TESTING A MODEL OF HEALTH-RELATED QUALITY OF LIFE IN WOMEN LIVING WITH HIV

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Testing a Model of Health-Related Quality of Life in Women Living with HIV Infection

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The diagnosis of HIV infection in women may adversely affect their health and their health-related quality of life (HRQoL). At present, research about women living with HIV infection and the multiple factors that contribute to their HRQoL is limited. The purpose of this study was to test the revised model of HRQoL by Wilson and Cleary (Ferrans et al., 2005) using a secondary analysis of baseline data from 178 women who participated in two independent randomized controlled studies. This linear model includes inter-related components (biological function, symptoms, functional status, and general health perceptions) which lead ultimately to HRQoL. The primary aim was to examine the relationships among the five components of the model. The secondary aim was to examine the relationships among the individual (i.e. age, children, race, marital status, education) and environmental (i.e. HIV-related stigma, social support) characteristics that may impact biological function, symptoms, functional status, general health perceptions, and overall HRQoL among women living with HIV infection. Observed variables included: biological function (CD4 count and viral load), symptoms (depressive symptoms and energy/fatigue), functional status (physical and social functioning), general health perceptions (overall general health and mental health), environmental factors (social support and HIV-related stigma), and HRQoL (satisfaction with life and overall quality of life). Structural equation modeling (SEM) and path analysis were performed on multiple path models to examine the hypothesized multivariate relationships proposed in the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). Originally, a latent path model was planned. Due to problems with the measurement model, the latent path model was simplified and observed and hybrid path models were created. While the two main models for the primary and secondary aims did not fit well, *post hoc* modified models adding a path from symptoms to general health perceptions provided an adequate model fit. Women with lower viral loads, lower depressive symptoms, lower HIV-related stigma, higher social support, higher physical functioning, and higher general health perceptions had higher overall HRQoL. The results of this study have the potential to

assist healthcare professionals in improving health-related quality of life for women living with HIV infection.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

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1.0 INTRODUCTION

An estimated 35.3 million people worldwide are currently living with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) (UNAIDS, 2013). Globally, HIV is a debilitating, difficult to manage, infectious disease which often results in AIDS, and then death. In 2013, 2.1 million people worldwide were newly diagnosed with HIV; 1.5 million people died from AIDS (World Health Organization, 2014a). In the United States, 1.2 million people are currently living with HIV/AIDS (Centers for Disease Control and Prevention [CDC], 2014a). In 2012, almost 50,000 people were newly diagnosed with HIV and in 2011 nearly 14,000 people died from AIDS, with a cumulative death toll of almost 650,000 people in the United States (US) since the start of the epidemic (CDC, 2014a; CDC, 2014b).

Worldwide, HIV is mainly transmitted through sexual intercourse and intravenous drug use. In 2012, 90 percent of people in the United States were infected through sexual intercourse and only 7 percent through intravenous drug use (CDC, 2014b). While men who exclusively have sex with men (MSM) are the largest risk group in the United States, comprising 47.1% of the total number of people living with HIV/AIDS, women who have sex with men (WSM) comprised 26.7% of the total number living with HIV/AIDS as of 2009 (Blair et al., 2014).

HIV/AIDS has become a chronic disorder due to medical advances, new drug therapies, and improved methods of care. By the end of 2013, 12.9 million people worldwide were receiving antiretroviral treatment (ART), with two million people with HIV/AIDS being newly enrolled in ART in 2013, a record-breaking year (WHO, 2014b). As of 2010, 363,000 people in

the United States were in treatment for HIV/AIDS, representing only 33% of the total number of people living with HIV in the United States (CDC, 2014b). Survival rates have dramatically improved with the widespread use of ART. Life expectancy has increased from 36.1 years in 2000-2002 to 51.4 years in 2006-2007 (Samji et al., 2013).

The fact that people with HIV/AIDS are living longer has led to a shift of classification of the infection from an acute disease to a chronic disorder (Hickner, 2014). Managing treatment for a chronic disorder can be burdensome and challenging. People living with HIV/AIDS have special needs associated with their diagnosis including needing constant treatment, living with its side effects, and getting long-term follow-up. While ART provides maintenance for the disease, it also has very high toxicity that might cause other health problems. Other challenges associated with living with HIV/AIDS include limited access to medical care in an overburdened health care system, financial considerations, HIV stigma, and mental health issues (Aranda-Naranjo, 2004; Chu & Selwyn, 2011; Deeks et al., 2013; Palmisano & Vella, 2011). Together these challenges have an impact on an individual's overall health-related quality of life (HRQoL).

According to the World Health Organization (WHO), quality of life (QoL) is defined as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (Herman et al., 1998, p. 1570). HRQoL "refers to how health impacts an individual's ability to function and his or her perceived well-being in physical, mental, and social domains of life" (Coons et al., 2000, p. 14). HRQoL is a more specific construct generally defined as a subjective evaluation of one's life along a number of dimensions relating to an individual's health (Herman et al., 1998). QoL and HRQoL are conceptually different, yet both aim to assess an individual's health and overall well- being. In the nursing and public health literature, QoL and HRQoL are used

interchangeably, oftentimes within the same studies. Therefore, QoL and HRQoL will be used interchangeably throughout this report.

Research examining HRQoL of persons across the continuum of HIV has primarily been limited to the evaluation of the effectiveness of medical and pharmacological treatments for HIV largely in men (Lorenz et al., 2001; Lubeck & Fries, 1997; Mrus et al., 2005). However, there is growing recognition that for persons (both men and women) with HIV, HRQoL is an important outcome in itself; predictors include psychological and social factors such as depressive symptoms, HIV stigma, and social support (Andrinopoulos et al., 2011) and physiological factors such as CD4 count and viral loads (Basavaraj et al., 2010).

1.1 SIGNIFICANCE OF THE PROBLEM: WOMEN, QUALITY OF LIFE, AND HIV

HIV/AIDS is the number one cause of death in women of reproductive age (Ribeiro, 2008). By the end of 2011, over 220,000 women in the US were living with HIV/AIDS (CDC, 2014a). The Center for Disease Control and Prevention (CDC) has estimated that women now represent about 25% of the total number of people living with HIV/AIDS (CDC, 2014a). The CDC has also reported that the majority of women (84%) who contract HIV do so through heterosexual contact (CDC, 2014a). Women are more susceptible to contracting HIV than men during unprotected vaginal sex (CDC, 2014c). Transmission of the infection from men to women during heterosexual intercourse is eight times more likely to occur than from women to men (Floridia et al, 2008). Additionally, women have different physical complications from HIV infection compared to men, such as vaginal yeast infections, pelvic inflammatory disease, and human papillomavirus (HPV) (NICHD, 2013).

Women also have different emotional complications from HIV, compared to men. Women are more likely to suffer from moderate to severe depression (Loutfy et al., 2013). Women living with HIV must also attempt to maintain support systems and manage HIV stigma. This can be difficult because of negative societal perceptions of individuals living with HIV. Understanding the effects of HIV on a woman's ability to maintain her functional status is imperative. Research has shown that women living with HIV have a lower overall HRQoL than men (Mrus et al., 2005; Vigneshwaran et al., 2013). Preserving a woman's self-image and HRQoL is critical.

Multiple factors impede women from receiving treatment for HIV and seeking the mental, emotional, psychological, and financial support of others (Clum et al., 2013). Women often balance multiple roles within the family, such as wife, mother, caregiver, and support to other family members (Edwards, Irving, & Hawkins, 2011). Children without a mother's emotional support may do poorly in school and exhibit emotional disturbance. Therefore, the impact of HIV on women can negatively affect family systems. Further, women who cannot fulfill responsibilities within the family and/or maintain independence can adversely affect both the family and societal economy with a decline in workforce productivity and an increased need for social services, such as disability benefits (Marini & Stebnicki, 2012). Thus, women living with HIV must be helped to manage their HIV in order to maintain and improve their HRQoL (Andrinopoulos et al., 2011). Current HIV research is beginning to focus more on women living with HIV/AIDS; however, researchers have a limited understanding of the various unique obstacles faced by women with this disease. Due to the lack of literature on the factors influencing the HRQoL of women living with HIV/AIDS, there is a need for more research specifically focused on women.

1.1.1 Model overview

Although some research has been conducted with women living with HIV in the US, there are limited findings that show a clear understanding of the factors that contribute to women's HRQoL. Multiple models have been constructed to explain HRQoL. Three examples include: Wilson and Cleary conceptual model of HRQoL (1995), revised Wilson and Cleary (Ferrans et al., 2005), and the World Health Organization International Classification of Functioning, Disability, and Health (WHO ICF) (2014) (Bakas et al., 2012).

The WHO ICF "provides a standard language and framework for the description of health and health-related states" (WHO, 2002, p. 2). This model was designed to measure the level of an individual's function in society as a whole, regardless of the reasons for an individual's disability. Originally created in 1980, the WHO ICF model has evolved to focus on the impact of health-related issues as opposed to the causes of disease (Bakas et al., 2012). The WHO ICF model is considered to be a "biopsychosocial model," combining both medical and social models of disability and therefore encompassing different aspects of health (e.g. biological, individual, and social) (WHO, 2002). The components in the WHO ICF model (represented in Figure 1) include: Body Functions and Structure, Activity, Participation, Environmental and Personal Factors (WHO, 2002).

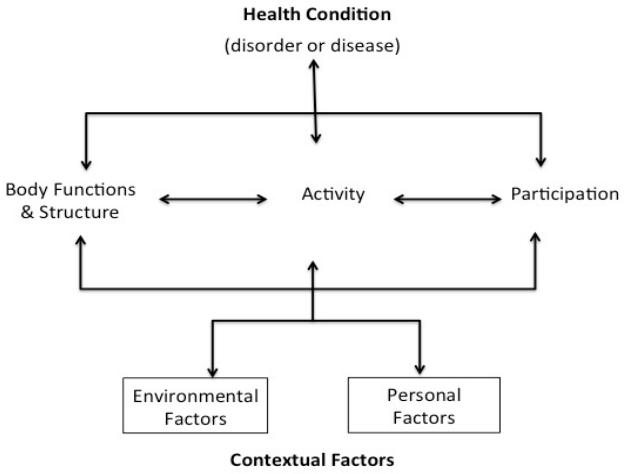

Figure 1. World Health Organization Model of International Classification of Functioning, Disability, and Health

Wilson and Cleary (1995) developed a model that combines health beliefs from the medical and social sciences and shows how various patient outcomes are related. This model explains an individual's HRQoL in terms of a number of components that are causally linked (represented in Figure 2). The components of the model include: Biological and Physiological Variables, Symptom Status, Functional Status, General Health Perceptions, Characteristics of the Individual, Characteristics of the Environment, Nonmedical Factors, and Overall QoL (Wilson & Cleary, 1995).

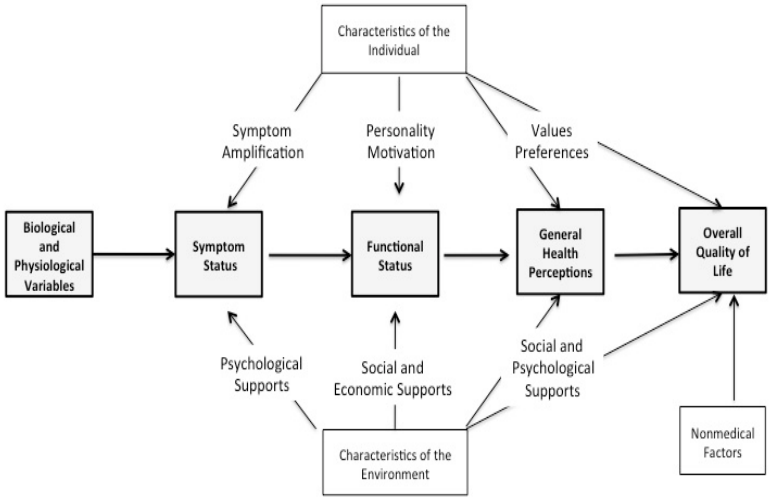

Figure 2. Wilson and Cleary Model of Quality of Life (1995)

Ferrans et al. (2005) created a revised version of the Wilson and Cleary (1995) model of HRQoL. Like the Wilson and Cleary (1995) model, Ferrans et al. (2005) proposed causal paths; however, the components of the model and their relationships are slightly different. In this revised model the components include: Biological Function, Symptoms, Functional Status, General Health Perceptions, Characteristics of the Individual, Characteristics of the Environment, and Overall QoL (represented in Figure 3). In this model, Wilson and Cleary's (1995) "Biological and Physiological Variables" were changed to "Biological Function" and the component "Nonmedical Factors" was removed. According to Ferrans et al. (2005), there was no need to include "Nonmedical Factors" as an independent component because these factors can be attributed to either individual or environmental characteristics. The name of the first component of the model was changed to "Biological Function" because "alterations in biological function directly or indirectly affect all components of health, including symptoms, function status, perception of health, and overall quality of life" (Ferrans et al., 2005, p. 338).

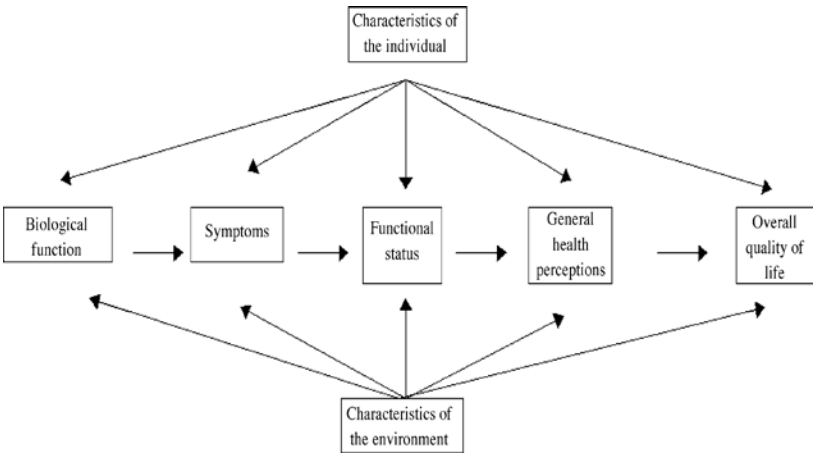

Figure 3. Revised Wilson and Cleary Model of Health-Related Quality of Life (Ferrans et al., 2005)

While all three models take into account various physical and psychological factors that influence an individual's HRQoL, each model expresses the components and their relationships differently. Wilson and Cleary (1995) failed to give examples of characteristics of the environment and individual. Ferrans et al. (2005), on the other hand, added to the Wilson and Cleary (1995) model by including detailed explanations of the environmental and individual constructs and incorporating "Nonmedical Factors" into these components. Another weakness of the Wilson and Cleary (1995) model is that individual and environmental characteristics do not contribute to "Biological and Physiological Variables," whereas both the revised Wilson and Cleary and the WHO ICF models clearly indicate these associations. In the WHO ICF model, "Environmental" and "Personal Factors" are linked with "Body Functions and Structure" (WHO, 2002). Ferrans et al. (2005) built upon the Wilson and Cleary (1995) model by acknowledging that the severity of disease is influenced by both individual and environmental characteristics and added paths to indicate these associations.

The conceptual framework of the WHO ICF is very flexible making the model translatable across many disciplines and applicable to people of different regions and cultures (WHO, 2002). The model can be used internationally, even for children and youth, and can easily be understood by heath care workers, researchers, policy-makers, and the public (WHO, 2002). While the WHO ICF is a broad model that can be applied to multiple health conditions, it is not specific to HRQoL as are the Wilson and Cleary (1995) model and the revised Wilson and Cleary model (Ferrans et al.,2005). The integration of biological and psychosocial factors and their effects on HRQoL is important in the context of HIV. HRQoL is the main outcome variable in both the Wilson and Cleary model (1995) and the revised Wilson and Cleary model (Ferrans et al., 2005), making these models superior to the WHO ICF for HRQoL focused HIV research. Although Wilson and Cleary's (1995) model provided the foundation, the revised model is a more current and useful model for assessing HRQoL in people living with HIV/AIDS.

Thus, the theoretical framework chosen for this study is based on the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). The model provides a direct causal path of the following: biological function, an assessment of symptoms, functional status, an individual's perception of her general health, and HRQoL as the outcome variable (Ferrans et al., 2005). According to Wilson and Cleary, the factors in the model can have inter-relationships "at every level of the model, although they are not represented in the Figure" (Wilson and Cleary, 1995, p. 63). This can also be said about the model by Ferrans et al. (2005) because the revised model adopted the same fundamental concepts as the original. Assessing these relationships as they pertain to women may provide insight into gender-specific challenges of people living with HIV. Further, findings have the potential to improve the health outcomes of this population. This study testing the revised model of Wilson and Cleary (Ferrans et al., 2005) is important because

it adds to the current knowledge and understanding of the basic components which affect the health status of women living with HIV.

1.2 PURPOSE OF THE STUDY

The overall purpose of this study was to test the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005) in order to better understand the components that influence HRQoL for women living with HIV. Examining this topic has created a novel conceptualization within HRQoL theory to improve patient-centered outcomes and care interventions for women living with HIV. This study was unique because it focused solely on women in the United States, a population that has been absent from much of the literature. The findings of this study have the potential to benefit women living with HIV/AIDS by serving as foundational evidence to create interventions to improve HRQoL for this population.

1.3 RESEARCH AIMS

1.3.1 Primary aim

The primary aim of this study was to examine the relationships among the five central components of the revised Wilson and Cleary (Ferrans et al., 2005) model (biological function, symptoms, functional status, general health status, overall quality of life).

1.3.2 Secondary aim

The secondary aim was to examine the relationships among the individual (i.e. age, children status, race, marital status, education) and environmental (i.e. HIV stigma, social support)

characteristics that may impact biological function, symptoms, functional status, general health perceptions, and overall quality of life among women living with HIV infection.

1.4 DEFINITION OF TERMS

1.4.1 HIV/AIDS

Human immunodeficiency virus (HIV) is an infection transmitted by an exchange of bodily fluids, such as blood, semen, and breast milk (CDC, 2015a). HIV attacks the immune system by destroying CD4 cells (i.e. T cells). As CD4 cells are compromised, the body can no longer fight off infection. Three stages of HIV have been identified: acute infection, clinical latency, and HIV-stage 3, also called acquired immunodeficiency syndrome (AIDS). Currently, there is no cure for HIV (CDC, 2014d).

1.4.2 Biological function

Biological function refers to the physical state of the individual (Wilson & Cleary, 1995; Ferrans et al., 2005) and includes any measurable descriptor used to classify the biological status. In HIV/AIDS biological function can be measured by CD4 cell count, viral load, and other clinical indicators that help to monitor the progression of HIV infection. Biological function, as a theoretical construct, was measured in this study by CD4 cell count and viral load.

