HIV-INFECTED WOMEN WHO DO AND DO NOT REPORT INTIMATE PARTNER VIOLENCE: VIRAL REPLICATION AND ADHERENCE TO ANTIRETROVIRAL MEDICATIONS

A DISSERTATION

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To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Debra Trimble entitled "HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence: Viral Replication and Adherence to Antiretroviral Medications." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing Science.

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DEDICATION

Many HIV-infected persons locally and world-wide have profoundly changed the trajectory of my professional life and deeply influenced my personal life. Milagros was the name of my first HIV-infected patient. It was her story and situation that stimulated my desire and passion to provide care for those infected with HIV. This work is dedicated to all of you who have allowed me the privilege of providing your care—especially Milagros. Until there is a cure…I will believe in a miracle that ends HIV and violence against those infected.

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ABSTRACT

DEBRA TRIMBLE

HIV-INFECTED WOMEN WHO DO AND DO NOT REPORT INTIMATE PARTNER VIOLENCE: VIRAL REPLICATION AND ADHERENCE TO ANTIRETROVIRAL MEDICATIONS

DECEMBER 2010

Accounting for one-half of all new infections worldwide, women are the fastest growing group newly infected with HIV. Intimate partner violence affects 50% or more women worldwide with associated effects on morbidity and mortality. An intersection between HIV infection and intimate partner violence among women has been established. Yet research specifying the associated health effects of the intersection is lacking. No published studies examining the relationship between intimate partner violence, viral replication and adherence to antiretroviral medications among HIV-infected women were identified.

This research examined antiretroviral adherence and viral replication among HIV-infected women who did and did not report intimate partner violence. This non-experimental, comparative descriptive study recruited 272 HIV-infected women who had received health care for the previous 12 months at a publically-funded HIV specialty clinic. Participants were interviewed using the Severity of Violence Against Women Scale (SVAWS), the Danger Assessment (DA) and the Domestic Violence Specific

Morisky Medication Adherence Scale. Viral load values were obtained by medical record abstraction.

The first hypothesis, that HIV-infected women who reported intimate partner violence would have lower adherence scale scores compared to women who did not report violence in the previous 12 months, was tested using the *t* test for independent samples. Fisher's Exact test was used for testing the second hypothesis that HIV-infected women who reported intimate partner violence in the past 12 months would have a greater proportion of detectable viral replication compared to women who did not report intimate partner violence. Hypotheses three and four, that SVAWS and DA total scores would be inversely correlated with medication adherence scores, were tested with Pearson's *r* correlations. Analyses found HIV-infected women who reported intimate partner violence in the past 12 months had significantly lower adherence scores $t(262.1) = 4.91$, $p < .001$) and significantly greater proportions of detectable viral replication compared to women who did not report intimate partner violence (Fisher's Exact $p < .001$). No significant associations were found between total SVAWS and DA scores and the adherence scores of the HIV-infected women who reported intimate partner violence in the past 12 months.

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CHAPTER I

INTRODUCTION

Intimate partner violence and human immunodeficiency virus (HIV) infection affect millions of women globally. Intimate partner violence, both physical and sexual, has emerged as a global public health concern (Afifi, et al., 2008; Garcia-Moreno, Jansen, Ellsberg, Heise, & Watts, 2006). While intimate partner violence and HIV can each affect both genders, women are disproportionately affected (Breiding, Black & Ryan, 2008; Joint United Nations Programme on HIV/AIDS ([UNAIDS], 2008; Centers for Disease Control and Prevention [CDC], 2009). New HIV infections are occurring at an alarming rate. Women have become the fastest growing group among people newly infected with HIV, accounting for more than one-half of all the HIV infections worldwide (UNAIDS, 2008). Women living with HIV worldwide numbered 15.4 million in 2007, with the United States (U. S.) being one of the countries with large numbers of cases in the world (UNAIDS, 2008). Over 201,000 cumulative cases of HIV have been reported in female adults and adolescents in the U. S. and dependent areas (CDC, 2008). Females are at higher risk than males to be victims of physical partner violence, childhood sexual abuse and adult sexual abuse. Each year women experience approximately 4.8 million partner related physical and sexual assaults where men experience about 2.9 million partner related physical assaults (CDC, 2009). Over 1500 deaths related to partner violence occurred in 2005; 78% were females (CDC, 2009).

HIV is now considered a chronic, treatable illness. However, adherence to antiretroviral therapy medications is essential for controlling viral replication, preventing further immunosuppression and progression of HIV disease to acquired immunodeficiency syndrome (AIDS) or death (Atkinson & Petrozzino, 2009; Branson & McDougal, 2008; Lopez, Jones, Villar-Loubet, Arheart & Weiss, 2010). The presence of both intimate partner violence and HIV in a woman's life has been shown to lead to more adverse health outcomes (Marfrin-Ledet & Porche, 2003). Previous research has suggested that stressful life events, post-traumatic stress and depression—all possible consequences of intimate partner violence—can lead to poorer treatment adherence and disease progression (Antelman et al., 2007; Delahanty, Bogart, & Figler, 2004; Boarts, Sledjeski, Bogart, & Delahanty, 2006). Furthermore, more severe violence against women has been shown to negatively correlate with adherence to HIV medication (Lopez, 2010).

