSTRUCTION: TEXT OF QUESTION SHOULD BE OPTIONAL, "[ ]'S, AFTER FIRST TIME.	MCQ.260 Which biological [blood] family member? CODE ALL THAT APPLY
a. **diabetes**? YES . . . . . 1 NO . . . . . 2 (b) REFUSED . . . . . 7 (b) DON'T KNOW . . 9 (b)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99
b. **Alzheimer's disease**? YES . . . . . 1 NO . . . . . 2 (c) REFUSED . . . . . 7 (c) DON'T KNOW . . 9 (c)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99
c. **asthma**? YES . . . . . 1 NO . . . . . 2 (d) REFUSED . . . . . 7 (d) DON'T KNOW . . 9 (d)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99
d. **arthritis**? YES . . . . . 1 NO . . . . . 2 (e) REFUSED . . . . . 7 (e) DON'T KNOW . . 9 (e)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99

e. **osteoporosis or brittle bones**? YES . . . . . 1 NO . . . . . 2 (f) REFUSED . . . . . 7 (f) DON'T KNOW . . 9 (f)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99
f. **high blood pressure or stroke before the age of 50**? YES . . . . . 1 NO . . . . . 2 (g) REFUSED . . . . . 7 (g) DON'T KNOW . . 9 (g)	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99
g. **heart attack or angina before the age of 50**? YES . . . . . 1 NO . . . . . 2 REFUSED . . . . . 7 DON'T KNOW . . 9	MOTHER . . . . . 1 FATHER . . . . . 2 MOTHER'S MOTHER . . . . . 3 MOTHER'S FATHER . . . . . 4 FATHER'S MOTHER . . . . . 5 FATHER'S FATHER . . . . . 6 BROTHER . . . . . 7 SISTER . . . . . 8 OTHER . . . . . 9 REFUSED . . . . . 77 DON'T KNOW 99

MCQ.270 Did {your/SP's} biological mother **ever** fracture her hip?

YES 1
NO . . . . . 2 (END OF SECTION)
REFUSED . . . . . 7 (END OF SECTION)
DON'T KNOW . . . . . 9 (END OF SECTION)

MCQ.280 About how old was she when she fractured her hip (the **first** time)?

|___|___|___| (END OF SECTION)
ENTER AGE IN YEARS

REFUSED 777
DON'T KNOW 999

MCQ.290 Was she. . . .

under 50 years old, or 1
50 years old or older? 2
REFUSED 7
DON'T KNOW 9

APPENDIX E
STEPS FOR TABLE 4.8 CALCULATIONS

The higher the functional capacity score, the higher the functional capacity.

No PAD Group equation:
FC = 0 +9.904 (male) –coef (age) + coef (abi) = 9.904

PAD Group equation:
FC = 0.188 + 4.795 (male) –coef (age) + coef (abi)= 4.983

No PAD-PAD difference, males:
9.904 – 4.983= 4.921

No PAD Group equation:
FP = 0+ -0.362 (male) –coef (age) + coef (abi) = -0.362
PAD Group equation:
FP = 0.782 + -0.453 (male) - coef (age) + coef (abi) = -0.329
The No PAD-PAD group difference, males:
-0.362 - -0.329 = -0.033

FP:
The higher the functional performance score, the worse the functional performance.
The difference in functional performance between males and females is larger in the PAD group than the non-PAD group.

APPENDIX F STEPS FOR

TABLE 4.9 CALCULATIONS

Group No PAD:
FC intercept set to zero (default)
FP intercept set to zero (default)

FL for Age free to vary for FC (-0.454)
FL for Age free to vary for FP (0.070)

Group PAD:
FC intercept free to vary (-16.925)
FP intercept free to vary (-2.354)
FL for age free to vary for FC (-0.231)
FL for age free to vary for FP (0.114)

Calculations:
No PAD= 0 + fl*AGE
PAD= -16.925+ fl*AGE

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