1.4.3 Symptoms

Symptoms refers to the psychosocial, emotional, or cognitive state the individual is experiencing at the time of evaluation (Ferrans et al., 2005; Wilson & Cleary, 1995). Depressive symptoms and fatigue were selected to represent symptoms in this study.

1.4.4 Functional status

Functional status refers to an individual's ability to perform specific tasks (Ferrans et al., 2005; Wilson & Cleary, 1995). These tasks may include grocery shopping, keeping medical appointments, or balancing a checkbook. Physical functioning and social functioning were chosen to represent functional status in this study.

1.4.5 General health perceptions

General health perceptions describe an individual's perception of one's own health status based on the person's biological, symptom, and functional status (Ferrans et al., 2005; Wilson & Cleary, 1995). In this study, mental health as a construct follows the definition by Hays et al. (1995): mental health encompasses depression and emotional issues, anxiety, nervousness, and happiness/sadness. In this study general health and mental health were identified as the indicators of general health perceptions.

1.4.6 Overall quality of life

Overall QoL refers to how satisfied an individual is with life and is often used as an outcome in clinical trials (Ferrans et al., 2005; Wilson & Cleary, 1995). "Life satisfaction includes the individual's appraisal of dimensions that go beyond health and function and takes into consideration the individual's degree of happiness in relation to his or her beliefs, values, and needs in multiple life domains" (Eller & Mahat, 2007, p 19). QoL and satisfaction with life were selected to represent a subject's overall QoL.

1.4.7 Characteristics of the individual

Characteristics of the individual pertain to factors or correlates that contribute to defining a person's life situation (Ferrans et al., 2005). These include demographic descriptors. The characteristics of the individual for this study included age, children status, race, marital status, and education. These are factors which may impact biological function, symptoms, functional status, general health perceptions, and overall QoL.

1.4.8 Characteristics of the environment

Characteristics of the environment refer to factors outside of the individual which may impact biological function, symptom status, functional status, general health perceptions, and overall HRQoL. They address the individual's interactions with others as a member of society (Ferrans

et al., 2005). In this study, the characteristics of the environment that were examined were HIV-related stigma and social support.

2.0 LITERATURE REVIEW

This chapter reviews the literature and presents what is known about the relationships within the revised Wilson and Cleary model of health-related quality of life (HRQoL) (Ferrans et al., 2005) and about women living with HIV. Literature was searched using the NCBI (National Center for Biotechnology Information, a research tool of the National Library of Medicine at National Institutes for Health) to access the following databases: PMC (PubMed Central for life sciences journal literature), PsycInfo (literature of the American Psychological Association), and Pubmed (which includes the full content of MEDLINE for biomedical journal literature). The keywords used in the search included: quality of life, health-related quality of life, satisfaction with life, model of QoL, women and HIV, viral load, CD4 count, depressive symptoms, fatigue, pain, physical functioning, social functioning, mental health, overall health, social support, HIV stigma, age, children, education, marital status, and race. This chapter discusses factors influencing HRQoL, relationships within the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005), and factors affecting women living with HIV.

2.1 FACTORS AFFECTING WOMEN LIVING WITH HIV

HIV permeates multiple aspects of a person's life: physical, mental, and emotional (NINDS, 2014; Dalmida, 2006; Edwards, 2006). The literature about women living with HIV addresses a wide-range of topics from mother-to-child transmission of HIV (Walcott et al., 2012) to

medication adherence (Erlen et al., 2002), and includes women who are married and single. For example, married women attempting to manage their HIV reported less satisfaction with receiving support from their husbands (Edwards & Hawkins, 2011). Edwards and Hawkins (2011) found that married women neglected their own health regimen to take care of their HIV infected husbands. This literature review focuses on topics highly relevant to HRQoL of women living with HIV.

2.1.1 Disclosure

Disclosure is an integral part of the adjustment process of accepting and living with HIV and is a link to preventing the spread of HIV infection (Hult et al., 2012). Disclosure of HIV serostatus can be difficult for women. Many must consider the perceptions of intimate partners, friends, family, and the community once their HIV status becomes known (Clum et al., 2013; Nyblade et al., 2009; Swendeman et al. 2006). Serovich et al. (2012) found that in a sample of 125 women living with HIV, almost 50% of intimate partners and family members were told of the diagnosis within the first month of diagnosis. Nevertheless, the fear of disclosing their condition can prevent them from receiving medical assistance from healthcare professionals and receiving the psychological and financial support of others, which can in turn affect their HRQoL (Kalichman & Grebler, 2010; Serovich et al., 2012; Wolitski et al., 2009). In a longitudinal study with individuals newly diagnosed with HIV, Hult et al. (2012) interviewed 50 people (8% women) living with HIV/AIDS (PLWHA) and found that approaches to disclosure were affected by life context and that PLWHA perceived HIV disclosure as either a stressor or a stress-coping mechanism.

Challenges of disclosure also include maintaining privacy. Peterson (2010) interviewed 45 women living with HIV and reported that they were concerned that disclosing to family would mean that others would find out about their HIV status. They feared that family would not keep their diagnosis private. Nondisclosure can be problematic for women living with HIV, as disclosure is needed to access HIV health services and social support. Fear of stigma is a primary reason for nondisclosure, leading to multiple challenges for women attempting to manage HIV (Hult et al., 2010; Peterson, 2010).

2.1.2 Stigma

Stigma is most often defined as an "attribute that is deeply discrediting," reducing someone "from a whole and usual person to a tainted, discounted one" (Goffman, 1963, p. 3). In HIV health care, stigma is often intertwined with discrimination carried out by health care workers and manifested by differential treatment, denial of care, disclosure of HIV status without consent (to family members or others), verbal abuse, gossip, and neglect (Nyblade et al., 2009). Women with HIV must learn to manage such negative encounters.

In a sample of 183 participants, Colbert et al. (2010) found that women reported higher levels of stigma than men on all four subscales of Berger's HIV Stigma Scale: personalized stigma ($p < 0.001$), disclosure ($p = 0.001$), negative self-image ($p = 0.001$), and perceptions of public attitudes ($p < 0.001$). One reason for higher stigma in women is that stereotypes related to HIV differ by gender– women are labeled as promiscuous while men are labeled as homosexuals (Sayles et al., 2007). Stigma can marginalize a woman and hinder her from achieving her fullest potential. Perceived stigma can cause a woman to become mentally and emotionally paralyzed.

The threat of becoming socially marginalized, abandoned, and losing close partners can be overwhelming and can bring about low self-esteem (Sengupta et al., 2011).

In a qualitative study Peterson (2010) interviewed 45 women between 19 to 64 years old who were primarily African American (80%) and found that fear of stigma prevented them from seeking HIV information and social support. Moreover, isolation, depressive symptoms, and low medication adherence were identified as outcomes of perceived HIV stigma (USDHHS, 2012). As a result, women with HIV often avoid getting the treatment that they need (Peterson, 2010). When a woman perceives that she is being stigmatized, those feelings are often internalized (whether or not the stigma she experiences is actual or perceived) and can have a destructive effect (Sengupta et al., 2011). Furthermore, the woman does not seek the continued support necessary to successfully carry out the demanding HIV care regimen.

Although women living with HIV often feel stigmatized, many welcome and appreciate interactions with individuals and groups interested in their plight and the challenges that they face. In a pilot study involving 24 African American women, Rao et al. (2012) tested a new intervention through a workshop led by an HIV-positive African American woman. Subjects who participated in this peer-led workshop showed decreased levels of internalized stigma ($p = 0.05$) (Rao et al., 2012). This finding suggests that under comfortable circumstances, women can be helped to manage their disease and reduce perceived stigma.

As HIV progresses fulfilling work responsibilities becomes a challenge for women living with HIV (Webel & Higgins, 2012). Webel and Higgins (2012) interviewed 48 women living with HIV of whom only 20% were employed. One Caucasian participant reported that after disclosing her HIV serostatus to an employer, she was not fired but they made her "time there miserable" (Webel & Higgins, 2012, p. 7). Working women with HIV agreed that they

intentionally chose jobs that would allow them to avoid having to disclose their HIV serostatus. Multiple researchers have reported in their studies that the more than 50% of women with HIV were unemployed (Colbert et al., 2010; Messer et al., 2013; Psaros et al., 2012; Vyavarharkar et al., 2012; Webel & Higgins, 2012).

2.1.3 Mental Health

PLWHA are living longer because of highly active anti-retroviral therapy (HAART); nevertheless, they struggle with the physical and emotional challenges associated with the disease. For a sample of 914 men and women, 50 years or older, Grov et al. (2010) reported that in addition to HIV stigma, mental health issues such as major depressive symptoms and loneliness were interrelated, pervasive, and enduring components associated with living with HIV. However, this study did not find that women were more likely to have major depression than men (38.7% and 39.2%, respectively) (Grov et al., 2010). Walsh et al. (2012) examined the experiences, needs, and internet use of 20 women newly diagnosed with HIV using a telephone interview format. This study concluded that newly diagnosed women should be referred to mental health services early in their treatment as these researchers found that newly diagnosed women were more likely to perceive HIV stigma than those who had been living with HIV infection for a number of years. Early health care support could help to close the gap between new diagnoses and entry into health care treatment. Walsh et al. (2012) suggested that waiting for this population to acquire the level of coping skills and illness acceptance on their own would ultimately decrease their QoL because they are less likely to seek and stay in treatment.

Isolation, as a depressive symptom, is another major challenge with which women with HIV must contend (Grov et al., 2010). When a woman is diagnosed with HIV, the embarrassment and shame associated with this disease may cause her to lose touch with her friends and family. Because of depressive symptoms, an HIV infected woman will likely isolate herself from others, which will directly or indirectly affect family members, friends and coworkers (Hult et al., 2012). Another form of isolation comes with caretaking. In a qualitative study of five married HIV positive African American women, Edwards et al. (2011) found that women who assumed the responsibility of caretaker for their husbands felt isolated and sacrificed their own QoL to care for their sick spouses. In another qualitative study by Edwards (2006), 20 HIV positive African American women were interviewed in order to assess the effect of social support on medication adherence. Surprisingly, women with children reported that their kids were their main source of social support as opposed to being a burden.

2.1.4 Quality of Life

The literature addressing QoL of women living with HIV has increased in the last several years. However, there has been conflicting evidence when comparing QoL between men and women. Mrus et al. (2005) conducted a study designed to simultaneously assess gender differences and compare ART regimens. In this clinical trial, 202 females and 976 males in the United States and Puerto Rico were randomly assigned to a drug regimen, and their HRQoL was monitored at baseline, 24 weeks, and 40 weeks (Mrus et al., 2005). HRQoL was measured using the AIDS Clinical Trials Group (ACTG) QoL Survey, a modification of the Medical Outcomes Study. At

every time point, women expressed lower QoL than men on nearly every domain measured (Mrus et al., 2005). However, the only statistically significant domain was in mental health ($p = 0.046$) (Mrus et al., 2005). In contrast, Feinberg et al. (2011), using the Functional Assessment of HIV Infection (FAHI) survey to measure HRQoL in a randomized controlled trial of 193 women and 142 men from the United States, Canada and Puerto Rico, found that while women had slightly lower HRQoL scores than men at baseline (not statistically significant), they had greater improvement in HRQoL than men over the 48 week time period. . Further, in a cross-sectional study of 60 men and 60 women in rural India, Vigneshwaran et al. (2013) found using the MOS-HIV Health Survey that women scored lower than men on both overall HRQoL (women 43.6, men 54.6, $p < 0.0001$) and perceived QoL (women 43.8, men 65.4, $p < 0.0001$). These conflicting results may have been due to physiological and psychological factors unique to women that affect their QoL. Women are more susceptible than men to mental illness such as mood and anxiety disorders and depression which could lead to lower overall QoL (Linzer et al., 1996). Another explanation for these conflicting results might be that the researchers used different instruments to measure HRQoL.

2.2 FACTORS INFLUENCING HRQOL

The revised model of HRQoL by Wilson and Cleary (Ferrans et al., 2005) addresses five domains: biological function, symptom status, functional status, general health perception, and overall quality of life (see Figure 3). In addition, this model suggests that the environment and the individual characteristics (and circumstances) of a person exert a significant impact on one's HRQoL.

2.2.1 Biological function

Measurements of biological function are medical indicators of health. These measurements are "molecular, cellular, and whole organ level processes" (Ferrans et al., 2005, p. 338) including clinical data such as CD4 count, viral loads, and weight loss. Physiological factors are a patient's first indication of illness, measured and reported by his or her physician. Higher CD4 count and lower viral loads are good indicators for better health and are associated with higher general health status (Clingerman, 2003). Physiological factors such as disease progression, CD4 count, and viral load are not only clinical indications of disease severity, but also are associated with a patient's HRQoL (Basavaraj et al., 2010; Vyavaharkar et al., 2012). Higher CD4 count and lower viral loads have been associated with higher QoL (Ruiz-Perez et al., 2005; Armon et al., 2012). Women who had a CD4 count higher than 200 were more likely to have a higher QoL (McDonnell et al., 2000).

Baseline biological function has also predicted both positive changes (Lorenz et al, 2006) and negative changes (Feinberg et al., 2011) in QoL over time during drug treatment studies. In an 18-month longitudinal study assessing HIV treatment and HRQoL changes, Lorenz et al. (2006) analyzed 2267 data for men and women and found that patients with CD4 count over 200 had greater improvements in overall health. In this study, Lorenz et al. (2006) measured HRQoL using a single question: "How would you rate your quality of life, overall?" However, using data from the GRACE (Gender, Race, And Clinical Experience) study, Feinberg et al. (2011) found that lower baseline CD4 count predicted improvements in HRQoL. CD4 count was only measured at baseline.

Biological functions, such as disease progression, CD4 count, and viral load, play a role in a patient's physical and emotional symptoms in addition to HRQoL. Disease severity can lead to psychological complications such as depression, fear, and anxiety. Chronic depressive symptoms have been associated with lower CD4 cell count and higher mortality rates (Ickovics et al., 2001).

2.2.2 Symptoms

Symptoms are the expression of a disease on a patient's physiological and psychological status. According to Ferrans et al. (2005), symptom status most commonly refers to "frequency, intensity, and distress" (p. 339). Symptoms can be either physical or mental. Physical symptoms include but are not limited to fatigue and pain. Fatigue is "tiredness that is unrelieved by a full night of sleep" (Jenkin et al., 2006, p 1124). Psychological symptoms include but are not limited to fear, worry, and depression. Vance et al. (2010) found that there are higher levels of depression among people living with HIV than in the general population.

HIV-related symptoms, both mental and physical, contribute to a lower QoL (Basavaraj et al., 2010; Phaladze et al., 2005; Vyavaharkar et al., 2012). In a study of 743 men and women in sub-Saharan Africa, patients who expressed more severe HIV-related symptom intensity (measured by the Revised Sign and Symptom Checklist for Persons with HIV Disease) had lower overall satisfaction with life ($p = 0.01$) (Phaladze et al., 2005). In the aforementioned longitudinal study by Lorenz et al. (2006), participants who had fewer total symptoms ($p < 0.001$) and higher overall QoL ($p < 0.001$) at baseline had higher QoL at the end of the study. In

the same study, patients who had worsening symptoms over time showed significant decreases in overall health ($p < 0.001$) and QoL ($p < 0.001$) (Lorenz et al., 2006).

Patients with higher levels of depressive symptoms (Andrinopoulos et al., 2011; Vyavaharkar et al., 2012) and symptom intensity (Phaladze et al., 2005) had lower baseline QoL and also showed a decrease in QoL over time (Lorenz et al., 2006). In a cross-sectional study conducted by Vyavaharkar et al. (2012) on 399 women from the rural southeastern United States, depressive symptoms were associated with lower levels of QoL ($r = -0.34$, $p < 0.05$). In a longitudinal study of 179 young women (ages 15 to 24 years), Andrinopoulos et al. (2011) found that the occurrence of serious clinical depression was associated with lower levels of satisfaction with life ($p < 0.001$). People who suffered from depression were also found to have higher fatigue (Barroso et al., 2013; Voss, 2005).

HIV-related symptoms can prevent women living with HIV/AIDS from participating in their daily activities and social engagements. Researchers have shown that patients who experience fatigue (Barroso et al., 2010) or physical limitations (McReynolds, 1998) were more prone to depressive symptoms. Women with lower physical ($r = -0.44$, $p < 0.01$) and lower social ($r = -0.61$, $p <0.01$) functioning had higher levels of depression (Eller & Mahat, 2007). White et al. (2012) also found that less physical functioning was associated with more depression. In the same study, participants with higher physical functioning and better problem solving showed signs of lower depression (White et al., 2012).

2.2.3 Functional Status

Functional status is one's ability to participate in day-to-day activities. According to Wilson and Cleary (1995), there are four domains of functional status: "physical function, social function, role function, and psychological function" (p. 61). Functional status includes physical activity, energy levels, and performance of everyday tasks. Higher levels of functioning indicate better overall general health.

Physical functioning refers to everyday physical activities, while social functioning represents everyday social activities. According to Basavaraj et al., "many people living with HIV/AIDS find it challenging to attend to daily tasks of living, participate in moderate to vigorous physical activities, or have sufficient energy or vitality to engage in an active social life while managing HIV/AIDS" (2010, p. 76). People living with HIV, who had better overall functioning (Phaladze et al., 2005), and who participated in frequent physical activity ($r = 0.49$, $p < 0.01$) (Clingerman, 2004), had a higher overall QoL than their less active counterparts. In a study of 98 HIV-positive Nepali women, both social functioning ($r = 0.47$, $p < 0.01$) and physical functioning ($r = .32$, $p < 0.01$) had a significant relationship with satisfaction with life (Eller & Mahat, 2007). Physical functioning was also positively correlated with QoL (Gielen et al., 2001). People living with HIV/AIDS who participated in more frequent physical activity also showed higher overall general health perceptions ($r = 0.46$, $p < 0.05$) (Clingerman, 2003).

2.2.4 General Health Perceptions

General health perceptions are a combination of biological function, symptom status, and functional status and are unique to each individual (Ferrans et al., 2005; Wilson & Cleary, 1995). General health perceptions are "an integration of all of the health concepts… as well as others such as mental health, and they are by definition a subjective rating" (Wilson & Cleary, 1995, p. 62). Better general health perceptions reflect a higher overall health as perceived by the individual.

Overall general health and mental health have been associated with many of the factors that contribute to a person's QoL. Women who had higher general health perceptions had higher levels of physical functioning (Eller & Mahat, 2007). Women with better mental health had greater satisfaction with life (Eller & Mahat, 2007). Moreover, people who had increased social support had higher mental health scores (Degroote et al., 2014; Gielen et al., 2001) and better overall health perceptions (Cowdery & Pesa, 2002).