Problem of Study

The World Health Organization and Global Coalition on Women and HIV/AIDS (2004) describes an intersection between intimate partner violence and HIV infection in women as follows: 1) direct transmission of HIV through sexual violence; 2) indirect transmission of HIV through sexual risk-taking; 3) indirect transmission of HIV through inability to negotiate condom use; 4) indirect transmission of HIV by partnering with men at higher risk of HIV infection; 5) violence as a consequence of being HIV-positive. While an understanding of this intersection is important in the development of effective interventions for HIV prevention and violence against women, there is little research that

documents an association between recent partner violence and HIV medication adherence. The purpose of this study was to enhance understanding about antiretroviral adherence among women who are HIV-infected and experience recent partner violence. Specifically, this study examined antiretroviral adherence as measured by the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, Ang, Krousel-Wood, & Ward, 2008) and viral replication as measured by HIV RNA reverse-transcriptase polymerase chain reaction (RT-PCR), known as the viral load laboratory value, among English and Spanish-speaking HIV-infected women who did and did not report intimate partner violence and who attended a primary care facility for women with HIV.

Rationale for the Study

Campbell and colleagues' (2008) systematic review illuminated a need for research that further investigates the effects of partner violence and HIV-infection in women. The United Nations Millenium Development Goals include both the promotion of gender equality and empowerment of women as well as the target of halting and reversing the spread of HIV by 2015 (United Nations Development Programme, 2007). Proposed objectives for Healthy People 2020 include reducing numbers of HIV cases that progress to AIDS and reducing deaths due to HIV infection (U. S. Department of Health and Human Services, 2009). These goals require effective interventions based on further research addressing the association between intimate partner violence and antiretroviral adherence among HIV-infected women. There is a paucity of such research. No published reports were identified that describe antiretroviral adherence among HIV-infected women who report intimate partner violence. This study was proposed to close

the gap in literature and provide information that could contribute to the development of interventions that facilitate antiretroviral adherence among HIV-infected women who experience intimate partner violence.

Theoretical Framework

The Betty Neuman Systems Model (Neuman & Young, 1972) guided the study. Neuman's model provided the best framework for this research examining the relationship of experiences or behaviors and health, specifically intimate partner violence and effects on the health of the HIV-infected woman. Additionally, Neuman's model, which has been used across cultures, was found to be ideal for this population of women.

Neuman views the person as whole, but at the same time as an open system, experiencing and reacting to personal and environmental influences. The model at the most simplistic level is two components—stress and reaction to stress (Neuman, 1982). A representation of the Neuman Systems Model adapted for this study is presented in Figure 1.

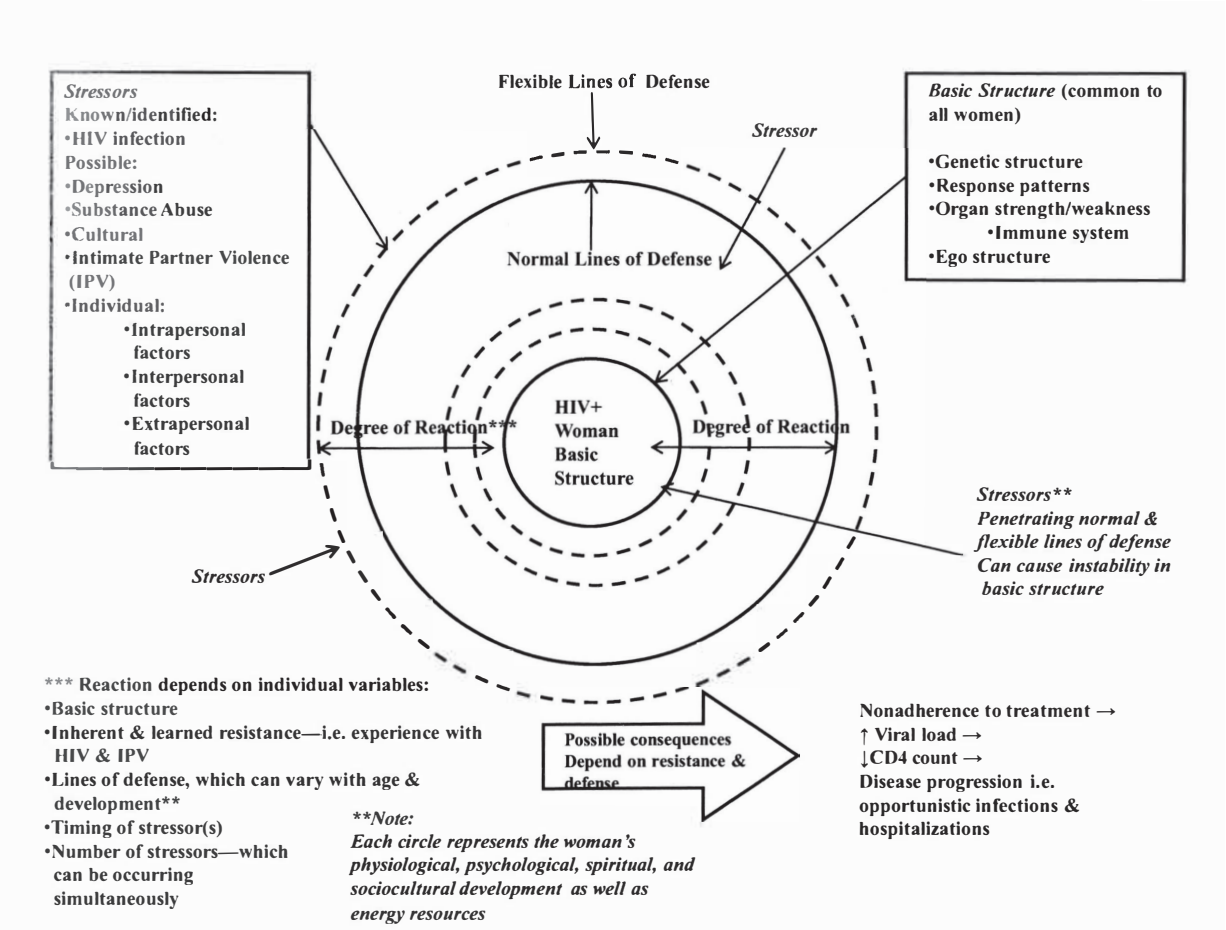


Figure 1. Adapted Neuman Systems Model.