2.2.5 Characteristics of the Individual and Environment

Characteristics of the environment such as social support and HIV stigma may influence all aspects of a patient's overall health. HIV stigma is an end result of discrimination and has a negative impact on a person's overall well-being. Both perceived and internalized stigma have been shown to negatively affect QoL ($r = -0.38$, $p < 0.05$) in people living with HIV (Vyavaharkar et al., 2012).

While HIV-related stigma affects PLWHA's overall QoL, it also affects many other aspects of their health. Research has shown that patients who had higher HIV-related stigma exhibited more severe signs and symptoms and had lower overall physical health (Colbert et al., 2010; White et al., 2012). HIV-related stigma has also been shown to negatively affect a person's psychological well-being. People who showed signs of higher levels of HIV-related stigma had higher levels of depression (Clum et al., 2009; Logie et al., 2013; Vyavaharkar et al., 2012; White et al., 2012). Also, patients who did not show signs of depression had lower perceived HIV-related stigma ($p < 0.0001$) (Galvan et al., 2008). White et al. (2012) conducted a cross-sectional study of 150 people living with HIV (20.7% women and 68.7% African American) to assess whether HIV-related stigma, social support, and problem-solving skills affected a patient's depressive symptoms. Their findings showed that there was a moderately strong positive relationship between HIV-related stigma and depressive symptoms ($r = 0.54$, $p < 0.01$). This study also found that patients with lower levels of HIV-related stigma displayed higher social problem solving (White et al., 2012).

While HIV-related stigma is a negative environmental factor affecting a patient's overall health, social support can have a strong positive impact on a patient's life. Individuals with a high level of social support have better overall QoL (Andrinopoulos et al., 2011; Basavaraj et al., 2010; Vyavaharkar et al., 2012). Emotional support (Barger et al., 2009) and support from friends (Clingerman, 2004) are the most influential environmental predictors of higher overall QoL.

Social support was found to not only improve a patient's mental health (Cowdery & Pesa, 2002), but also improve physical health, such as lower viral loads (Clingerman, 2003). More social support was associated with more frequent levels of physical activity (Clingerman, 2003).

Patients who showed less severe signs and symptoms of HIV were more likely to have social support ($r = -0.26$, $p < 0.01$) (White et al., 2012). People with more social support also had fewer depressive symptoms (Clum et al., 2009; Vyavaharkar et al., 2012; White et al., 2012). In a study conducted by White et al. (2012), patients with better social support had higher levels of social problem solving. Colbert et al. (2010) showed that social support significantly predicted physical health in women ($b = 0.334$, $p = 0.003$). Furthermore, higher levels of social support, especially from friends (Galvan et al., 2008) were associated with lower levels of HIV stigma (Clum et al., 2009; Colbert et al., 2010; Logie et al., 2013; White et al., 2012). A cross-sectional study by Galvan et al. (2008) examined the relationship between social support and HIV stigma in 283 HIV positive African American adults (25.8% female). Social support from family ($p < 0.05$) and friends ($p < 0.001$) significantly predicted lower HIV stigma (Galvan et al., 2008). Greater social support was also associated with better health perceptions in women (Cowdery & Pesa, 2002).

Individual characteristics play an important role in the QoL of PLWHA. Demographic variables such as race, age, and religious beliefs factor into a patient's health. A person's race may determine how the body reacts to certain diseases including HIV/AIDS because of genetics. For instance, African Americans are more prone to diseases such as type 2 diabetes (CDC, 2011). In a six-month study with 423 HIV-positive homosexual men, Easterbrook et al. (1996) found that African American men had a slower CD4 count decline than white men. Some studies have suggested that African American women have a higher QoL than white women (Mrus et al., 2005; Vyavaharkar et al., 2012). In drug treatment studies of men and women, African Americans have shown greater improvement in HRQoL than Whites (Feinberg et al.,

2011). African Americans have also been shown to have more social support (Colbert et al., 2010).

The literature reports conflicting results on the relationship between age and QoL. Studies have shown a negative correlation between age and physical health (measured by the MOS-HIV scale) ($p = 0.009$) (Ruiz-Perez et al., 2005), a positive correlation between age and QoL (measured by the Chronic Illness Quality of Life Ladder) ($r = 0.15$, $p < 0.01$) (Vyavaharkar et al., 2012), and no significant correlation between age and QoL (measured using an adaptation of the Diabetes Quality of Life scale for youth) ($p = 0.878$) (Andrinopoulos et al., 2011). Despite these conflicting findings, patients who were diagnosed with HIV more recently had a lower QoL (measured using the Chronic Illness Quality of Life Ladder) than those who were diagnosed in the past (Vyavaharkar et al., 2012). A patient's age may also influence physiological factors and symptoms, such as viral load, pain, and fatigue. Age may also affect an individual's response to the environment. Older patients may have more established social support systems and less HIV stigma. Regardless of a patient's age, the length of time since diagnosis has been found to be associated with HIV stigma; for example, patients who were diagnosed more recently were found to have higher levels of HIV stigma ($p < 0.05$) (Galvan et al., 2008).

Demographic characteristics based on life choices such as education, marital status, and having children can be expected to influence a woman living with HIV/AIDS; however, researchers have failed to agree on this issue. Studies connecting education and QoL are conflicting. Vigneshwaran et al. (2013) found that patients with more education had a significantly higher ($p < 0.05$) perceived QoL, while Andrinopoulos et al. (2011) found a positive trend that was not statistically significant between education and QoL ($p = 0.056$). Patients with higher education also have shown increased levels of overall health (Lorenz et al.,

2006). On the other hand, less educated individuals have been shown to have a higher satisfaction with life than their more educated counterparts (Phaladze et al., 2005). More education is associated with both lower HIV stigma (Wagner et al., 2010) and better physical and work-role functioning (Vidrine et al., 2003). In addition to a woman's education, the choice to have children could also have an impact on a woman's health. In the context of women living with HIV, having children has not been found to affect QoL (Andrinopoulos et al., 2011); however, women with no children have been found to have higher levels of social support (Logie et al., 2013).

2.3 SUMMARY

There is a paucity of literature examining women with HIV and their HRQoL, underscoring the need for this study. This review of the literature has discussed factors influencing HRQoL and factors affecting women living with HIV. The literature review has provided a foundation for this study testing the revised model of HRQoL by Wilson and Cleary (Ferrans et al., 2005) with the primary aim being to determine if this model explains HRQoL in women living with HIV.

3.0 METHODOLOGY

The following chapter describes the methodology used in this study. Here, a description of the parent study and the research design are introduced. A detailed account of data collection and data management is described. Next, all measures used in this study are defined and justification for sample size is explained. Lastly, there is a section that specifies which statistical methods were employed to address the study aims.

3.1 PARENT STUDIES

3.1.1 Research Design of Parent Studies

This study was a secondary analysis using baseline (i.e. pre-intervention) data pooled from two independent randomized controlled trials (R01 NR04749, *Adherence to Protease Inhibitors and Quality of Life*, and 2R01 NR04749, *Improving Adherence to Antiretroviral Therapy*, Principal Investigator, J. A. Erlen). The first parent study examined the efficacy of an intervention to enhance adherence to antiretroviral therapy (ART) in persons living with HIV (R01 NR04749, Principal Investigator, J. A. Erlen). The intervention was a nurse-delivered, telephone-based, cognitive-behavioral program designed to enhance ART adherence. Participants were randomly assigned either to the intervention plus usual care or usual care only. The main aim of this parent study was to test the efficacy of the structured intervention compared to usual care on ART adherence over time. The secondary aims of the study assessed relationships among ART adherence, health-related quality of life (HRQoL), and clinical response.

The second parent study was a continuation of the earlier clinical trial, adding an individualized intervention as a third treatment arm (2R01 NR04749, Principal Investigator, J. A. Erlen). Subjects with HIV and taking ART were randomized to one of three treatment groups: structured intervention, individualized intervention, and usual care (control). The structured intervention consisted of the same telephone-based adherence program from the first parent study and was considered to be a nurse-*directed* intervention approach and had a pre-defined order to the delivery of the intervention sessions. In contrast, the individualized intervention, based on a subject's needs, was considered to be a tailored intervention approach. The primary aim of the second parent study was to test the efficacy of the structured and individual ART-adherence interventions compared to usual care over time. The secondary aim of this study, as in the first parent study, focused on testing the associations of ART adherence with clinical response and HRQoL.

3.1.2 Sample

Inclusion criteria for both parent studies were the following: HIV-infected individuals over 18 years old who were currently taking antiretroviral therapy, with no cognitive dysfunction at baseline, who lived in a private residence in the community, spoke English, and had access to a telephone. No individuals were excluded based on race, gender, or ethnicity. Individuals who lived with someone already in the study, were not willing to use the electronic event monitor (EEM), had a hearing impairment and could not hear when using the telephone, were diagnosed with HIV dementia, were blind, or had motor impairment in their upper extremities were excluded. In the second study, individuals who were in the treatment group in the first study or

in the HAART Care Study were excluded. The first parent study was conducted from April 1999 to November 2002 and included 215 HIV-infected men and women recruited from western Pennsylvania and eastern Ohio, university-based clinics, and comprehensive HIV care centers, as well as self-referral. The continuation study (March 2004 to March 2007) consisted of 352 HIV-infected men and women with the same inclusion and exclusion criteria as the initial parent study. Out of the 35 subjects, who were randomly assigned to the usual care group in the first study and who also participated in the second study, just the female participants were included in the current study. Only their baseline data collected for the second study were used in this secondary data analysis in order to analyze the most recent data for each individual.

3.1.3 Sample Size and Power

The sample sizes for the parent studies were estimated to test the differences in mean of adherence over time between the intervention and usual care groups. For the first study it was estimated that 100 randomly assigned participants per group (200 total) would yield a power of 0.80 at a significance level of 0.01. The study successfully recruited 215 subjects of which 200 were randomized. Power calculations for the second parent study indicated that a total of 300 randomly assigned subjects would yield a power of 0.80 at a significance level of 0.01 to detect a difference in adherence response between the groups of $f = .132$. A sample of 352 patients was enrolled in the second study. There were 35 subjects from the second study who had also participated in the first study. For these repeat participants, only the records for the second study were used in the current secondary data analysis, resulting in a sample size from the first study of 180 (215 minus 35). This 180 combined with the 352 from the second study resulted in a total

sample size of 532 different men and women between the two studies (1R01 NR04749 and 2R01 NR04749, Principal Investigator, J. A. Erlen).

3.2 RESEARCH DESIGN

For this secondary analysis a cross-sectional, correlational research design was applied using only the baseline data pooled from the aforementioned parent studies. Due to the fact that this was a secondary analysis, inclusion and exclusion criteria for this study were the same as in the parent studies except for gender; only women were selected for the current study.

3.3 DATA COLLECTION

3.3.1 Overview of Data Collection Procedures

Data from the parent studies used in this secondary analysis were de-identified by the data manager for the parent studies. The data from the two studies were merged and organized using IBM® SPSS® Statistics version 22.0 (IBM Corp., Armonk, NY).

3.3.2 Data Management

A software program called TELEform™ Elite (version 6.0, Cardiff Software, Inc., Vista, CA) was used in the parent study to design the data collection forms and for scanning the questionnaires, and retrieving and verifying data from the instruments. An Oracle database (version 9i, Oracle Corporation, Redwood Shores, CA) was used for data storage and

management. All data from the parent study were de-identified by the data manager and moved to a secure University of Pittsburgh server allowing only research staff access. For the current study, baseline data from both parent studies for the eligible female subjects were provided to the investigator by the data manager and compiled to form one pooled dataset. For this secondary study, data were organized and analyzed using IBM® SPSS® Statistics version 22.0 (IBM Corp., Armonk, NY) and M*plus* version 7.31 (Muthén & Muthén 1998-2012).

3.3.3 Human Subjects

This study was a secondary analysis using baseline data from the two parent studies. This study used only pre-existing records which were de-identified by the data manager and therefore met the criteria for an exempt study by the Institutional Review Board (IRB). The researcher of this study received no identifying information and consequently subjects could not be identified either directly or indirectly from the dataset that was used. The data could not be linked back to any subject identifying information in the parent study. This study was approved by, the Institutional Review Board (IRB #PRO15030443). The approval letter is included in Appendix A.

3.4 MEASURES

3.4.1 Overall Quality of Life

The construct of overall QoL was measured with two variables from two different instruments. Overall QoL was measured with the Medical Outcomes Study (MOS-HIV). The MOS-HIV is an instrument frequently used to measure various health outcomes for patients with HIV (Wu et al., 1991). One question from the instrument addresses overall QoL: "How has the quality of your life been during the past 4 weeks? That is, how have things been going for you?" This item was based on a 5-point Likert scale ranging from "Very well" (1) to "Very bad" (5). Due to the direction of the response, the scores were reverse-coded to indicate lower values as lower QoL.

Satisfaction with life was measured with the Satisfaction with Life Scale (SWLS). This instrument is a 5-item survey representing a subject's overall life satisfaction. Each item was rated on a 7-point Likert scale ranging from 1, "strongly disagree" to 7, "strongly agree" (Diener et al., 1985). In this study, Cronbach's alpha for the satisfaction with life instrument was 0.86.

3.4.2 Biological Function

Biological function was represented by CD4 count and viral load. CD4 refers to the CD4 T-lymphocyte, a biological measurement that indicates severity of disease. Higher count of CD4 indicate better health, while lower count of CD4 indicate greater immune deficiency. The CD4 count of healthy adults range from 500 to 1200 cells/mm^3. Fewer than 200 cells/mm^3 is an

indicator that the HIV has progressed to Stage 3 infection, which is AIDS (AIDS.gov, 2015a). Viral load refers to the number of HIV-1 viral particles found in each milliliter of blood. Higher viral loads indicate worse disease (AIDS.gov, 2015b). Both CD4 count and viral loads were obtained from the Medical Record Review (MRR) form at baseline. When medical records were unavailable, some of the data were obtained via self-report.

3.4.3 Symptoms

Depressive symptoms and fatigue were used to represent symptoms. Depressive symptoms were measured using the total score of the Beck Depression Inventory II (BDI-II). Items were rated on a 4-point Likert scale from 0 (least depressed) to 3 (most depressed), and the total score was the sum of all 21 items. According to Beck et al. (1996), severity of depressive symptoms was measured as follows: 0 to 13 ("minimal"), 14 to 19 ("mild"), 20 to 28 ("moderate"), and 29 to 63 ("severe"). Cronbach's alpha for the first parent study for BDI-II was 0.91 (n=215, 1R01 NR04749). Cronbach's alpha for the current study was 0.92. The energy/fatigue subscale of the MOS-HIV was used to measure participants' levels of fatigue. The subscale is comprised of four questions: "How often on the past 4 weeks… Did you feel full of pep? Did you feel worn out? Did you feel tired? Did you have enough energy to do the things you wanted to do?" Higher values reflect higher energy levels. According to Wu et al. (1997), based on eight different studies, Cronbach's alpha for energy/fatigue ranged from 0.78 (n=117) to 0.88 (n=1022). Cronbach's alpha for the current study was 0.84.

3.4.4 Functional Status

Functional status was used to measure an individual's ability to accomplish day-to-day activities, both social and physical. Functional status was assessed using the "Social Functioning" and "Physical Functioning" subscales from the MOS-HIV instrument. Social functioning was measured with one question: "How much of the time, during the past month, has your health limited your social activities (like visiting with friends or close relatives)?" Physical functioning was measured with six questions that inquired if specific physical activities had been limited (e.g. climbing, bending, and walking). Subjects with higher values were better able to perform day-to-day activities. According to Wu et al. (1997), based on eight different studies, Cronbach's alpha for physical functioning ranged from 0.83 (n=205) to 0.89 (n=162). For this current study, Cronbach's alpha was 0.91.

3.4.5 General Health Perceptions

General health perceptions were measured using the "General Health" and "Mental Health" subscales from the MOS-HIV instrument. General health is a self-perceived evaluation of the individual's health and was measured with one question: "In general, what would you say your health is?" The Mental Health subscore of the MOS-HIV is comprised of five questions relating to the participant's nervousness, calm, and happiness. According to Wu et al. (1997), based on eight different studies, the alpha coefficient for mental health ranged from 0.80 (n=99) to 0.87 (n=68). For this study, Cronbach's alpha was 0.87.

3.4.6 Characteristics of the Environment

Characteristics of the environment included social support and HIV stigma. These constructs were measured using the total scores of the Inventory Support Evaluation List (ISEL) and the HIV Stigma Scale. The Inventory Support Evaluation List (ISEL) is a 40-item instrument designed to measure the level of support patients receive (Cohen & Syme, 1985). Cohen and Syme (1985) define social support as "the resources provided by other persons" (p. 4). The items on the instrument were on a 4-point ordinal scale ranging from 0 to 3 and responses followed a true/false format ranging from "definitely false" to "definitely true." Higher scores indicated greater social support. Cronbach's alpha for this study was 0.95.

The HIV Stigma Scale is a 40-item measure developed to assess social and emotional aspects of perceived HIV stigma (Berger et al., 2001). Items were ranked using a 4-point Likert scale ranging from 1 to 4. Higher scores indicated greater perception of HIV stigma. The instrument contained four subscales: personalized stigma, disclosure, negative self-image, and perceptions of public attitudes about people living with HIV (Berger et al., 2001). For this study, the total HIV stigma score was used instead of the partitioned subscales. The total HIV stigma score was calculated by summing the four subscales. Research has shown that the instrument yields a satisfactory internal consistency with a Cronbach's alpha of 0.96 in a study of 318 participants living with HIV (Berger et al., 2001). For the current study, Cronbach's alpha was 0.95.

3.4.7 Characteristics of the Individual

Characteristics of the individual were measured at baseline using the Socio-demographic Questionnaire (SDM). The questionnaire is a 24-item self-report instrument designed by the Center for Research in Chronic Disorders at the University of Pittsburgh School of Nursing. Socio-demographic data used to assess the characteristics of the individual included age (in years), race (white or nonwhite), children (yes or no), marital status (partnered or not), and education (graduated from high school or not).

3.5 DATA ANALYSIS

3.5.1 Data Screening and Preliminary Analysis

Missing values were assessed for each of the variables. If more than 10% of data were missing from a particular variable, an alternative variable was explored. If less than 10% of data were missing, pairwise deletion was used (Bennett, 2001). In the structural equation modeling analysis, full information maximum likelihood estimation was used to address the missing data. Viral load and CD4 T-cell count had the most missing values: 153 and 152 valid responses, respectively. The remaining variables from the main path had between 174 and the complete 178 responses: overall QoL (n=176), satisfaction with life (n=176), mental health (n=175), general health (n=175), social functioning (n=174), physical functioning (n=176), depressive

symptoms (n=176), and energy/fatigue (n=175). For the environmental factors, HIV-related stigma had 171 responses and social support had 176 responses. Individual characteristics (age, race, education, children, and marital status) were recorded for all of the women in the sample (n=178).

All continuous variables were explored graphically in order to determine their distributions. The following variables were found to deviate from a univariate normal distribution due to severe skewness: CD4 count, viral load, depressive symptoms, physical functioning, social functioning, general health, QoL, and satisfaction with life. Viral load was severely right-skewed (skewness = 6.125). A $\log_{10}$ transformation was applied to viral load in an effort to normalize the observed data distribution. Square root transformations were also applied to CD4 count, total depressive symptoms, and social functioning in an effort to approximate univariate normal distributions.

For categorical variables (race, children, education, and marital status), frequency distributions were assessed in order to identify any sparsely populated categories. If distributions were extremely skewed with unpopulated categories, categories were meaningfully combined. Marital status was originally a nominal variable with seven different categories: never married (35.4%), currently married (15.2%), living with partner (9%), widowed (10.7%), separated (7.3%), divorced (20.8%), and other (1.7%). This variable was transformed to a dichotomous variable. "Currently married" and "Living with partner" were combined to represent "Partnered" and all other categories were combined to signify "Not Partnered." Women who are "Partnered" potentially have help and support at home from a significant other. However, women who are "Partnered" could also have the burden of caring and supporting for a sick loved one. Education level was also dichotomized to depict women who did or did not graduate from

high school. A very small number of women completed a higher level of education, making the dispersion very skewed. Participants had the following options to declare as their race: White (37.6%), Black (59.6%), Latino (5.1%), American Indian (1.1%), Eskimo (0%), Pacific Islander (0%), Asian (0%), Unknown (5.1%), and Other (0.1%). Because the categories other than white and black were so small (11%), race was dichotomized into white and non-white.

Data exploration was performed and graphs were plotted for each variable (box plots) and bivariately (scatter plots) to determine outliers or potentially influential points. Bivariate correlations, variance inflation factors (VIFs), and tolerance were used to assess multicollinearity. Serious multicollinearity was not present based on the following criteria: VIFs greater than 10 and tolerance less than 0.10 (Kline, 2011). For individual variables, measures of central tendency (mean, median, and spread (standard deviation and interquartile range) were computed and used to identify univariate outliers for continuous type variables. Bivariate scatterplots and linear regression with Mahalanobis distance were used to identify multivariate outliers and potentially influential points. Mahalanobis distance was calculated for each subject and a histogram and box plot of these distances were plotted to reveal multivariate outliers.

3.5.2 Descriptive Statistics

Univariate descriptive statistics for continuous variables were calculated: mean, median, range (maximum and minimum values) and standard deviation. Frequency count and percentages were reported for all categorical variables. Also, since all categorical variables in this study (race, marital status, children, and education) were nominal variables, the mode was calculated as a measure of central tendency. Bivariate descriptive statistics were represented through pairwise

correlations that were reported in a correlation matrix. Pearson product-moment correlations were used unless non-parametric (Spearman rank-order) correlations were necessary (e.g. if data did not follow a bivariate normal distribution). A significance level of .05 was established *a priori* and used for two-sided hypothesis testing for all statistical tests in this study.

3.5.3 Structural Equation Modeling (SEM)

Structural Equation Modeling (SEM) is an approach used for a collection of statistical techniques that assess the relationships among latent constructs and the observed variables that represent them. Latent variables are theoretical constructs, while observed or measured variables are the actual variables that the data represent. For example, in this study, biological function was a latent variable and CD4 count and viral load were the observed variables chosen to assess biological function for each individual. Table 1 shows the definitions of the latent constructs and observed variables that represented these constructs in this model. Path analysis (described in section 3.5.4) is a type of SEM.

Latent variable path models were developed using a two-step approach. First, the measurement model was estimated and fit. Second, once the fit of the measurement model was determined, actual estimation of the latent variable path model was performed. In this study, the latent variable path model was estimated using maximum likelihood estimation (ML) and fit was assessed using standard fit indices. A model with a "good fit" met the following criteria: a Root Mean Square Error of Approximation (RMSEA) less than or equal to 0.05 ("poor fit" greater than or equal to 0.10), a Comparative Fit Index (CFI) greater than 0.95, and a Standardized Mean Square Residual (SRMR) less than or equal to 0.08 (Kline, 2011). Finally, the model chi square

statistic was assessed at a significance level of 0.05. Although the sample size was near 200, the additional standard fit criteria were considered. A *post hoc* exploratory analysis was also conducted. Several modified models were created based on modification indexes, a *post hoc* technique used to add paths of a model based on the observed data (Kline, 2011). These modified models were also estimated and reported. All SEM analyses were accomplished using M*plus* version 7.31 (Muthén & Muthén,1998-2012) structural equation modeling software.

3.5.4 Path Analysis

Path analysis was used to assess the relationships of multiple variables with the assumption of direction: causality. For example, the first component in the model is biological function and there is a path that leads directly to symptoms. Therefore, based on this model, biological function directly affects symptoms. The Ferrans' et al. revised Wilson and Cleary (2005) model of HRQoL is a *recursive* path model, meaning that its paths are *unidirectional* (Kline, 2011). Since each component of the model is a latent variable which is measured by a set of observed variables, this was considered to be a latent variable path model. Standardized path coefficients were reported and considered significant at $p < 0.05$.

Table 1. Theoretical and Operational Definitions of Variables

Components of Model	Theoretical Definition	Operational Definition
Biological Function	"Biological function is viewed broadly and encompasses molecular, cellular, and whole organ level processes."	*CD4 Count* *Viral Load*
Symptoms	A symptom is defined as "a patient's perception of an abnormal physical, emotional, or cognitive state." • "Global measures are broad and include many varied symptoms." • "Symptom-specific measures pertain to a particular symptom" (e.g. fatigue or anxiety or depression). • "The most common dimensions of symptoms that are measured include frequency, intensity, and distress."	*Depressive Symptoms* *Energy/Fatigue*
Functional Status	"…the ability to perform tasks in multiple domains such as physical function, social function, role function, and psychological function."	*Physical Functioning* *Social Functioning*
General Health Perceptions	"…two defining characteristics of general health perceptions: (a) they integrate all the components that come earlier in the model, and (b) they are subjective in nature… a synthesis of all the various aspects of health in an overall evaluation."	*General Health* *Mental Health*
Overall Quality of Life	"…subjective well-being related to how happy or satisfied someone is with life as a whole."	*Quality of Life* *Satisfaction with Life*
Characteristics of the Individual	"…categorized as demographic, developmental, psychological, and biological factors that influence health outcomes." • Biological factors : BMI, skin color, family disease history • Demographic factors: sex, age, marital status, ethnicity	*Age* *Race* *Children* *Education* *Marital Status*
Characteristics of the Environment	"…are categorized as either social or physical…. Social environmental characteristics are the interpersonal or social influences on health outcomes, including the influence of family, friends, and healthcare providers… Physical environment characteristics are those settings such as the home, neighborhood, and workplace that influence health outcomes either positively or negatively."	*HIV-Related Stigma* *Social Support*

3.6 SAMPLE SIZE AND POWER ANALYSIS

Only 108 of the subjects in the second parent study (the more recent study) were female. In order to obtain an adequate sample size, women from the first parent study were added to this sample. Out of the 532 unique subjects from the two parent studies, 178 were female. According to Kline (2011), a ratio of 20:1 for number of subjects to number of estimated parameters is ideal for conducting a path analysis. In the case of the primary analysis of this study, 14 main path coefficients were estimated. Therefore $14 \times 20 = 280$ subjects would be required for the primary aim. The study sample of 178 did not yield an adequate sample size to test the primary aim of this study.

3.7 STUDY AIMS

3.7.1 Primary Aim

The primary aim of this study was to test the main path of the revised Wilson and Cleary HRQoL (Ferrans et al., 2005) model – the directional relationships of biological function (CD4 count and viral load), symptoms (depressive symptoms and energy/fatigue), functional status (physical functioning and social functioning), general health perceptions (general health and mental health), and the primary outcome variable, HRQoL (overall QoL and satisfaction with life). A latent variable path analysis was used to examine the relationships among the five main components of the revised Wilson and Cleary model of

HRQoL proposed by Ferrans et al. (2005) (biological function, symptoms, functional status, general health status, and overall QoL).

3.7.2 Secondary Aim

In order to examine the relationships among the individual and environmental characteristics and the main components of the Ferrans' et al. adapted HRQoL model, several paths were added. The following variables were included: age, children, race, education, and marital status as individual characteristics; and HIV-related stigma and social support as environmental characteristics. The main path portion of the Ferrans' et al. (2005) adapted HRQoL model was initially expanded considering each set of characteristics separately and then further expanded considering both sets of characteristics simultaneously. These were first accomplished separately due to the small sample size in this study.

4.0 RESULTS

This chapter presents the results of this study. The first section describes the results of the preliminary analysis of the data. In the next section, the study sample is described. Finally, the results of the structural equation modeling (SEM) analysis and path analysis are reported.

4.1 PRELIMINARY ANALYSIS

Box plots were plotted for each of the transformed continuous variables in order to assess for univariate outliers. No extreme univariate outliers were found. Bivariate scatterplots were plotted for pairs of continuous variables to check for outliers and potentially influential points along with linear association. These graphs displayed no obvious bivariate outliers and were overall linear. However, using Mahalanobis distance four multivariate outliers were identified that were not evident in the bivariate scatterplots. All four of these women were in the age range of 29 to 39 years old, slightly younger than the average age of 42 years in this sample. Half were married at the time of the surveys. Half were African American and the other half were white. Only one of the four graduated from high school, which was surprising considering over half of the women in this sample reported finishing high school. Not one of these four women was employed. This was not atypical, because 82.6% of the women in the sample were unemployed. There was only one extreme multivariate outlier (greater than three times the interquartile range above the 75^{th} percentile of Mahalanobis distance). This woman was African American who graduated from vocational school, and was 39 years old. Surprisingly, while this woman had the highest possible score for QoL (100) and a "minimal" score for depressive symptoms (6), she had low satisfaction with life (6) and a relatively low general health score (20) (see Table 2 for overall sample description).

4.2 COMPARISON OF STUDIES

The key study variables from the two parent studies were compared in order to ensure the data from the studies could be pooled (see Table 2). The only significant differences found between the studies were in age ($p = .001$) and race ($p = .006$). The women in the first study were slightly younger than the women in the second study ($mean_1 = 39.4$, $mean_2 = 42.1$). In the first study, a greater percentage of women were white than in the second study ($study_1 = 50\%$ versus $study_2 = 29.6\%$).

Correlations among variables were mostly the same between the two studies (using Fisher's r to z transformation). The only variables that varied in relationships across the studies were partnership and CD4 count. Women in the second study who were neither married nor living with a partner had higher mental health ($r = .270$, $p < .01$) and higher overall health ($r = .201$, $p < .05$). These relationships did not hold for women in the first study ($p = .006$, $p = .016$, respectively). In the first study, however, women who had a partner had higher ($p = .019$) satisfaction with life ($r = -.300$, $p < .01$), higher ($p = .024$) CD4 count ($r = -.295$, $p < .05$) and a lower ($p = .026$) viral load ($r = -.290$, $p < .05$). In the first study, white women had higher ($p = .006$) CD4 count than women who were nonwhite ($r = -.297$, $p < .05$), although there was no association between race and CD4 count in the second study.

Table 2. Study Comparison

Characteristic	Total (N=178) Mean±SD or n (%)	Study 1 (n=70) Mean±SD or n (%)	Study 2 (n=108) Mean±SD or n (%)	Test Statistic	p-value
MOS-HIV Quality of Life (n=176)	60.7±25.3	61.8±23.2	59.9±26.7	t = 0.482	.631
Satisfaction with Life (n=176)	17.5±7.7	17.3±7.9	17.7±7.6	t = -0.348	.729
MOS-HIV Mental Health (n=175)	59.4±24.2	59.8±22.2	59.2±25.4	t = 0.167	.867
MOS-HIV General Health (n=175)	46.3±24.6	47.9±22.0	45.3±26.2	t = 0.678	.499
MOS-HIV Social Functioning (n=174)	69.8±31.1	69.3±31.0	70.1±31.4	t = 0.219	.827
MOS-HIV Physical Functioning (n=176)	64.2±31.1	65.2±34.0	63.4±29.2	t = 0.373	.709
Depressive Symptoms (BDI-II) (n=176)	15.7±11.8	14.8±10.4	16.3±12.6	t = -0.600	.550
MOS-HIV Energy/Fatigue (n=175)	48.5±23.1	47.5±21.3	49.2±24.2	t = -0.472	.638
CD4 Count (n=152)	520.4±399.9	528.3±390.1	513.8±410.1	t = 0.330	.742
Viral Load (log_{10}) (n=153)	2.725±1.2	2.855±1.3	2.616±1.9	t = 1.180	.240
HIV Stigma (Total) (n=171)	77.0±17.9	80.2±16.8	74.8±18.3	t = 1.920	.057
Social Support (ISEL Total) (n=176)	78.4±23.4	79.4±22.1	77.7±24.3	t = 0.493	.623
Age	41.7±7.6	39.36±7.8	43.1±7.2	t = -3.320	**.001**
White	67 (37.6)	35 (50.0)	32 (29.6)	$X^2 = 7.508$	**.006**
Finished High School	118 (66.3)	43 (61.4)	75 (69.4)	$X^2 = 1.221$	.269
Have Children	145 (81.5)	56 (80.0)	89 (82.4)	$X^2 = 0.163$	.686
Partnered	43 (24.2)	22 (31.4)	21 (19.4)	$X^2 = 3.329$	.068

4.3 SAMPLE SUMMARY

The women (N = 178) in this sample were, on average, 42 years old, with ages ranging from 24 to 61 years. The majority of the women in the sample (59.6%) were African American; 37.6% of the women were white. Latinas comprised 5.1% and American Indians 1.1%. Over 80% of the women reported a religious preference: 60% were Protestant, 17% were Catholic, less than 1% were Jewish, and 22% reported "other." Less than a quarter of the women (24.2%) were "partnered" (either currently married or living with a significant other). Women who were never married accounted for 35.4%, while 28.1% were either separated or divorced. Over 10% (10.7%) of the women were widowed. The majority of the women (81.5%) had children but only 41% of the women in the sample had at least 1 child (under the age of 18) living in the household. While most of the women (66.3%) finished high school and 18.5% earned a general education diploma (GED), only 6.2% finished 4 years of college. Less than 2% of the sample finished graduate school with a masters or doctoral degree. Women employed at the time of the survey comprised 17.4% of the sample and just over half of those employed (58.1%) worked full time. The majority (60%) of the women were either disabled or unable to work. According to the 2000 Poverty Guidelines, nearly 30% of the gross household incomes were below the poverty line for a family unit of two or less (under $10,000 annually) (USDHHS, 2000).

Table 3. Descriptive Statistics for the Sample (N=178)

Characteristic		
	Mean	SD
MOS-HIV Quality of Life **	60.7	25.3
Satisfaction with Life **	17.5	7.7
MOS-HIV Mental Health **	59.4	24.2
MOS-HIV General Health **	46.3	24.6
MOS-HIV Social Functioning **	80.0*	31.1
MOS-HIV Physical Functioning **	64.2	31.1
Depressive Symptoms (BDI-II) **	13.0*	11.8
MOS-HIV Energy/Fatigue **	48.5	23.1
CD4 Count **	422.5*	399.9
Viral Load **	400.0*	278,868.4
Viral Load (log_{10}) **	2.7	1.2
HIV Stigma (Total) **	77.0	17.9
Social Support (ISEL Total) **	78.4	23.4
Age	41.7	7.6
	n	%
White	67	37.6
Finished High School	118	66.3
Have Children	145	81.5
Partnered	43	24.2

*Median, ** n < 178

4.4 RESULTS OF CORRELATION ANALYSES

Bivariate correlation analyses confirmed many of the expected associations among the measured variables in the revised model of health-related quality of life (HRQoL) (see Table 3). Overall QoL was positively correlated with general health ($r = .537$, $p < .01$) and mental health ($r = .612$, $p < .01$). Satisfaction with life had a positive relationship with overall health ($r = .412$, $p < .01$) and mental health ($r = .530$, $p < .01$). Overall general health was also found to have a positive association with social functioning ($r = -.486$, $p < .01$) and physical functioning ($r = .516$, $p < .01$). (Social functioning was not

measured in the same direction as the other variables; higher social functioning values represent lower social functioning. Therefore, negative correlations actually signify a positive relationship.) Mental health had a positive relationship with social functioning ($r = -.515$, $p < .01$) and physical functioning ($r = .424$, $p < .01$). Social functioning was negatively associated with both depressive symptoms ($r = .435$, $p < .01$) and energy/fatigue ($r = .596$, $p < .01$). Physical functioning also had a negative relationship with depressive symptoms ($r = -.331$, $p < .01$) and energy/fatigue ($r = -.548$, $p < .01$). Depressive symptoms had no significant correlation with either viral load or CD4 count ($p \geq .05$). Energy/fatigue also had no significant correlation with either CD4 count or viral load ($p \geq .05$).

Social support had positive associations with overall QoL ($r = .413$, $p < .01$), satisfaction with life ($r = .406$, $p < .01$), general health ($r = .338$, $p < .01$), mental health ($r = .642$, $p < .01$), physical ($r = .209$, $p < .05$) and social ($r = -.407$, $p < .01$) functioning. Social support had negative relationships with depressive symptoms ($r = -0.558$, $p < .01$) and energy/fatigue ($r = -.483$, $p < .01$). Social support had no significant correlation with CD4 count ($r = .066$, $p > .05$), but did have a significant negative correlation with viral loads ($r = -.165$, $p < .05$). HIV-related stigma had negative correlations with overall QoL ($r = -.462$, $p < .01$), satisfaction with life ($r = -.498$, $p < .01$), general health ($r = -.492$, $p < .01$), mental health ($r = -.601$, $p < .01$), physical ($r = -.260$, $p < .01$) and social ($r = .369$, $p < .01$) functioning. HIV stigma did not have a statistically significant association with either CD4 count or viral load. HIV-related stigma did, however, have positive relationships with both depressive symptoms ($r = .592$, $p < .01$) and energy/fatigue ($r = .522$, $p < .01$).