(Adapted from diagram in *The Neuman Systems Model (3rd ed.)*, Neuman, 1995).

From the present perspective of this study, the HIV-infected woman, as an open system, seeks to establish and maintain stability as she experiences and reacts to stressors. The model identifies flexible lines of defense surrounding the woman that can be protective against stressors. Stressors, such as HIV infection, can have positive or negative effects on her. Intimate partner violence is another such stressor. Any stressor

can penetrate the lines of defense and resistance, ultimately impacting the woman's treatment adherence and ability to manage her own HIV disease. Internal lines of resistance activate in an effort to stabilize the system. Maintenance or re-establishment of stability is dependent on lines of defense and resistance. Inability to maintain or re-establish stability in the presence of or following the stressor of intimate partner violence can result in stressor reactions that may include decreased adherence or total nonadherence to the antiretroviral medication regimen. As a consequence of the decreased adherence, increased viral replication as measured by the HIV RNA viral load may occur. These negative stressor reactions of nonadherence and resultant viral replication may ultimately lead to disease progression.

Neuman's model guided this research which explored the impact of intimate partner violence on antiretroviral adherence and viral replication among HIV-infected women who reported physical or sexual intimate partner violence compared to women who did not report intimate partner violence. Based on the research results presented in this report, the Neuman model will provide a framework for future evidence-based nursing interventions designed to mitigate the effect of intimate partner violence, thereby decreasing stress, reinforcing the lines of defense and resistance, and ensuring a steady state and solid core of the woman with HIV.

Assumptions

The Neuman Systems Model is based on assumptions applied in the following manner for this research study:

1. Each individual HIV-infected woman as an open system is a composite of her innate characteristics and is unique.
2. Multiple known, unknown and universal environmental stressors exist, based on the interrelationship of physiological, psychological, sociocultural, developmental and spiritual variables, and which have potential for disturbing stability in the HIV-infected woman.
3. The stability of the HIV-infected woman is a dynamic composite of the interrelationship of these variables, all of which may affect the virological replicative capacity as well as her immunologic state.
4. The interrelationship of the variables described determine the point at which the cushioning effect of flexible lines of defense is no longer able to prevent a stressor from breaking through the normal line of defense in the HIV-infected woman.
5. Each HIV-infected woman has a normal line of defense or stability state which has evolved in response to her environment.
6. Each HIV-infected woman has internal resistance factors which function to return her ultimately to a higher level of stability after stressor reactions.
7. The HIV-infected woman is in a dynamic and constant energy exchange within her environment (Neuman, 1989).

Research Hypotheses

This research tested four hypotheses:

1. HIV-infected women who report physical or sexual intimate partner violence on the Severity of Violence Against Women Scale during the previous 12 months will have significantly lower adherence to antiretroviral medications as measured by Domestic Violence Specific Morisky Medication Adherence Scale compared to women who do not report intimate partner violence in the previous 12 months.
2. HIV-infected women who report physical or sexual intimate partner violence on the Severity of Violence Against Women Scale in the previous 12 months will have a greater proportion of detectable viral replication measured by the two most recent HIV RNA viral load tests taken at least three months apart in the previous 12 months compared to women who do not report intimate partner violence in the previous 12 months.
3. HIV-infected women who report physical or sexual intimate partner violence in the previous 12 months as measured by the Severity of Violence Against Women Scale will report a total Severity of Violence Against Women Scale score that is inversely correlated with the total Domestic Violence Specific Morisky Medication Adherence Scale score.
4. HIV-infected women who report physical or sexual intimate partner violence in the previous 12 months on the Severity of Violence Against Women Scale

will report a total score on the Danger Assessment that is inversely correlated with the total Domestic Violence Specific Morisky Medication Adherence Scale score.

Definition of Terms

- Intimate partner violence, occurring on a continuum, is defined as threatened, attempted or completed physical or sexual violence or emotional abuse by a current or former partner, i.e. spouse, ex-spouse, boyfriend or dating partner (Black & Breiding, 2008). For purposes of this study, intimate partner violence is operationalized as a positive response to any item on the physical and sexual subscales, questions 20 to 46, of the Severity of Violence Against Women Scale (Marshall, 1992) as reported by the HIV-infected woman.
- The Severity of Violence Against Women Scale (Marshall, 1992) is a 46-item instrument that asks about the frequency of given acts of violence by an intimate partner over the last 12 months using a four-point scale, with a score of one indicating no occurrence of the abusive act, two indicating the act occurred once, three meaning the act occurred two or three times, and four meaning it occurred four or more times. The points for each item are scored and added for a total value. For purposes of this study a positive answer to any question between numbers 20 and 46 indicates a report of intimate partner violence in the most recent 12 months. Additionally, the total Severity of Violence Against Women Scale score was used in correlation to total adherence scale scores.