The only individual characteristic that was significantly associated with any variables of interest in the model was race. Race was found to have a positive correlation with both social functioning ($r = .179$, $p < .05$) and overall QoL ($r = .194$, $p < .05$), suggesting that white women had both a lower QoL and lower social functioning than women who were nonwhite.

Table 4. Correlations among Study Variables, Overall and by Study

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1		.451**	.612**	.537**	-.425**	.350**	-.457**	.499**	.017	-.062	-.462**	.413**	-.017	.194*	-.052	-.119	-.032
		.640**	.648**	.564**	-.366**	.412**	-.399**	.429**	.200	-.181	-.462**	.413**	-.128	.233	-.055	-.140	-.221
		.344**	.601**	.535**	-.498**	.339**	-.557**	.562**	-.090	-.008	-.443**	.342**	.033	.084	-.084	-.035	.089
2			.530**	.412**	-.193*	.191*	-.515**	.332**	.128	-.123*	-.498**	.406**	.022	.021	-.069	-.105	-.098
			.559**	.308**	-.165	.199	-.409**	.239*	.126	-.130	-.479**	.351**	-.194	.084	-.060	-.048	-.300*
			.517**	.499**	-.291**	.281**	-.611**	.481**	.159	-.147	-.469**	.412**	.098	-.001	-.030	-.123	.059
3				.605**	-.515**	.424**	-.734**	.685**	.124	-.257**	-.601**	.642**	.135	.103	-.113	-.090	.095
				.584**	-.478**	.403**	-.720**	.554**	.104	-.313**	-.590**	.561**	.004	.082	-.016	.004	-.154
				.621**	-.533**	.470**	-.768**	.793**	.171	-.224*	-.598**	.645**	.092	.101	-.186	-.036	.270**
4					-.486**	.516**	-.558**	.637**	.176*	-.059	-.492**	.338**	-.009	.105	-.090	.050	.043
					-.494**	.472**	-.536**	.557**	.171	-.147	-.470**	.229	.038	.098	.111	.172	-.172
					-.573**	.636**	-.604**	.694**	.203	-.031	-.508**	.370**	-.173	.083	-.179	-.053	.201*
5						-.571**	.435**	-.596**	-.081	.129	.369**	-.407**	-.083	-.179*	.012	.019	-.015
						-.580**	.355**	-.634**	-.143	-.257*	.431**	-.413**	-.024	-.192	.034	-.034	.160
						-.599**	.542**	-.553**	.016	-.037	.349**	-.355**	.028	-.149	.018	.098	-.186
6							-.331**	.548**	.078	-.103	-.260**	.209*	-.036	.158	-.159	.109	-.071
							-.299*	.567**	.075	-.166	-.241*	.245*	-.100	.085	-.097	.127	-.180
							-.440**	.555**	.113	-.086	-.273**	.206*	-.103	.184	-.166	.045	.098
7								-.557**	-.065	.144	.592**	-.558**	-.159	-.040	-.006	.081	-.025
								-.540**	-.137	.336**	.601**	-.436**	-.135	.028	-.209	.000	.133
								-.621**	-.031	.007	.579**	-.563**	-.042	-.130	.140	.128	-.128

8									.041	-.154	-.522**	.483**	.118	.165*	-.054	.004	.140
									-.040	-.203	-.409**	.320**	.079	.101	.157	.120	-.012
									.127	-.121	-.566**	.550**	-.015	.175	-.175	.016	.243*
9										-.412**	-.073	.066	.076	-.041	-.097	.032	-.107
										-.441**	-.077	.126	.007	-.297*	.043	.056	-.295*
										-.440**	-.061	.043	.097	.146	-.157	.017	.071
10											.134	-.188*	-.157	.007	.142	.010	.091
											.247*	-.182	-.090	.154	.051	-.014	-.293*
											.003	-.168	-.173	-.056	.110	.030	-.032
11												-.500**	-.074	-.022	.089	.086	-.070
												-.550**	.026	-.156	.003	-.068	.122
												-.478**	-.037	.061	.117	.100	-.223*
12													.116	.152	-.108	-.091	.086
													.082	.278*	-.097	-.039	-.159
													.057	.077	-.077	-.043	.314**
13														.020	-.020	-.126	.005
														.002	-.120	-.120	-.025
														-.013	.054	-.094	-.049
14															-.083	-.138	.107
															-.088	-.214	.000
															-.098	-.020	.194*
15																-.022	-.033

																-.029 -.043	-.096 -.080
16																	-.015 .031 .043
17																	

1 Overall Quality of Life, 2 Satisfaction with Life, 3 Mental Health, 4 General Health, 5 Social Functioning, 6 Physical Functioning, 7 Depressive Symptoms, 8 Energy/Fatigue, 9 CD4 Count, 10 Viral Load, 11 HIV-related Stigma, 12 Social Support, 13 Age, 14 White Race, 15 Finished High School, 16 Have Children, 17 Married or Partnered. ** $p < 0.01$, * $p < 0.05$. First row in each cell denotes pooled sample statistics; second and third rows denote study 1 and study 2, respectively.

4.5 STRUCTURAL EQUATION MODELING RESULTS

To address the aims of this study, structural equation modeling (SEM) was used to conduct latent variable path analysis, where both measurement and structural linear relations are considered. Unfortunately, problems were encountered with the estimation/fitting of the underlying measurement model. The fitting of the model for the original latent variable path analysis model specified, which included two observed/measured variables for each latent variable of main path model, resulted in some parameter estimates that were inadmissible. Specifically, the latent variables of symptoms and general health perceptions had an inadmissible correlation of -1.123, indicating a problem with estimation (correlations should be between -1 and 1). In addition, the measured variable of energy/fatigue was more strongly correlated with both measured variables of the latent variable of general health perceptions, overall general health and mental health, than with the latent variable of symptoms. Accordingly, several simplified path models were considered. Observed variable path models using only a single observed variable to represent each latent construct (viral load, depressive symptoms, physical functioning, overall general health, and overall QoL) and hybrid models, which included both latent and observed variables, with only biological function configured as a latent variable and measured by viral load and CD4 count, were fit to provide insight into further model development and model modifications (suggested through *post hoc* analysis). The hybrid model was also considered as nearly 15% of values from CD4 count and viral load were missing. Having two indicators reflecting a

single latent variable strengthens the construct. Each indicator represents a different aspect (i.e. CD4 count or viral load) of the latent construct and the combination of the two makes the latent factor more reliable. All of the models that were considered with their fit statistics and indices are reported in Table 4.

4.5.1 Model Fit

As displayed in Figure 4, the first model, an observed variable path model using viral load (log base 10 transformed), depressive symptoms (square root transformed), physical functioning, general health, and overall QoL and no characteristics of the individual or environment, demonstrated a poor fit ($X^2 = 50.529$, df=6, $p < .001$, RMSEA = .222, CFI = .727, SRMR =.321). In addition to the results of hypothesis testing supporting poor model fit, the Root Mean Square Error of Approximation (RMSEA) was higher than the suggested maximum 0.10, the Comparative Fit Index (CFI) was lower than the suggested minimum 0.95, and the Standardized Root Mean Square Residual (SRMR) was higher than the suggested maximum 0.08 indicating a "poor fit" (Kline, 2011). All standardized paths in the model were significant (highest p-value, $p = .048$). The strongest standardized path coefficient was the path connecting physical functioning with general health ($\beta = .530$, $p < .001$).

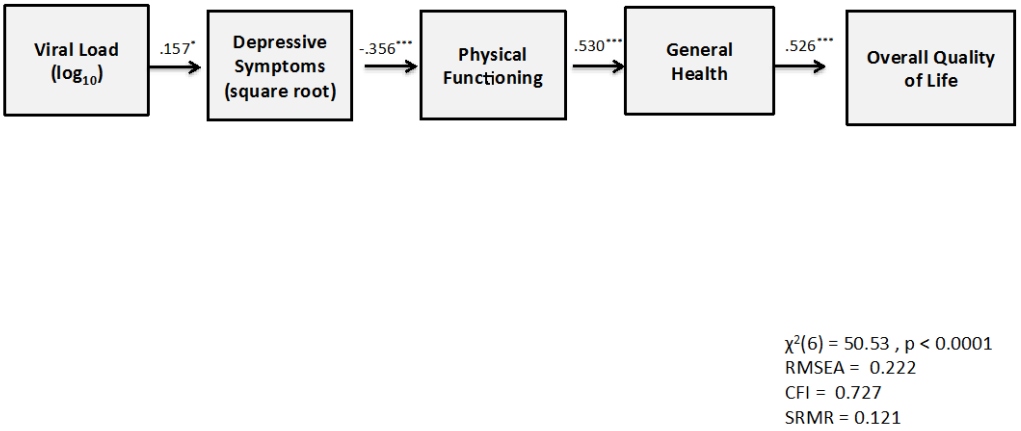

Figure 4. Main Observed Variable Path Model using Observed Variables

Based on the model modification indexes (MI), a path was added *post hoc* from depressive symptoms to general health (Figure 5). This modified model demonstrated an improved fit from the first model (X^2 = 10.598, df = 5, p = .060, RMSEA = .086, CFI = .966, SRMR = .043), with only the RMSEA exceeding the maximum suggested threshold for a "good fit". All paths in this modified model were significant (highest p-value, p = .048). The strongest standardized path coefficient was that of overall QoL on general health (β = .527, p < .001).

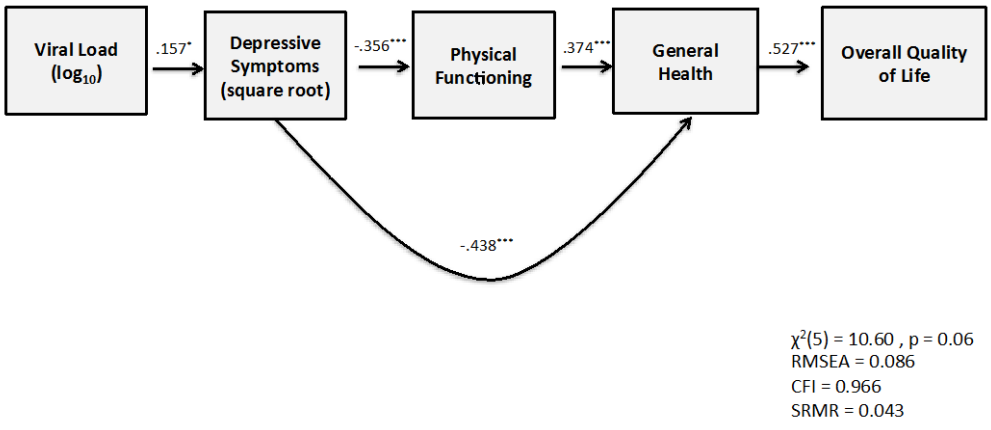

Figure 5. Modified Main Observed Variable Path Model with a Path Added from Depressive Symptoms to General Health

The hybrid model included the observed variables of depressive symptoms, physical functioning, general health and overall QoL and the latent variable of biological function, which was measured by two observed variables, viral load and CD4 count (Figure 6). This model was poor fitting ($X^2 = 69.6$, df=9, $p < .001$, RMSEA = .194, CFI = .754, SRMR = .112); however, all paths, other than the path for depressive symptoms on biological function, were statistically significant ($p < 05$). The standardized path coefficient of general health on physical functioning had the strongest path coefficient in this model ($\beta = .564$, $p < .001$).

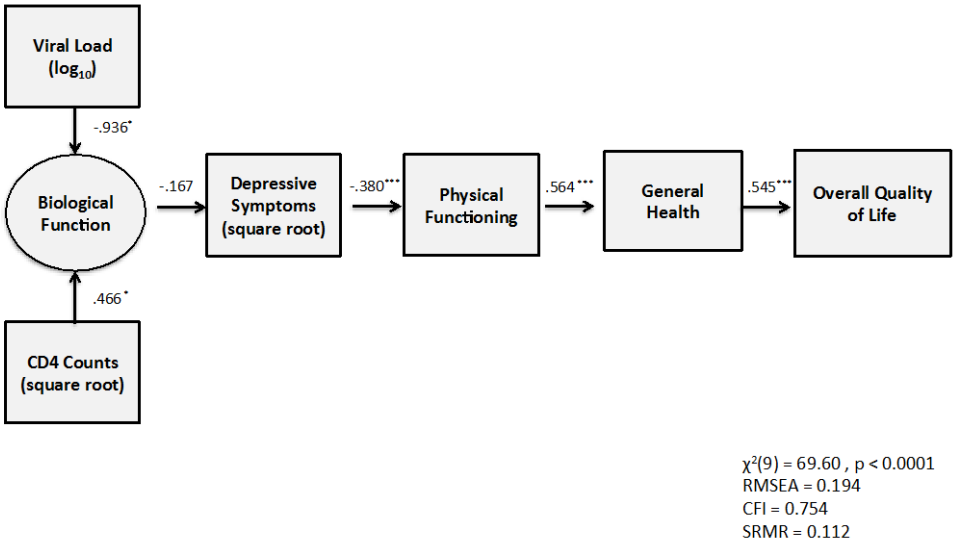

Figure 6. Main Path Model using Biological Function as a Latent Variable

This model was also modified *post hoc* based on MI and a path was added from depressive symptoms to general health (Figure 7). Again, this modified model did not fit well ($X^2 = 23.375$, df = 8, $p = .003$, RMSEA = .104, CFI = .938, SRMR = .052). All paths were significant other than the path from biological function to depressive

symptoms (p = .131). The strongest standardized path coefficient was again that for overall QoL on general health (β = .546, p < .001).

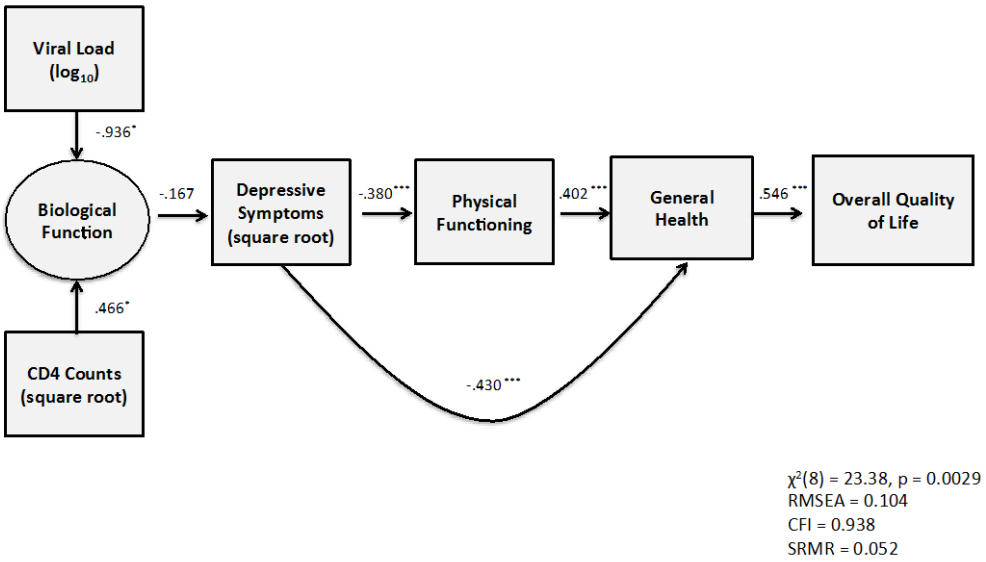

Figure 7. Modified Main Path Model using Biological Function as a Latent Variable and Adding a Path from Depressive Symptoms to General Health

Based on the MI, another model was created with two additional paths from depressive symptoms to general health and also from depressive symptoms to overall QoL (Figure 8). The RMSEA, the CFI, and the SRMR were all within the thresholds suggesting a good model fit (X^2 = 9.887, df = 7, p = .195, RMSEA = .048, CFI = .988, SRMR = .036). Only the standardized path coefficient from biological function to depressive symptoms was not significant (p = .131).

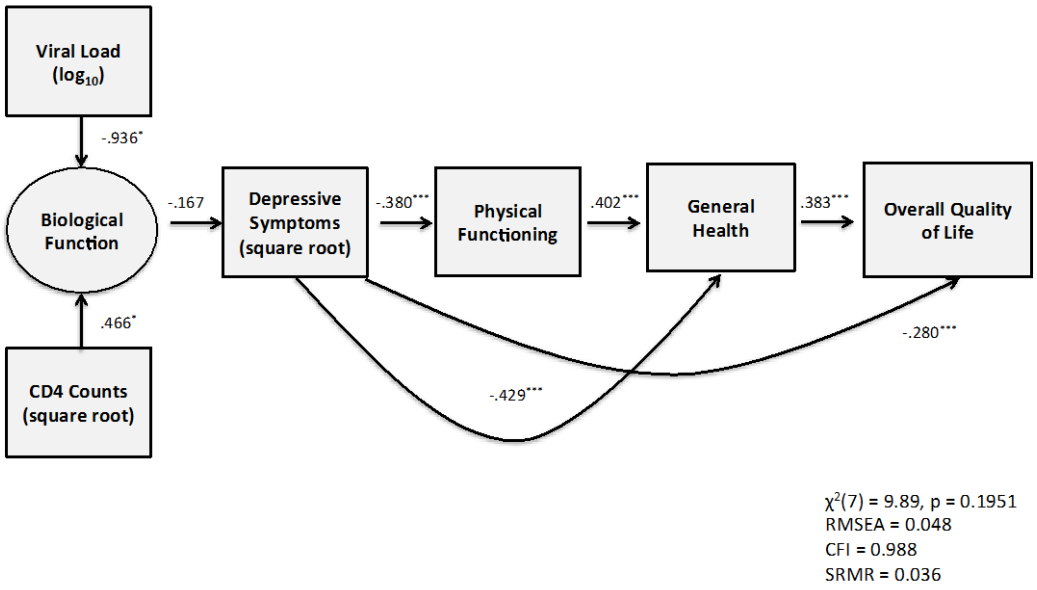

Figure 8. Modified Main Path Model with Biological Function as a Latent Variable and with Paths Added from Depressive Symptoms to General Health and to Overall Quality of Life

In Figure 9, individual characteristics (age, children, partnered, finished high school, and race) were simultaneously added to the original observed variable path model. In this figure, only statistically significant paths involving individual characteristics were reported, although all paths were included in the model. This model demonstrated a lack of fit ($X^2 = 63.8$, df = 6, $p < .001$, RMSEA = .233, CFI = .735, SRMR = .068), according to the chi-squared statistic, RMSEA, CFI, and the SRMR. Also, the only individual characteristic significantly contributing to the prediction of any of the main pathway components was age. Only the standardized path coefficient from age to viral load was statistically significant ($\gamma = -.169$, $p = .033$). The largest path coefficient in this model was from physical functioning to general health ($\beta = .565$, $p <$

.001). In this model, the path coefficient from viral load to depressive symptoms was not significant (γ = .196, p = .069).