The Danger Assessment (Campbell, 1986) is a 20-item yes or no questionnaire used to identify risk of murder by a partner. For purposes of this study the Danger Assessment score is the total number of affirmative answers, including weighted question values, from the instrument. Although the Danger Assessment is most often used to determine a woman's risk of death related to intimate partner violence, it was employed in this study as another means of assessing the level of violence against the HIV-infected woman and force of stressors against her lines of defense and resistance. The total Danger Assessment score was used in correlation to total medication adherence scale scores for this study.

- The HIV viral load, a laboratory test, which can be performed using either branched chain DNA (bDNA) or HIV RNA reverse transcriptase-polymerase chain reaction (RT-PCR) methodologies, quantifies viral particles in the serum and is used as a measure of antiretroviral effectiveness (Ferri, 2010; Bartlett, Gallant & Pham, 2009). For purposes of this study, the HIV viral load is a laboratory measure of viral particle replication by RNA PCR methodology, reported as a number between 48 and 3,000,000. The most recent two viral load tests performed at least three months apart in the past 12 months were used. The viral load was reported as detectable if viral replication was quantified or undetectable if no viral replication could be quantified, as determined by the type of viral load test ordered, performed and reported by the laboratory based on the lowest level of detection of that particular test.

- Adherence is defined as the extent to which a person continues an agreed-upon mode of treatment under limited supervision when faced with conflicting demands (The American Heritage Medical Dictionary, n.d.). A standardized definition of adherence or measurement of adherence has not been agreed upon among HIV clinicians and researchers (Holzemer, Corless, Nokes, et al., 1999). The Morisky Medication Adherence Scale is an eight-item questionnaire that assesses medication adherence utilizing self-report. Each item in the questionnaire measures a specific medication-taking behavior. The first seven questions are dichotomous yes or no questions phrased to avoid "yes-saying" bias by reverse wording questions about the way patients might experience failure or nonadherence (Morisky, Ang, Krousel-Wood & Ward, 2008). Only one question of the scale asks specifically if the HIV medication was taken at any specific time, in this instance yesterday. The final item response is in a five-point Likert format. Permission was obtained from the author to customize wording for this study to reflect HIV medications and partner violence and to entitle the scale as the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008). For purposes of this study, adherence was the self-reported totaled score obtained with the Domestic Violence Specific Morisky Medication Adherence Scale questions one through eight.

Limitations

Some study limitations should be considered. Generalizability of results is limited for several possible reasons. The samples size might not have been large enough to test all hypotheses for significance. Additionally, the convenience sample of participants for

this study were all obtained from one large, urban, publically-funded HIV specialty clinic and was limited to only women who were willing to be interviewed, who might have been at the clinic during the time period in which recruitment occurred, and the accuracy of their self-reported answers.

Summary

Gender and ethnic disparities may place a woman at risk for both HIV infection and intimate partner violence. Both HIV infection and partner violence are stressors that may significantly impact the core stability and well-being of women. The presence of both stressors in a woman's life may result in poor adherence to antiretroviral medications and viral replication, ultimately leading to HIV disease progression and adverse health consequences. Evidence-based interventions that may improve antiretroviral adherence and decrease a woman's risk for partner violence cannot be proposed without research investigating the association between partner violence and antiretroviral adherence among HIV-infected women. This study examined the association between physical and sexual intimate partner violence, antiretroviral adherence and viral replication among HIV-infected women.

CHAPTER II

REVIEW OF THE LITERATURE

Despite the existence of highly effective antiretroviral medications that treat HIV infection and can reduce transmission of the virus, millions of persons worldwide continue to be infected with HIV. Progression of HIV infection to AIDS and death occurs in many due to the lack of adequate treatment (UNAIDS, 2008). Globally, 15.7 million women are estimated to be infected with HIV (UNAIDS, 2009). Illustrating the growing impact of HIV on women, the proportion of women with an AIDS diagnosis in the U. S. grew from eight per cent in 1985 to 27% in 2007 (CDC, 2009). Moreover, more than 280,000 adult and adolescent women in the U. S. currently live with an HIV or AIDS diagnosis (CDC, 2009).

Intimate partner violence affects women with an estimated 4.8 million partner related physical and sexual assaults reported annually (CDC, 2009). A number of these women are also infected with HIV. Some women are infected as a result of the acts of violence and others experience violence because they are infected (Klein, Tesoriero, Leung, et al., 2008). The intersection of intimate partner violence and HIV infection and best practices for care of these women is an emerging field.

HIV is considered a treatable chronic illness in the U. S., but strict adherence to medication regimens is required to achieve viral suppression, preventing development of viral resistance and possible disease progression (Bangsberg, Acosta, Gupta, et al, 2006).

While barriers to adherence and possible interventions to address such barriers have been studied, a gap exists in the research addressing the relationship between intimate partner violence and adherence to antiretroviral medications among HIV-infected women (Lichtenstein, 2006).

Search Method

A literature review was conducted online utilizing Medline, CINAHL, and PsychINFO databases. The search occurred between January 2009 and July 2010 utilizing MeSH terms: human immunodeficiency viruses (HIV), spouse abuse, battered women, antiretroviral therapy and adherence. Further references were identified from research article reference lists, searching specific journal indexes, the related article links available through the library website, as well as governmental and epidemiological websites such as the Centers for Disease Control and Prevention. Searches grouping terms together were most successful in directing the search with limitations of research published in the past five years. Other limitations employed were studies published in the English language, those utilizing human subjects, and full text availability directly online or through the inter-library loan service. Once identified, relevant literature was organized on basis of intimate partner violence, adherence to antiretroviral medications and the potential intersection of intimate partner violence and adherence to antiretrovirals among HIV-infected women. The following sections of this chapter address the research found in these areas, concluding with a summary identifying the gaps in current research that lead to the conception of this study.