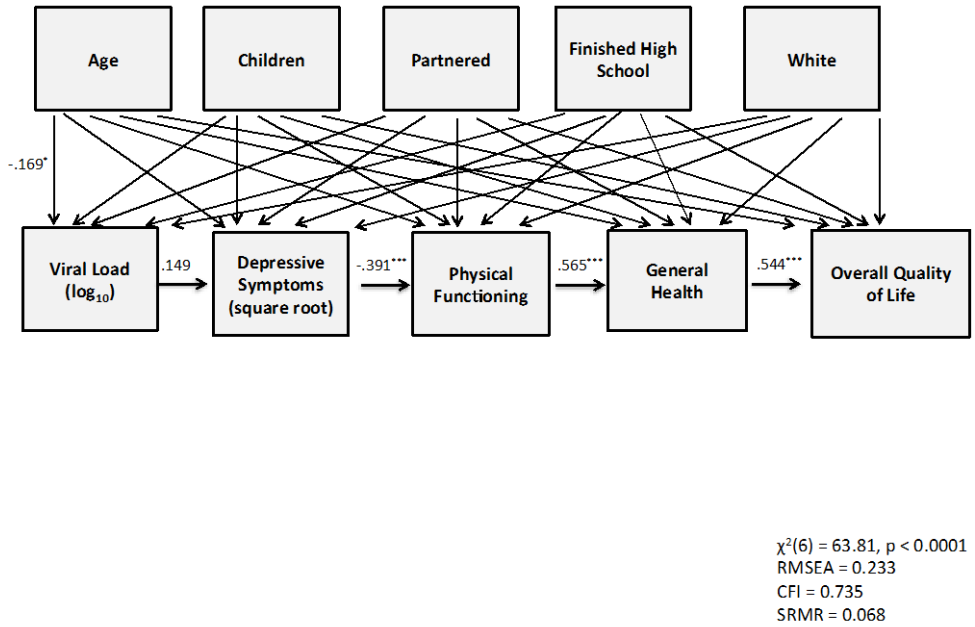

Figure 9. Observed Variable Main Path Model with Individual Characteristics

When the model was modified *post hoc* adding a path from depressive symptoms to general health (Figure 10) based on MI, the model fit improved (X^2 = 14.901, df = 5, p = .011, RMSEA = .105, CFI = .955, SRMR = .026) with only the chi-squared statistic and the RMSEA fit index suggesting a poor fit for the modified path model. The path between age and viral load remained significant (γ = -.169, p = .035). In this modified model, the strongest relation was general health predicting overall QoL (β = .545, p < .001).

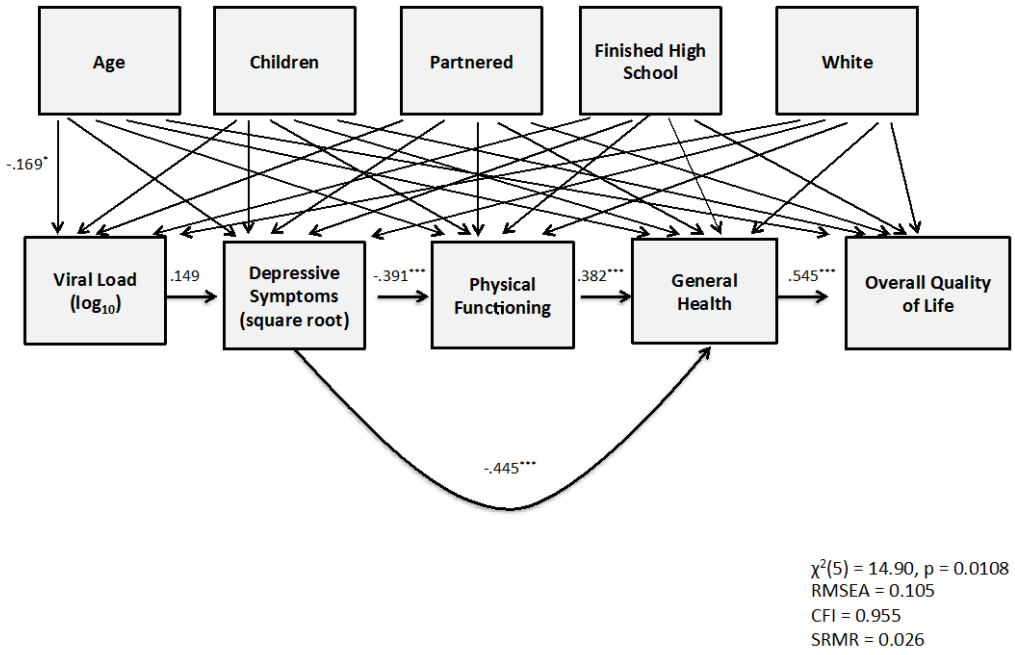

Figure 10. Modified Main Observed Variable Path Model with Individual Factors and a Path Added from Depressive Symptoms to General Health

In Figure 11, the environmental characteristics (social support and HIV stigma) were both added to the model of the observed variables: viral load, depressive symptoms, physical functioning, general health, and overall QoL. The SRMR indicated a good model fit; however, the chi-squared statistic, RMSEA and CFI did not ($X^2 = 25.41$, df = 6, $p < .001$, RMSEA = .138, CFI = .935, SRMR = .043). In this model, the paths for the environmental factors of social support and HIV-related stigma to either viral load or physical functioning were not significant. Also, the path from social support to general health was not significant. The only relationship in the main path that was not significant was between depressive symptoms and viral load ($\gamma = .046$, $p = .489$). The path coefficient from depressive symptoms to physical functioning was -.325 ($p < .001$). The strongest relation in this model was between physical functioning and general health

(β=.463, p < .001). The path between general health and overall QoL was .416 (p < .001).

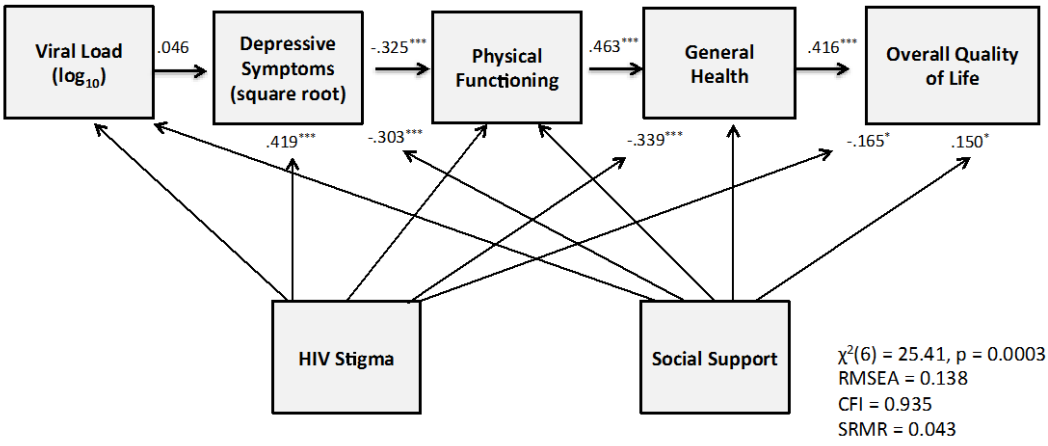

Figure 11. Main Observed Variable Path Model with Environmental Characteristics

Based on the modification indices, adding a path from depressive symptoms to general health (Figure 12) improved the overall model fit (X^2= 5.947, df = 5, p = .311, RMSEA = .033, CFI = .997, SRMR = .019) according to all the standard fit indices and the chi-squared test statistic. In this figure, only statistically significant paths involving environmental characteristics were reported, although all paths were included in the model. In this model, the paths between social support and depressive symptoms (β= -.303, p < .001) and overall QoL (β = .150, p = .034) were significant. HIV-related stigma had significant paths to every component other than viral load (p = .429) and physical functioning (p = .539).

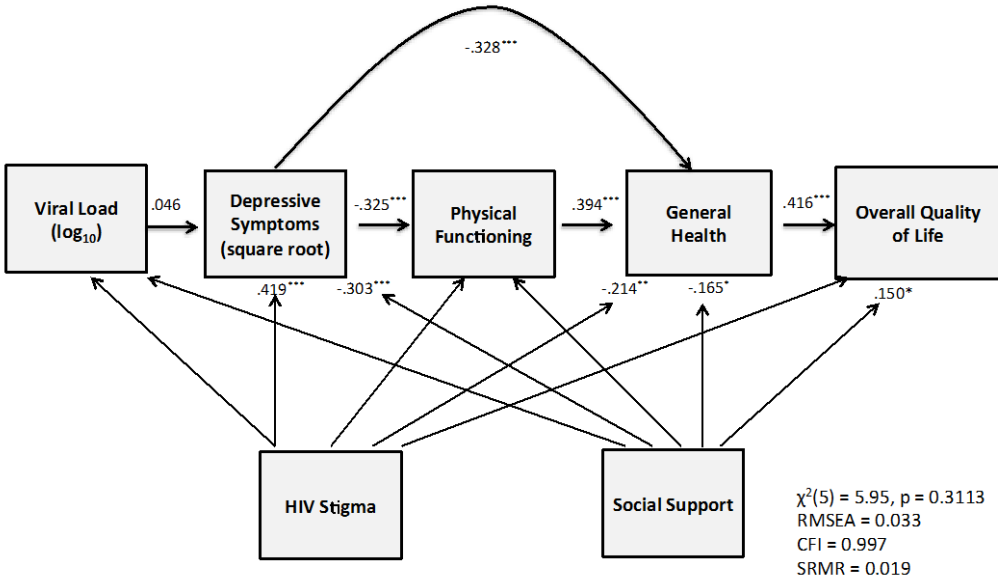

Figure 12. Modified Main Observed Variable Path Model with Environmental Characteristics and Path Added from Depressive Symptoms to General Health

The hybrid path model with the latent variable of biological function and including all of the individual factors (Figure 13) also did not fit well ($X^2 = 73.64$, df = 14, $p < .001$, RMSEA = .155, CFI = .762, SRMR = .068). There was a significant path between age and biological function ($\beta = .182$, $p = .045$) and a trend ($.05 \leq p < .10$) for the path from age to physical functioning ($\beta = -.129$, $p = .054$). There were also trends for the paths for physical functioning on both education ($\beta = .129$, $p = .057$) and race ($\beta = -.121$, $p = .075$).

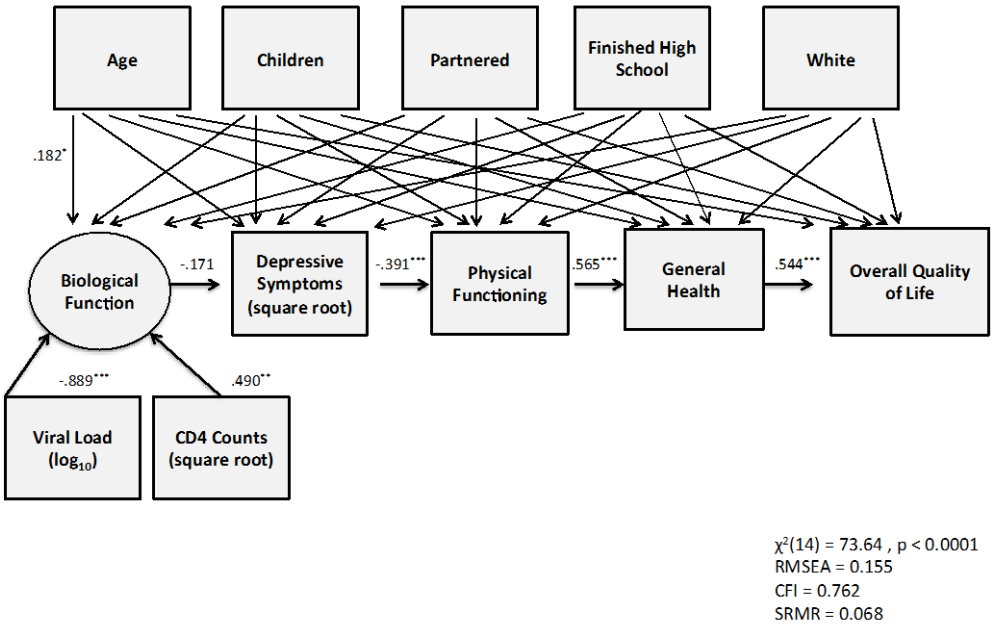

Figure 13. Main Path Model with Individual Characteristics and Biological Function as a Latent Variable

Figure 14 represents the model modified *post hoc* based on MI, where a path between depressive symptoms and general health was added to the path model including the latent variable of biological function and the remaining observed variables (depressive symptoms, physical functioning, general health, and QoL). While this model fit based on standard fit indices (X^2= 24.736, df = 13, p = .025, RMSEA = .071, CFI = .953, SRMR = .033), the only individual factor with a significant path was age, which related to biological function (γ = .182, p = .045).

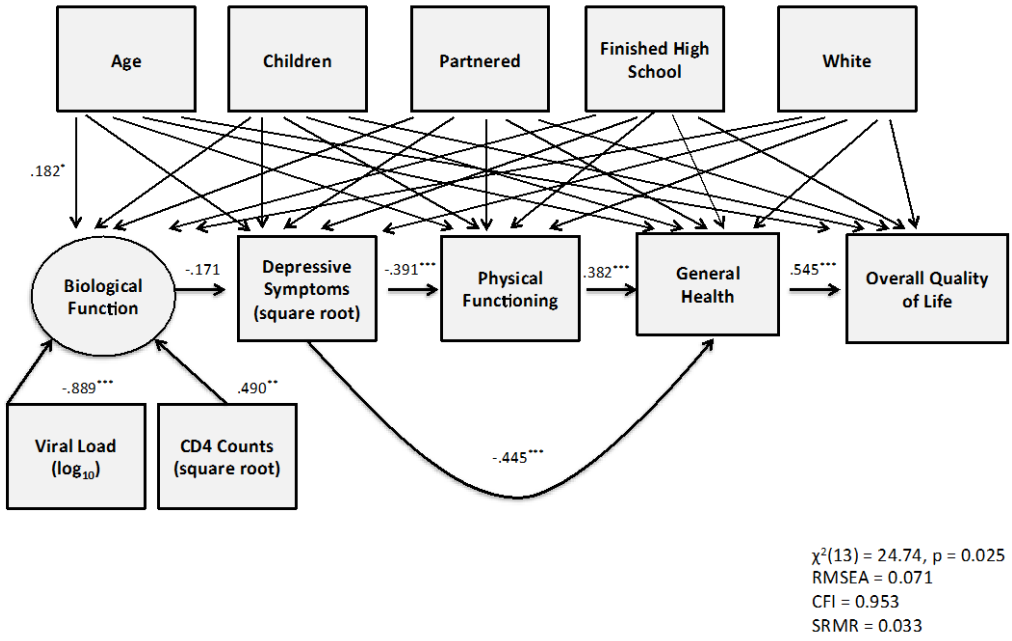

Figure 14. Modified Main Path Model with Individual Factors and Biological Function as a Latent Variable and Path Added from Depressive Symptoms to General Health

Figure 15 illustrates the hybrid path model where the environmental factors were simultaneously added. Only SRMR (.046) indicated that this model was a good fit (X^2 = 32.504, df = 11, p < .0001, RMSEA = .107, CFI = .934). The paths connecting social support and HIV-related stigma to depressive symptoms and QoL were significant. Also, the path connecting HIV-related stigma to general health was significant (γ = -.339, p < .001). The strongest path coefficient in this model connected general health and physical functioning (β = .463, p < .001).

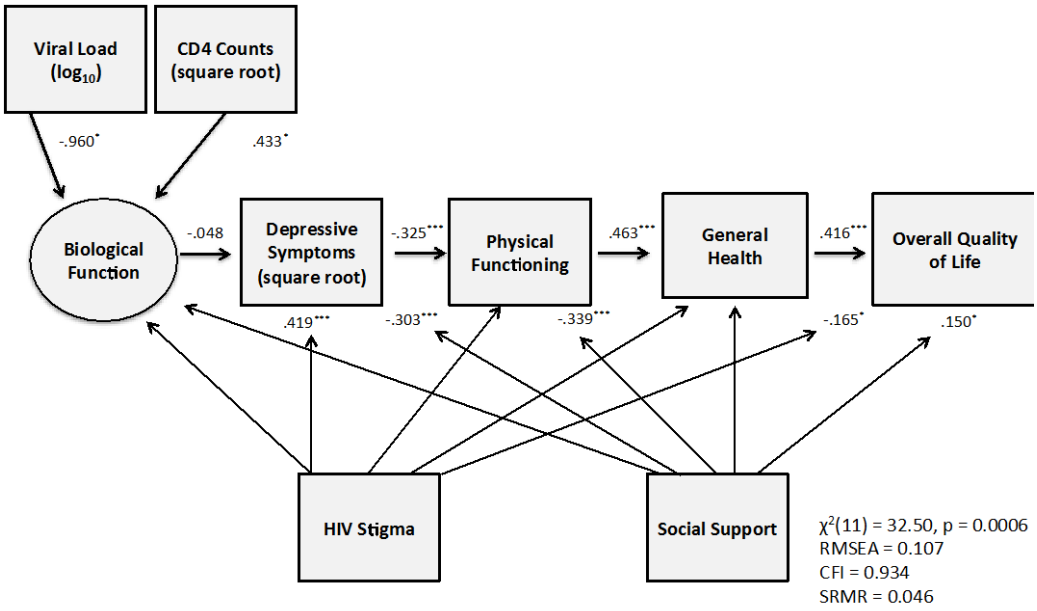

Figure 15. Main Path Model with Environmental Characteristics with Biological Function as a Latent Variable

Figure 16 illustrates another modified model, explored *post hoc* based on MI. A path from depressive symptoms to general health was added to the model that included environmental factors and biological function as a latent variable. The chi-squared test and all fit indices showed that this model had a good fit ($X^2 = 13.04$, df = 10, p = .221), RMSEA = .042, CFI = .991, SRMR = .029). In this model, both environmental factors had significant paths with depressive symptoms and overall QoL. Also, there was a significant path between HIV-related stigma and general health ($\gamma = -.214$, p = .002). The path added *post hoc* from general health to depressive symptoms was also significant ($\beta = -.238$, $p < .001$). In this model the strongest path coefficient represented the relation between HIV-related stigma and depressive symptoms ($\gamma = .419$, $p < .001$).

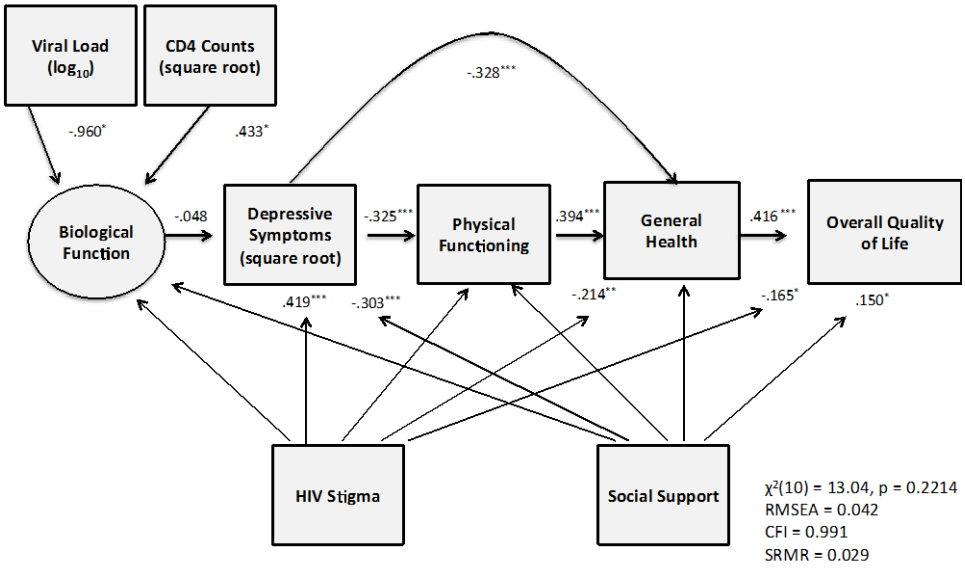

Figure 16. Modified Main Path Model with Environmental Characteristics with Biological Function as a Latent Variable and Path Added from Depressive Symptoms to General Health

The full observed variable path model including both individual and environmental characteristics (Figure 17) demonstrated a good fit according only to the SRMR ($X^2 = 26.635$, df = 6, $p < 0.001$, RMSEA =.142, CFI =.932, SRMR =.027). As for many of the previous models involving either individual or environmental characteristics, the path from age to viral load was the only significant path from the individual characteristics to the components of the main observed variable path model ($\gamma = -.176$, $p = .002$). Both environmental characteristics had significant paths only to depressive symptoms and QoL. Also, HIV-related stigma had a significant path to general health ($\gamma = -.471$, $p < .001$).

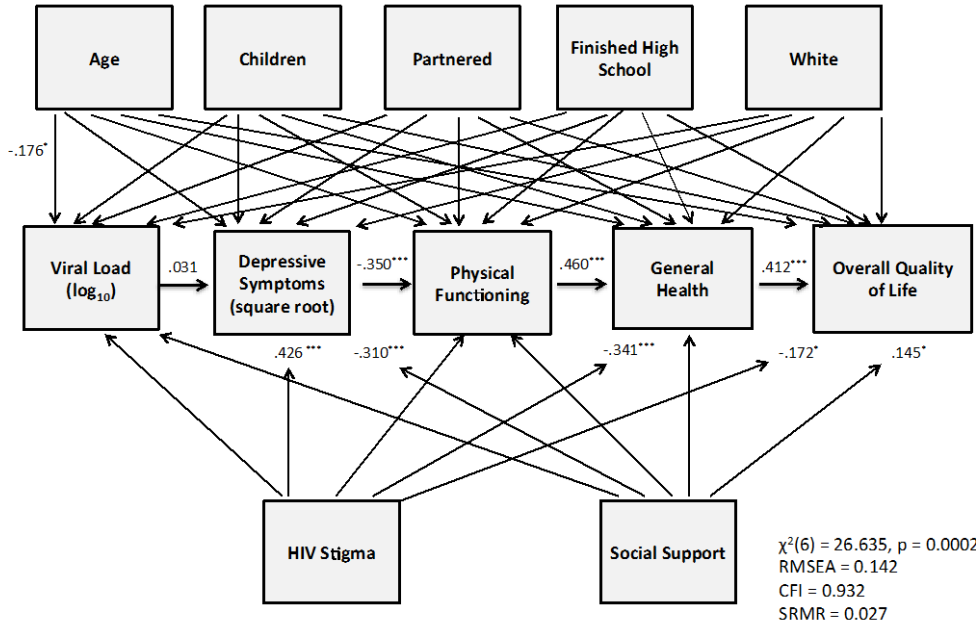

Figure 17. Main Observed Variable Path Model with Individual and Environmental Characteristics

Another *post hoc* modified model was explored based on MI, adding a path to this full, observed path model between depressive symptoms and general health (Figure 18). This modified model fit well according to the chi-squared test statistic and all fit statistics and indices ($X^2 = 5.04$, df = 5, p = .411, RMSEA = .007, CFI = 1.000, SRMR = .011). The added path from depressive symptoms to general health was significant ($\beta = -.349$, $p < .001$)

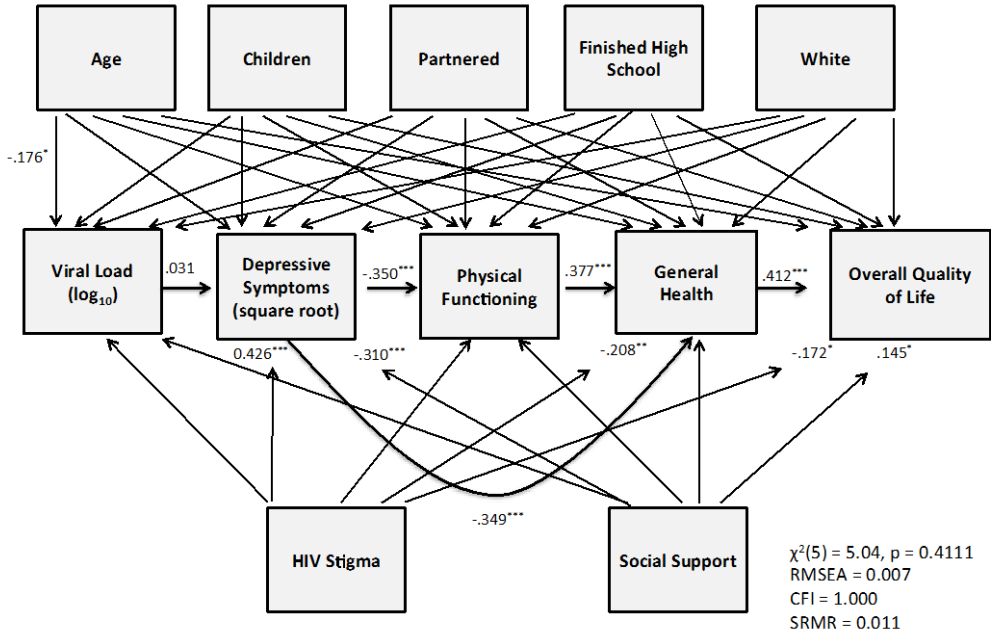

Figure 18. Modified Main Observed Variable Path Model with Individual and Environmental Characteristics and Path Added from Depressive Symptoms to General Health

Finally, a hybrid path model with all environmental and individual factors and biological function as the only latent variable was fit (Figure 19). This model

demonstrated a good fit based on only the SRMR index (X^2 = 35.50, df = 16, p = .003, RMSEA = .084, CFI = .941, SRMR = .031).

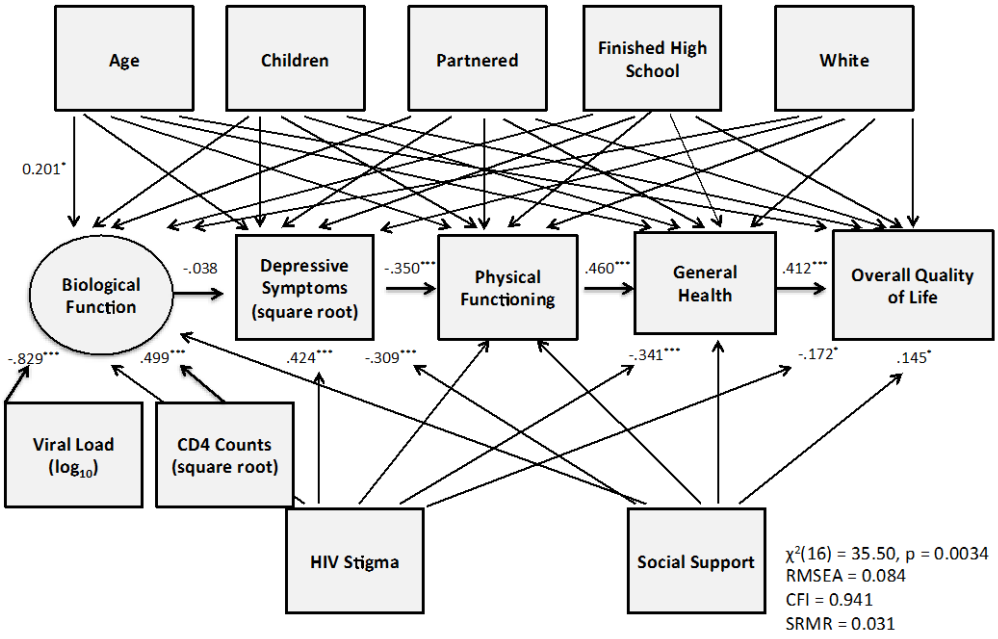

Figure 19. Main Path Model with Individual and Environmental Characteristics with Biological Function as a Latent Variable

Table 5. Structural Equation Model and Path Analysis Results

Model	N	RMSEA	CFI	SRMR	X^2	df	p
Main Path Model using Observed Variables	151	.222	.727	.121	50.5	6	<.0001
Modified Main Path Model with a Path Added from Depressive Symptoms to General Health	151	.086	.966	.043	10.6	5	.060
Main Path Model using Biological Function as a Latent Variable	178	.194	.754	.112	69.6	9	<.0001
Modified Main Path Model using Observed Variables and Biological Function as a Latent Variables with a Path Added from Depressive Symptoms to General Health	178	.104	.938	.052	23.4	8	.003
Modified Main Path Model using Observed Variables and Biological Function as a Latent Variable with Paths Added from Depressive Symptoms to General Health and from Depressive Symptoms to Overall Quality of Life	178	.048	.988	.036	9.9	7	.195
Main Path Model using Observed Variables with Individual Characteristics	178	.233	.735	.068	63.8	6	<.0001
Modified Main Path Model using Observed Variables with Individual Characteristics with a Path Added from Depressive Symptoms to General Health	178	.105	.955	.026	14.9	5	.011
Main Path Model using Observed Variables with Environmental Characteristics	171	.138	.935	.043	25.4	6	<.001
Modified Main Path Model using Observed Variables with Environmental Characteristics with a Path Added from Depressive Symptoms to General Health	171	.033	.997	.019	5.9	5	.311
Main Path Model using Observed Variables and Biological Function as a Latent Variable with Individual Characteristics	178	.155	.762	.068	73.6	14	<.0001
Modified Main Path Model using Observed Variables with Individual Characteristics and Biological Function as a Latent Variable with a Path Added	178	.071	.953	.033	24.7	13	.025

from Depressive Symptoms to General Health							
Main Path Model using Observed Variables and Biological Function as a Latent Variable with Environmental Characteristics	171	.107	.934	.046	32.5	11	<.001
Modified Main Path Model using Observed Variables and Biological Function as a Latent Variable with Environmental Characteristics and a Path Added from Depressive Symptoms to General Health	171	.042	.991	.029	13.04	10	.221
Main Path Model using Observed Variables with Individual and Environmental Characteristics	171	.142	.932	.027	26.6	6	<.001
Modified Main Path Model using Observed Variables with Individual and Environmental Characteristics and a Path Added from Depressive Symptoms to General Health	171	.007	1.00	.011	5.0	5	.411
Main Path Model using Observed Variables and Biological Function as a Latent Variable with Individual and Environmental Characteristics	171	.084	.941	.031	35.5	16	.003
RMSEA: Root Mean Square Error of Approximation CFI: Comparison Fit Index SRMR: Standardized Mean Square Residual							

4.5.2 Strength of Relationships

The main aims of this study were focused on testing the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005) in women with HIV. The primary aim was to examine the relationships among the five central components of the model (biological function, symptoms, functional status, general health perceptions, overall QoL). The secondary aim was to examine the relationships among the individual (i.e. age, children, race, marital status, education) and environmental (i.e. HIV-related stigma, social support) characteristics that may impact biological function, symptoms, functional status, general

health perceptions, and overall QoL among women living with HIV infection. Although many models were explored in the previous section, only the observed variable path models will be described here because they adequately address the research aims. The main path model (Figure 5) with paths connecting viral load, depressive symptoms, physical functioning, overall general health, and overall QoL addressed the primary aim. The secondary aim was addressed using the full, observed variable path model (Figure 17) including all of the individual characteristics and environmental characteristics.

In the model assessing only the main path among the five components (Figure 4), all of the path coefficients were significant. The path between depressive symptoms and viral load was .157 ($p = .048$), indicating a relatively weak, positive relationship between biological function and symptoms. The path between physical functioning and depressive symptoms was slightly stronger and negative ($\beta = -.356$, $p < 0.001$). The strongest path coefficient in the model connected overall general health with physical functioning ($\beta = .530$, $p < .001$), indicating a moderate positive relationship between general health and functional status. The last path in this model demonstrated a moderate positive relationship between overall QoL and general health ($\beta = .526$, $p < .001$).

In the *post hoc* modified model with a path added from depressive symptoms to overall general health, the path coefficients remained nearly the same (Figure 5). In this model, however, the strongest path coefficient connected overall general with overall QoL ($\beta = .527$, $p < .001$). The path coefficient between depressive symptoms and overall general health indicated a moderate, negative relationship ($\beta = -.438$, $p < .001$).

In the full path model (Figure 17) including individual and environmental characteristics, many path coefficients were not statistically significant. The main path in

this model was similar to the previous model (with only the five main components); however, the relationship between depressive symptoms and viral load was not significant ($\gamma = .031$, $p = .656$). The path coefficient between physical functioning and depressive symptoms was -.350 ($p < .001$), indicating a significant weak to moderate negative association between functional status and symptoms. Again, the strongest path coefficient in the model was between general health and physical functioning and was positive ($\beta = .460$, $p < .001$). Overall QoL and general health shared a moderately strong positive path coefficient of .412 ($p < .001$).

The only significant path coefficient in this model that connected any of the individual factors to the main components was the path between age and viral load; this was a weak, negative relationship ($\gamma = -.176$, $p = .027$). There were, however, several path trends between demographic variables and the main model components. Path coefficients connecting physical functioning with age ($\gamma = -.118$, $p = .087$), children ($\gamma = -.121$, $p = .08$), education ($\gamma = .130$, $p = .058$), and race ($\gamma = -.129$, $p = .065$) all with p-values less than 0.10. There was also a path trend between overall QoL and whether or not a woman was partnered ($\gamma = .104$, $p = .090$).

While many path coefficients between environmental factors and the main components in the model were significant, the strongest paths were linked to depressive symptoms. Depressive symptoms shared a moderately strong positive path coefficient ($\gamma = .426$, $p < .001$) with HIV-related stigma and a moderately negative path coefficient ($\gamma = -.310$, $p < .001$) with social support. Path coefficients connecting overall QoL and environmental factors were weak. The path between overall QoL and HIV-related stigma was weak and negative ($\gamma = -.172$, $p = .023$), while the path between overall QoL and

social support was weak and positive ($\gamma = .145$, $p = .039$). While there was no significant path between general health and social support, the path coefficient between HIV-related stigma and general health was moderately strong and negative ($\gamma = -.341$, $p < .001$).

In the *post hoc* modified model with both environmental and individual characteristics and a path added from depressive symptoms to overall general health, the path coefficients did not significantly change. While in the previous model (not modified), there was a significant pathway coefficient connecting age and viral load, this relationship was not present in the modified model. The strongest path coefficient in the main components of the model was the relationship between overall QoL and overall general health ($\beta = .412$, $p < .001$). Of all the environmental and individual characteristics, the pathway connecting HIV-related stigma and depressive symptoms was the strongest ($\gamma = .426$, $p < .001$). Finally, the path coefficient of depressive symptoms and overall general health was moderately negative ($\beta = -.349$, $p < .001$), implying that increased depressive symptoms are associated with decreased overall general health.

5.0 SUMMARY AND CONCLUSIONS

This chapter presents a summary of the findings from this study. Interpretation and discussion of the results, conclusions, and implications for nursing research are also addressed in this section.

5.1 STUDY SUMMARY

The current study was a secondary analysis using a cross-sectional, correlational research design to test the revised Wilson and Clearly model of health-related quality of life (HRQoL) (Ferrans et al., 2005) in women living with HIV/AIDS in western Pennsylvania and eastern Ohio. This study used baseline data pooled from two independent randomized controlled trials (R01 NR04749, *Adherence to Protease Inhibitors and Quality of Life*, and 2R01 NR04749, *Improving Adherence to Antiretroviral Therapy*, Principal Investigator, J. A. Erlen). The first parent study tested the efficacy of a nurse-delivered, telephone-based, cognitive-behavioral program designed to enhance adherence to antiretroviral therapy (ART) in both men and women living with HIV from April 1999 to November 2002 (R01 NR04749, Principal Investigator, J. A. Erlen). Subjects were randomly assigned to one of two treatment groups: intervention plus usual care or usual care only. The main aim of this parent study was to test the efficacy of the structured intervention compared to usual care on ART adherence over time. The secondary aim of the study was to assess relationships among ART adherence, HRQoL, and clinical response.

The second parent study. a continuation of the first parent study (from March 2004 to March 2007), added an individualized intervention as a third treatment arm (2R01 NR04749, Principal Investigator, J. A. Erlen). As in the first parent study, participants were randomly assigned to one of three treatment groups: structured intervention, individualized intervention, and usual care (control). The primary aim of the second parent study was to test the efficacy of the structured and individual ART-adherence interventions compared to usual care over time. The secondary aim of that study, as in the first parent study, focused on examining the associations of ART adherence with clinical response and HRQoL.

The primary aim of the current study was to test the main path of the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). This model proposed directional relationships of five constructs: biological function, symptoms, functional status, general health perceptions, and the primary outcome variable, HRQoL. To operationalize this model biological function was measured using CD4 count and viral load. Symptoms were measured using depressive symptoms and energy/fatigue. Functional status was measured using physical and social functioning. General health perceptions was measured using overall general health and mental health. HRQoL was measured using overall QoL and satisfaction with life. The secondary aim of this study was to test the full revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005), adding environmental characteristics (HIV-related stigma and social support) and individual characteristics (age, race, education, children, and marital status). The sample included 178 unique women living with HIV/AIDS who participated in the parent studies.