HIV and Global Epidemiological Impact

The blood-borne pathogen known as HIV is transmitted person to person by exchange of blood or bodily fluids. Transmission modes include sexual contact, sharing injection equipment, blood transfusion or mother-to-child in pregnancy or breastfeeding (Branson & McDougal, 2008). Definitive numbers for those who are currently living with or have died as a result of the HIV pandemic in the last 30 years are difficult to quantify but based on statistical modeling, current estimates indicate that 33.4 million persons globally are infected with HIV, with 15.7 million of those persons being women (UNAIDS, 2009). Worldwide, approximately two million persons died as a result of HIV or AIDS in the year 2008 (UNAIDS, 2009). It was estimated that over 25 million deaths had already occurred by the twenty-fifth anniversary of the HIV/AIDS pandemic in 2006 (Merson, 2006). Furthermore, by this anniversary, it was noted that AIDS had become the leading cause of premature death among persons age 15 to 59 (Merson, 2006). Although most of these infections and deaths have occurred in developing countries, the estimated cumulative deaths in the U. S. and dependent areas was almost 600,000 by the end of 2007 (CDC, 2009).

HIV and Women

Women are most likely to be infected through heterosexual sex followed by injection drug use, and this is consistent across most racial and ethnic groups (CDC, 2009). However, trends among HIV-infected women in the U. S. reveal that women of color are disproportionately affected by HIV or AIDS (CDC, 2009). While African American women account for only 12% of the U. S. population, 66% of the U. S. AIDS

cases in women 13 or older are among African American adolescent and adult women (CDC, 2009). Latinas make up 13% of the U. S. female population age 13 or older, but they account for 15% of the AIDS cases (CDC, 2009). Incidence and prevalence rates in African American women and Latinas further reveal the disproportionate patterns. CDC surveillance (2009) reveals the AIDS case rate among African American women is 22 times higher than white women (39.8 per 100,000 compared to 1.8 per 100,000) and 5 times higher in Latinas (8.9 per 100,000 compared to 1.8 per 100,000) than white women.

HIV is transmitted more efficiently from men to women during sexual intercourse than from women to men; furthermore, the presence of another sexually transmitted infection, especially if an ulcerative infection is present, increases the risk of transmission (Guthrie, Kiarie, Morrison, et al., 2009; Vergidis, Falagas & Hamer, 2009; U. S. National Institute of Allergy and Infectious Disease, 2006 [NIAID]). Compared to men, HIV-infected women in the U. S. are disproportionately found in lower socioeconomic levels, are more likely to lack health care coverage, are more likely to postpone care due to lack of transportation or physical health status, and are more likely to have responsibility for caring for children under the age of 18 in their homes (Kaiser Family Foundation, 2009). The risk for HIV infection related to intimate partner violence is associated with forced sex with an infected partner, limited or compromised negotiation of safer sex practices, and increased sexual risk-taking behaviors in women who experience violence and abuse. Violence and abuse towards women is also possibly more prevalent in women

experiencing the disparities listed above (Campbell, 2008). These disparities impact the disease trajectory for HIV-infected women in the U. S. and globally.

Viral Replication

HIV is an enveloped retrovirus that has two copies of genomic RNA in the viral capsid. HIV molecules possess receptors for the human CD4 molecule and co-receptors that facilitate cell membrane fusion. Upon transmission across a mucosal surface, HIV targets, infects and replicates itself in the human CD4 T lymphocytes and CD4-positive monocytes and macrophages. During replication via action of the reverse transcriptase enzyme, genomic RNA is transcribed into a DNA intermediate, then integrated into the human host cell genome, becoming proviral DNA. The provirus becomes the template from which new viral progeny are synthesized, replicating in an error-prone process that can lead to mutation (Branson & McDougal, 2008). A virus-host condition occurs in which proviral HIV then gains further access to more susceptible cells when the activated immune system supplies additional activated CD4-positive T cells, creating a self-propogating, chronic infection (Mehandru & Markowitz, 2008). Without access to and adherence to antiretroviral therapy, most HIV-infected persons would experience persistent and high-level viral replication with up to 10 billion virions produced each day (Saag, 2008). Viral load measurements or assays are the clinical laboratory tests that provide clinicians with a quantifiable number of plasma viral "copies" by which effectiveness and adherence to prescribed antiretroviral medications may be assessed (Saag, 2008).

Antiretroviral Adherence

Since the introduction of saquinavir, the first protease inhibitor in 1995, and the first non-nucleoside transverse inhibitor nevirapine in 1996, a dramatic decrease in morbidity and mortality in HIV-infected persons has occurred (Saag, 2008; CDC, 2009; Lima, Harrigan, Bangsberg, et al., 2009). Soon after these developmental milestones, clinical trials revealed that almost perfect adherence to antiretroviral therapy would be required to consistently inhibit viral replication (Williams & Friedland, 1997; Paterson, Swindells, Mohr, et al., 2000). Possibly no other chronic health problem requires such strict adherence to treatment for life or risk suffering the devastating consequences of nonadherence, which can include increased viral replication with possible resistant virus (Bangsberg, Kroetz, & Deeks, 2007; Gardner, Sharma, Peng, et al., 2008). Incomplete adherence to antiretroviral therapy over time has been strongly associated with increased mortality (Lima, 2009).

Adherence to antiretroviral medication most often determines both the effectiveness of the treatment and clinical trajectory of the infection (Atkinson & Petrozzino, 2009). In addition to individual health, adherence is recognized as a critical behavior that impacts public health as well. Because clinical outcomes are greatly impacted by level of adherence to HIV therapy, adherence research has exploded since 1996, resulting in a large body of literature that examines both adherence measures and strategies to improve adherence to antiretroviral therapy (Simoni, Amico, Pearson, & Malow, 2008). Additionally, studies have explored barriers and facilitators of adherence as well as predictors of adherence and nonadherence in the HIV-infected person

(Holzemer, Corless, Nokes, et al., 1999; Mills, Nachega, Bangsberg, et al., 2006; Pratt, Robinson, Loveday, et al., 2001; Sodergard, Halvarsson, Tully, et al., 2006).

Measures of Adherence

While accurate assessment of adherence is essential in clinical management of the treatment of HIV infection, it is widely accepted that no "gold standard" or universally validated measurement tool exists for clinical practice, especially in resource-poor settings or nonacademic research centers (Ross-Degnan, Pierre-Jacques, Zhang, et al., 2010). Researchers and clinicians employ multiple methods of measuring adherence to antiretroviral medications, sometimes using more than one method to balance the biases of self-report or possible errors of electronic monitoring devices (Atkinson & Petrozzino, 2009). Indirect methods of measurement include self-report, electronic drug monitoring, pill counts and pharmacy refills; direct measures of adherence include detection of antiretroviral drugs or their metabolites in plasma (Berg & Arnsten, 2006). The way a researcher operationalizes, measures and reports adherence must be carefully considered in the evaluation of outcomes of adherence research (Atkinson & Petrozzino, 2009).

In their meta-analysis of efficacy of interventions to improve adherence, Simoni and colleagues (2006) reported on 19 randomized controlled trials that met their stringent inclusion criteria, evaluating behavioral interventions with a total of 1839 participants. Nine of the studies included in their analysis utilized a form of electronic drug monitoring to measure adherence and 10 utilized self-report of adherence over either the past three or four days, past seven days or past 30 days. One of these studies utilized both electronic drug monitoring and self-report and another used self-report with determination of a

global adherence score based on a questionnaire and qualitative criteria. All but three of the 19 research studies also reported the viral loads as a measured outcome of adherence. It is noted that in these 19 studies, the greatest proportion of subjects were male, ranging 52.9% to 91% male. The only exception was a 2003 project in which all 174 subjects were female.

Strategies for Improving Adherence

Most interventions developed for adherence research utilize multi-modal approaches with interventions designed for skill building and behavioral modification along with additional social support, technology support and even modified directly observed therapy. Simoni's (2006) meta-analysis of interventions to improve adherence to antiretroviral medications primarily included randomized controlled trials which provided educational material about antiretrovirals; discussions about thoughts, motivations and expectations for taking antiretrovirals employing motivational interviewing or group therapy addressing stigma; behavioral strategies such as cue dosing or cognitive behavioral therapy; or external reminder systems such as pill boxes and electronic pagers. The aggregate effect size was significant (OR = 1.50, 95% CI: 1.16 to 1.94; $N = 1633$) with a homogenous effect ($Q = 20.3$, df = 18; $p = .26$). Overall, it was significantly more likely that subjects in the intervention arms (484 of 786 or 62%) would achieve 95% adherence or better than those in the control groups (426 of 847 or 50%).

Facilitators, Barriers and Predictors

To identify patient-reported barriers and facilitators to antiretroviral adherence, Mills and colleagues (2006) synthesized the results of 84 adherence studies, including 37

qualitative studies, from both developed and developing countries. While the majority of the studies were conducted in developed nations, 12 studies were conducted in developing countries. The most commonly reported patient-related barriers to adherence were: fear of disclosure; fear of taking medications in public; feelings of depression, hopelessness or being overwhelmed; substance abuse or addiction; forgetting to take the medications; and other problems such as suspicion of medical establishment, denial of HIV status, financial problems and homelessness. Medication beliefs, side effects and concern about long-term effects, complicated regimens, and body change concerns were additionally cited as barriers. Research participants also noted scheduling problems, interpersonal relationships and negative media and publicity as barriers to adherence.

Facilitators of antiretroviral adherence in the Mills (2006) research synthesis also followed the themes of patient-related facilitators, beliefs about medication, daily schedules and interpersonal relationships. Common patient-related facilitators included having self-worth, viewing adherence as a priority above substance abuse, acceptance of HIV status and receiving positive reinforcement from positive results of taking antiretrovirals. Belief in the efficacy of antiretrovirals and understanding the need for adherence were motivators cited by subjects. Learning to balance taking medications with daily schedules, having routines that could easily allow adjustments for adherence and the use of reminders were identified as facilitating successful adherence in these studies. Openly disclosing one's HIV status to family and friends along with positive relationships with health care providers was noted in this synthesis to promote and positively influence adherence.