In order to test the primary and secondary aims of the current study, structural equation modeling (SEM) and path analysis were performed. Bivariate correlations were assessed to test relationships among the variables in the model. Also, differences between the samples of the two parent studies were examined using the unpaired t-test for quantitative variables and the chi-square test for nominal variables. Results from these analyses showed that the two samples could be pooled.

5.2 DISCUSSION

5.2.1 Sample Characteristics

In this study, 106 of the women were African American (59.6%); 67 women were white (36.7%). According to the CDC, HIV diagnosis rates are highest for African American women. In 2010, 64% of newly infected women were African American and only 18% were white (CDC 2014b). The diagnosis rate of HIV in African American women (38.1 out of 100,000 women) is estimated to be 20 times that of white women (CDC 2015b). Previous studies have also included a large proportion of African American women. In studies conducted by Andrinopoulos et al. (2011) and Vyavaharkar et al. (2012), the participants were also mostly African American women (73% and 85.2% respectively).

The women in the current study were on average 42 years old, which was also congruent with previous studies. In a study by Logie et al. (2013), the average age of the 173 HIV/AIDS infected women who participated in this study was 40.7 years. Vyavaharkar et al. (2012) conducted a study using 399 female participants with HIV/AIDS; their mean age was 41.5 years.

Two-thirds of the women in the current study finished high school, which was similar to prior published reports. In two studies that included both men and women with HIV/AIDS, nearly three-quarters of the participants had a high school or higher level of education (Galvan et al., 2008; White et al., 2012). Of the women in the study by Logie et al. (2008), 69.4% had attained at least a high school education.

Only 24.2% of the women in this sample were partnered. Relationship status in this study was consistent with the sample of women in several other studies where less than 35% of women were married, in a relationship, or living with a partner (Logie et al., 2013; Vyavaharkar et al., 2012; White et al., 2012). The majority of the women who participated in this study had children (81.5%) but only 41% of these women had children living in their households. In the study by Logie et al. (2013), 67.9% of the women were caring for (or supporting) children. According to Abrefa-Gyan et al. (2015), people who have children and lower levels of social support have a lower QoL. In this study, only 17.4% of the women were employed. This finding is congruent with the literature, where several teams of researchers reported between 17% and 37% of women living with HIV/AIDS were employed (Messer et al., 2013; Psaros et al., 2012; Vyavarharkar et al., 2012; Webel & Higgins, 2012). Blalock et al. (2002) reported that people living with HIV who are employed have a significantly higher QoL than those that are unemployed.

5.2.2 Association of Variables

Prior to testing the primary and secondary aims focusing on the revised Wilson and Cleary model (Ferrans et al., 2005) of HRQoL, the bivariate relationships among the

components of the model were explored (see Table 3). As expected, women with better overall health and mental health had better HRQoL and satisfaction with life. Higher levels of functioning, both social and physical, were associated with higher overall general health and mental health. Women with higher physical and social functioning had better mental health and perceived general health. Higher levels of depressive symptoms and lower energy levels were associated with lower functioning. These findings support associations reported in the literature. For example, in a study assessing life satisfaction in HIV positive women in Nepal, Eller and Mahat (2007) showed that life satisfaction was positively associated with physical functioning, social functioning, and mental health. In another study assessing physical functioning, Clingerman (2003) showed that, in a sample of 70 men and 8 women, weekly vigorous activity duration was positively associated with overall health status. In a study with both men and women living with HIV/AIDS, White et al. (2012) found that people with higher levels of depressive symptoms had lower physical functioning. In a study on 278 women from the rural southeastern United States, Moneyham et al. (2005) showed that daily functioning was significantly and negatively associated with depressive symptoms.

Surprisingly, biological function was not associated with symptoms in this study. There was no relationship between CD4 count or viral load and depressive symptoms and energy/fatigue, which supports prior findings. Basavaraj et al. (2010) reported that CD4 count and viral load are associated with symptoms such as insomnia and pain. However, work by Barroso et al. (2010) showed that there is no significant association between physiological variables such as viral load or CD4 count and fatigue. A possible explanation could be that symptoms such as fatigue and pain are reflected at a later point

in time than when the blood samples are drawn for CD4 count and viral load. Changes in CD4 count and viral load may possibly predict symptoms that occur in the future. In this study, blood levels were obtained from patients' medical records or obtained through self-report. Therefore, CD4 count and viral load were not measured at the same time the self-report assessments were completed. Timing of the assessments could have been a factor in the lack of relationship demonstrated in this study between biological function and depressive symptoms and fatigue. Another explanation for the lack of relationships seen with depressive symptoms and fatigue could be that depressive symptoms and fatigue do not best describe "symptoms" for a woman living with HIV.

Greater social support was related to higher QoL, increased satisfaction with life, better general and mental health, improved physical and social functioning, less depressive symptoms, and higher energy levels in women in this study. These results are congruent with the findings in the literature that social support is an important factor in the overall health and QoL of a woman living with HIV/AIDS. The literature suggests that people living with HIV/AIDS who have better social support have higher HRQoL (Clingerman, 2003; Clum et al., 2009; Colbert et al., 2010; Cowdery & Pesa, 2002; Vyavaharkar et al., 2012; White et al., 2012). Women who have adequate support from family and friends might be more likely to adhere to drug treatment regimens, attend regular doctor appointments, and consequently their QoL might improve. Social support has also been shown to mediate the relationship between HIV symptoms and depressive symptoms in women living with HIV (Moneyham et al., 2005).

HIV-related stigma, on the other hand showed a negative association with a woman's overall health. Women with higher levels of HIV-related stigma had more

depressive symptoms, more fatigue, worse physical and social functioning, lower general and mental health, and decreased satisfaction with life and overall HRQoL. These findings support prior research where HIV-related stigma was shown to have a negative effect on many aspects of a woman's health such as higher levels of depression (Vyavaharkar et al., 2012; Logie et al., 2013) and lower levels of HRQoL (Vyavaharkar et al., 2012). Studies by both Logie et al. (2013) and White et al. (2012) demonstrated that HIV-related stigma is significantly positively associated with depression. Vyavaharkar et al. (2012) found that in rural women, there was a significant negative association between perceived and internalized stigma and QoL. Logie et al. (2013) used a revised version of the HIV-related stigma scale (which was used in the current study) (Berger et al., 2001), while White et al. (2012) and Vyavaharkar et al. (2012) used a perceived stigma scale (Sowell et al., 1997). Even though the researchers used different tools to assess stigma, the findings are similar.

5.2.3 Path Analysis

The primary aim of this study was to test the main path of the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). Structural equation modeling was employed to conduct an observed variable path analysis for the main five components of the conceptual model: biological function as identified by viral load, symptoms as depressive symptoms, functional status as physical functioning, general health perceptions as overall general health, and HRQoL as overall QoL. This observed variable path model did not demonstrate a good fit (Figure 4). However, the *post hoc* modified model that included an additional path from depressive symptoms to overall general health was a good fit

(Figure 5). While the modified model was exploratory and added *post hoc*, results confirmed hypothesized correlations among the variables that represented the five main components of the model as reported in the literature. The relationship between viral load and depressive symptoms was positive, indicating that women with higher viral loads had increased depressive symptoms. As expected, depressive symptoms and physical functioning had an inverse relationship; women with higher depressive symptoms exhibited lower physical functioning. Women who had greater physical functioning had better overall general health perceptions. Finally, as expected, women who reported higher general health perceptions reported higher overall QoL. In a study that combined 917 men and women (did not specify how many of each), Sousa et al. (2006) had similar results using a latent variable path SEM model to test the original Wilson and Cleary model (1995) of HRQoL. The analysis in the Sousa et al. (2006) study resulted in an exploratory *post hoc* modified path model with paths added from symptoms to both general health perceptions and overall QoL.

The secondary aim of this study was to test the entire revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005) by including the individual and environmental characteristics with the five main components. The full, observed path model (Figure 17) that considered individual factors (age, race, children, education, and marital status) and environmental factors (HIV-related stigma and social support) did not demonstrate a good fit. Again, a modified model with a good fit was generated *post hoc*, adding a path from depressive symptoms to overall general health (Figure 18). In this modified model, path coefficients yielded nearly the same results as in the previous model (the main observed path model with individual and environmental characteristics, Figure 17). The

only difference was that viral load did not have a significant path to depressive symptoms. In another study testing a modified version of the Wilson and Cleary model (1995) using 348 men and women, Vidrine et al. (2005) assessed behavioral factors and socio-economic factors as environmental and individual characteristics. While socio-economic status and behavior had significant associations with HRQoL, neither symptoms nor functional status had significant associations with HRQoL (Vidrine et al., 2005). The main path in the Vidrine et al. (2005) model was not consistent with the main path of the current study. The Vidrine et al. (2005) model, as stated previously, was a modified version of the original Wilson and Cleary (1995) model. In this modified model, the general health component was removed so that there was a direct path from functional status (role-specific) to QoL. Consequently, the main path consisted of: disease status, symptoms, role function, and generic QoL.

In the full, observed variable path model, paths from individual and environmental characteristics were assessed on each of the main components. The only demographic (individual) characteristic that had any relation with the main components of the model was age. Age and the biological factor viral load shared a significant negative path, indicating that the older a woman, the lower her viral load. A possible explanation for this finding could be that as women age, they become more concerned about their health and more responsible for their health-care regimens (i.e. taking medication and seeking help); however, there is very limited literature supporting a link between age and viral load. One study examining the association between age and viral load in 135 men and women living with HIV found that people who are older (greater than 50 years) have lower plasma viral load (Goodkin et al., 2004). Goodkin et al. (2004)

provided a possible explanation, stating that immunological differences between age groups could be the cause of the different viral load levels. These researchers also showed that older people had higher CD4 count than those who were younger (Goodkin et al., 2004). This study did not specifically examine this relationship in women.

While both environmental factors (HIV-related stigma and social support) were found to relate to depressive symptoms and overall QoL, they had no relationship with either viral load or physical functioning. Also, HIV-related stigma had a negative relationship with overall general health. There was no significant path coefficient between social support and overall general health. HIV-related stigma and social support may have a greater influence on a woman's emotional and psychological well-being as opposed to her physical well-being. As expected and as reported in the literature, HIV-related stigma had a negative association with general health perceptions and overall QoL (Vyavaharkar et al., 2012), while social support was positively associated with these variables (Cowdery & Pesa, 2002; Vyavaharkar et al., 2012). Vyavaharkar et al. (2012) showed that in a sample of rural women with HIV, both perceived and internal stigma had a negative association with QoL and perceived social support had a positive association with QoL. Cowdery and Pesa (2002) found that social support had a positive association with both mental health and general health perceptions in women living with HIV. Social support was found to be the strongest predictor of mental health scores (Cowdery and Pesa, 2002). In the current study, social support had the strongest relationship with mental health ($r = .642$, $p < .01$).

While the proposed observed path models created for both the primary and secondary aims of this study did not adequately fit, the modified path models are consistent

with Wilson and Cleary's original conceptual model of HRQoL (1995); however, in the modified path models, many path coefficients lacked statistical significance. Although the diagram depicts only paths from one component to the next, according to Wilson and Cleary, the factors in the models can have relationships "at every level of the model, although they are not represented in the Figure" (Wilson and Cleary, 1995, p. 63). To support that statement, this study demonstrated that the addition of the path from depressive symptoms to overall general health in both the main path model (Figure 5) and the full model (Figure 18) indicates that depressive symptoms not only are significantly related to a woman's functioning, but may also be related to a woman's overall general health. The literature has also shown that higher levels of depressive symptoms contribute to a lower QoL (Basavaraj et al., 2010; Holtz et al., 2014; Vyavaharkar et al., 2012).

5.3 LIMITATIONS

There were several limitations to this study. First, the fact that this was a secondary analysis raised several issues. The first issue was the timeframe of the parent studies. The first parent study began in 1999 and ended in 2002 and the second parent study started five years later in 2004 and ended in 2007.. This time span could have contributed to significant differences between the samples of women due to advances in drug treatment therapy. Therefore, the samples of the two studies were carefully examined prior to this secondary analysis to confirm that the data from the studies could be pooled. At the outset, the second parent study had a larger proportion of female African American participants (11% more). Also, participants in the second study were

slightly older than the first (3.7 year difference between the means). HIV-related stigma was slightly higher ($p = .057$) in the second study than in the first. All means of the variables were similar between the two studies (there were no significant differences between means of the two parent studies for any other measure of interest). The samples from the two parent studies were too small for a multiple sample approach.

Another possible limitation could have stemmed from the fact that subjects were recruited from the community; therefore, the investigators were not able to access medical records when subjects were not recruited directly from clinics. This inability to access records contributed to the incomplete data for biological function (viral load and CD4 count) even though there was an attempt to collect these data from the participants via self-report. Because this was a secondary analysis, measures were limited to the instruments used in the parent study. For example, the MOS-HIV scale was used for several of the observed variables in the model: energy/fatigue for symptoms, social and physical functioning, overall general health and mental health for general health perceptions, and overall QoL. Recall that the original measurement model proposed for this study was problematic. There were issues concerning several of the latent variables. It is possible that selecting different instruments might better represent these theoretical constructs. An alternative instrument used in the literature to measure symptoms is the Revised Sign and Symptom Check-list for HIV (SSC-HIVrev) (Holzemer et al., 2001). There is also an alternative instrument used to measure HRQoL called the Chronic Illness Quality of Life Ladder (CIQOLL). This instrument has several subscales including but not limited to physical and emotional domains and also has a time element (present, past, future, and life before diagnosis of HIV) (Murdaugh et al., 2006).

This study used a cross-sectional research design, and only included the baseline data for each of the measures. Cross-sectional designs are limited because causation cannot be established between the variables. Additionally, changes over time in the variables cannot be assessed. Even though there was a time lapse between the two parent studies, the women who participated in both studies had prior exposure to and completed the same instruments used for analysis in the current study. It is possible that women who participated in both studies were sensitized to the measure. Since only the most recent responses (from the second parent study) were used in the current study, there could be some bias for the responses for women who repeated the study. The most significant limitation of this study was the sample size. Only 178 unique women participated in the two parent studies; if a woman was eligible and participated in both studies, only her data from the most recent measures were used in this analysis. This total number of subjects was not an adequate sample size for the latent variable path analysis proposed to address the two research aims. A minimum of 280 subjects would have been needed to test the primary aim. Lastly, the sample of this secondary analysis was limited to women in western Pennsylvania and eastern Ohio and may not be generalizable to other populations of women living with HIV/AIDS, nationally and internationally. In 2010, 64% of newly infected women in the United States were African Americans, 18% were Whites, and 15% were Hispanics/Latinas (CDC, 2014b). In this sample, only 5.1% of the women were Latinas. This could be attributed to the region from which the women were sampled.

5.4 IMPLICATIONS

Further research focused on assessing the relationships among a woman's HRQoL and other health constructs (such as depression, mental health, pain, energy levels, coping, risk behavior, functioning, and worry) would contribute to the field of nursing and healthcare. Such research would need to involve examining these relationships temporally, using a longitudinal study approach as opposed to a cross-sectional analysis. A study with a longitudinal design assessing HRQoL constructs over time would help to clarify causation. Further research expanding the regions from which the sample is drawn would help to confirm that the revised Wilson and Cleary (Ferrans et al., 2005) model of HRQoL can be generalized. This approach would suggest a need for a multi-site study. Based on the findings of the current study, future studies might also benefit by using different instruments, such as the Revised Sign and Symptom Check-list for HIV (SSC-HIVrev) for symptoms or the Chronic Illness Quality of Life Ladder (CIQOLL) for HRQoL. Finally, the selection of different observed variables to represent the theoretical constructs might better represent the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). Based on the *post hoc* modified models in this study, paths were created relating depressive symptoms to overall general health. It is possible that depressive symptoms reflect a woman's emotional or psychological well-being more so than they represent a woman's biological or physiological symptoms. Depressive symptoms were more strongly correlated with both mental health ($r = -.734$, $p < .01$) and overall general health ($r = -.558$, $p < .01$) than they were with energy/fatigue ($r = -.557$, p

< .01). An alternative measurement model might include depressive symptoms within the latent construct of overall general health perceptions. Testing the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005) using a larger, more diverse sample of women from a broader geographic region over a specified period of time has the potential to yield important findings for healthcare providers and researchers.

Depressive symptoms were identified as an important factor in a woman's physical health and general health perceptions. The strong relationship between depressive symptoms and a woman's HRQoL was also reflected in the literature (Andrinopoulos et al., 2011; Holtz et al., 2014; Vyavaharkar et al. 2011). Since the women in this study with lower depressive symptoms had both higher physical functioning and better overall general health, designing and testing interventions to alleviate depressive symptoms need to be developed. In a study in Thailand focused on 127 pregnant adult women, high self-esteem, high emotional support and low physical symptoms were associated with lower levels of depressive symptoms (Ross et al., 2009). Based on the positive association of social support and negative association of HIV-related stigma on depressive symptoms, developing and testing programs to increase social support and decrease HIV-related stigma may decrease symptoms of depression and consequently improve a woman's HRQoL. More research is needed to explore the physical and psychosocial aspects that influence the HRQoL of women living with HIV/AIDS in the United States. Confirmation of these relationships can provide direction for additional future research.

5.5 CONCLUSION

The primary focus of this study was to test the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005) on women living with HIV/AIDS. The original Wilson and Cleary model of HRQoL (1995) has been tested on people (men and women) living with HIV/AIDS (Sousa et al., 2006; Vidrine et al., 2005); however, prior to this study the revised model had not yet been assessed for only women living with HIV/AIDS. Despite its limitations, the findings from this study suggest that the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005), with a *post hoc* modification connecting symptoms to general health perceptions, has been supported in a sample of HIV-infected women from western Pennsylvania and eastern Ohio. While the full, modified model fit, evidence from this study suggests that individual characteristics do not have an influence (based on the lack of significant path coefficients) on components of HRQoL in women living with HIV. On the other hand, results from this study suggest that environmental characteristics do have an influence on a woman's HRQoL. Based on this study, many health-related components contribute either positively or negatively to a woman's HRQoL. Women with lower viral loads, lower depressive symptoms, lower HIV-related stigma, higher social support, higher physical functioning, and higher overall general health had higher overall HRQoL.

APPENDIX A: IRB Exemption Approval

Memorandum

To: Nahed Alsayed
From: IRB Office
Date: 6/15/2015
IRB#: PRO15030443
Subject: Testing a Model of Health-Related Quality of Life in Women Living with HIV

The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section

45 CFR 46.101(b)(4)

APPENDIX B: Figure Permissions

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Licensed Content Date	Nov 10, 2005
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