Atkinson and Petrozzino (2009) compared the relative influence of psychosocial and treatment factors of nonadherence in more recent research. Similar to barriers cited in the Mills (2006) synthesis, comorbid predictors of nonadherence included alcohol and drug abuse, depression and other mental health problems. Although intimate partner violence was not specifically noted as a barrier to adherence or predictor of nonadherence directly, a number of consequences of intimate partner violence could directly and negatively impact an HIV-infected woman's adherence. Untreated depression or substance abuse as a result of intimate partner violence, fear of disclosure of her HIV status, and injuries that result from violence are a few examples that might negatively impact adherence (Lichtenstein, 2005; Pence, 2009). Factors found to be predictors of medication adherence were optimism, treatment self-efficacy and understanding treatment benefits and having shared treatment decision-making with a health care provider (Atkinson & Petrozzino, 2009).

Intimate Partner Violence and the Intersection with HIV

Intimate partner violence, both physical and sexual, is a global public health concern (Affi, 2008; Garcia-Moreno, 2006). Intimate partner violence affects women of all ages, ethnic groups, religions and socioeconomic status and is widespread around the world (Garcia-Moreno, 2006). An estimated five million women are physically or sexually assaulted by an intimate partner each year; 78% of the 1500 deaths that result from partner violence occur in women (CDC, 2009). The negative effects and consequences of IPV are pervasive and evident in a woman's mental and physical health, reproductive health and sexual autonomy (Sarkar, 2008).

Many women who experience intimate partner violence are HIV-infected or are at risk for becoming infected with HIV. Recent national and international research has revealed an association between partner violence and HIV infections (Campbell, 2008; Davila, Bonila, Gonzalez, Grinslade, & Villaruel, 2008; Sareen, Pagura, & Grant, 2009). The risk for HIV infection related to intimate partner violence is associated with forced sex with an infected partner, limited or compromised negotiation of safer sex practices, and increased sexual risk-taking behaviors in women who experience violence and abuse (Campbell, 2008). Intimate partner violence has been associated with unfavorable sexual/reproductive health consequences such as abortions, risk of HIV, pregnancy, childbearring, and birthcontrol issues (Coker, 2007; Sarkar, 2008); risky sex behaviors (Andersson, Ho-Foster, Mitchell, Scheepers, & Godstein, 2007); and anxiety and depression (Sarkar, 2008) .

Both intimate partner violence and a diagnosis of HIV can be considered stressful and traumatic for a woman. Previous research has suggested that stressful life events, post-traumatic stress and depression could lead to poorer treatment adherence and HIV disease progression (Delahanty, Bogart, & Figler, 2004; Lichtenstein, 2005; Boarts, Sledjeski, Bogart, & Delahanty, 2006). Lopez (2010) and colleagues investigated the differences in coping with AIDS-related stressors and adherence in seroconcordant and serodiscordant couples who were exposed to violence. Medication adherence for the total sample treated with antiretroviral medications was negatively correlated with extreme violence $r(188) = -.21$, $p = .01$). Intimate partner violence was measured by the Conflict Tactics Scale, which identifies violence across time, and was found to be correlated with

decreased medication adherence in women when examined by individual gender in this study (Lopez, 2010). Extreme violence was the only variable of all those measured that contributed to adherence (Lopez, 2010). No research was found on antiretroviral adherence and viral replication among HIV-infected women who do and do not report intimate partner violence in the past 12 months as measured by the Severity of Violence Against Women Scale (Marshall, 1992), a scale which measures both occurrence, frequency, and severity of physical and sexual violence.

Summary

The literature reveals an intersection between HIV infection and intimate partner violence among women. There are many barriers to antiretroviral adherence identified in the literature that may be related to intimate partner violence among HIV-infected women. However, there is a gap in the literature examining this possible relationship. No studies have explored the relationship of viral replication and antiretroviral adherence among HIV-infected women who do and do not report intimate partner violence in the past 12 months.

CHAPTER III

COLLECTION AND TREATMENT OF THE DATA

This non-experimental, comparative descriptive study examined antiretroviral adherence and viral replication measurements among HIV-infected women who did and did not report intimate partner violence in the past 12 months. This research design allowed for investigation of any association between antiretroviral medication adherence, viral replication and intimate partner violence among HIV-infected women to test the stated hypotheses.

Setting

The setting for this study was a large, urban, publically-funded specialty clinic. This clinic is part of a large county health system. Although services at this center are not totally free of cost, most of the women who receive HIV-related services do not possess any form of private insurance. Over 1400 women were among the more than 4600 persons who received HIV care at this specialty center in 2008 (Harris County Hospital District HIV Services, 2009).

Population and Sample

The population was HIV-infected women, ages 18 or older, who received HIV-related care and services at the specialty clinic. Demographics of the clinic revealed the largest proportions of women receiving care at the clinic were black non-Hispanic (71%)

and Hispanic (20%), with non-Hispanic white women accounting for eight percent of the females who attend the clinic (Harris County Hospital District HIV Services, 2009).

Women eligible for participation in the study met the following criteria: 1) HIV-infected, as documented in the medical record; 2) speak and understand English or Spanish; 3) have received care at the HIV specialty center for at least the past 12 months; 4) had been prescribed and had been taking antiretroviral medications for the past 12 months; 5) had at least two viral load measures that were separated by at least three calendar months documented in the past 12 months of care; and 6) reported having had an intimate partner relationship in the past 12 months. Women who were disabled as defined by the Texas Human Resources Code Chapter 123 Community Homes for Disabled Persons Location Act (n. d.) were excluded from participation in the study. Otherwise, any women who met these criteria were eligible to participate in the study.

Potentially eligible women were individually invited to participate in the study, recruited by the investigator from the general waiting areas where the women wait for clinic appointments with their individual providers, discharge from appointments, social support services, pharmacy needs or to access other HIV-related services. Women interested in learning more about the study were taken to a private room where details of the study were explained to them, questions were answered and informed consent for participation was completed. After signing informed consent, research instruments were administered by the researcher in the woman's preferred language, English or Spanish, in an interview format. The researcher read the questions to the women and recorded answers given by the women who had consented to participate.

Only one study was found which examined intimate partner violence and measured adherence. Lopez (2010) measured adherence and levels of violence among 145 HIV seroconcordant and serodiscordant couples ($N = 290$, 94 women). This study was an intervention study, included men and utilized different instruments for testing and measurement. The literature review revealed no studies similar to the one proposed from which to calculate a sample size. However, a pilot study done for recruitment feasibility and time to administer the instruments was done by the researcher and included a sample of 40 women.

This investigator's pilot data revealed at least 50% of the women reported intimate partner violence in the past 12 months, but a significant difference in the dependent variable HIV RNA viral load measures was not found. However, in the pilot study, inclusion criteria did not specify that women had to have been taking antiretroviral medications. Additionally, three different viral load tests are ordered by the providers at this clinic, with various sensitivities and different lower limits of detection of viral particles. These two factors lead to a large range and variability in viral load results, which may have contributed to lack of significant findings.

Despite these issues, selecting out cases in the pilot that would not have met inclusion for this current study allowed the researcher to identify results of 28 pilot participants from which power analysis was performed. An estimated effect size $d = .60$ indicated that a sample size of 88 could be used to test for significant differences in the mean viral load at $\alpha = .05$. However, four hypotheses were to be tested for this study, therefore $\alpha = .0125$ was necessary. The sample size proposed for the study was a total of

300 HIV-infected women, estimating about 50% would report intimate partner violence. It was calculated that this sample size would yield a small to moderate effect size ($\alpha = .0125$, power = .80) adequate to determine a significant difference in antiretroviral medication adherence scores and viral replication between the women who reported intimate partner violence and those who did not report violence.

Protection of Human Subjects

Approval to conduct the research was obtained from the Institutional Review Board of Texas Woman's University along with letter agreement from the research department of the agency, Harris County Hospital District. Appropriate measures were taken to ensure the protection of human subjects. Participants signed a written consent form offered in English or Spanish according to their preference. All participants were given an opportunity to ask questions surrounding the study and answers were provided prior to participation. Women were advised they could stop the interview at any point with no risk to their continued health care at the clinic. Strict measures were taken to safeguard personal health information by maintaining all files related to study under lock and key. In an effort to further protect privacy, unique identification numbers instead of names were used on all data collection forms.

Instrumentation

The five research instruments used in this study were: the investigator-developed Demographic Data Form (Appendix A); the Severity of Violence Against Women Scale ([Appendix B], Marshall, 1992); the Danger Assessment scale ([Appendix C], Campbell, 1986); the Domestic Violence Specific Morisky Medication Adherence Scale

([Appendix D], Morisky, 2008); and the investigator-derived Medical Record Data Collection Form (Appendix E). The Demographic Data Form (Appendix A) was used to collect information such as age, ethnicity, level of education, year of HIV diagnosis and living arrangements from the women. Abstraction of data such as HIV diagnosis date, antiretroviral medication history, and the viral load laboratory values from the medical chart was guided by the Medical Record Data Collection Form (Appendix E). These two investigator-developed forms were used in the pilot study.

The Severity of Violence Against Women Scale (Marshall, 1992) is a validated instrument developed to assess the seriousness, abusiveness, aggressiveness, violence, and threat value of acts of violence toward women. The instrument consists of 46 items which ask about the frequency of given acts of violence over the last 12 months, using a four point scale, with one indicating no report of the act, two equaling one occurrence, three indicating two or three occurrences of the act of violence, and four indicating four or more occurrences of the act of violence. The points reported for each act are scored for a total value. Construct validity of the Severity of Violence Against Women Scale was evaluated by factor analysis (Marshall, 1992). The Severity of Violence Against Women Scale has been shown to be reliable, with alpha coefficients of .89 to .97 on previous samples (Marshall, 1992; McFarlane, Parker, Soeken, Silva, & Reed, 1999; McFarlane, Soeken, & Wiist, 2000; Willson, McFarlane, Lemmey & Malecha, 2001; McFarlane, Malecha, Gist, et al., 2004).

The Danger Assessment (Campbell, 1986) is an instrument designed to help identify women at risk of being murdered by an intimate partner. The Danger Assessment

was scored by totaling the affirmative answers from the 20 yes or no questions, with specific weighting of questions two through nine. Alpha coefficient for the Danger Assessment was reported at .71 (Campbell, 1986). Construct validity of the Danger Assessment was assessed by predicting positive, moderate-to-strong correlations using the Conflict Tactics Scale, correlation coefficients of .43 to .55, (Campbell, 1986). Content validity was previously evaluated by experts such as law enforcement and women's shelter workers, as well as abused women themselves (Campbell, 1986) and the instrument has been validated in multiple studies. Furthermore, correlation between the Danger Assessment score and actual subsequent violence (r = .38) was greater than the other four assessment tools in the Intimate Partner Violence Risk Assessment Validation Study (Roehl, O'Sullivan, Webster, & Campbell, 2005).

The adapted Morisky Medication Adherence Scale ([Appendix D], Morisky, 1986; 2008) is an eight-item questionnaire that was administered to assess antiretroviral adherence. The original Morisky Medication Adherence Scale was a four-item scale developed to assess adherence to antihypertensives; the scale showed a relatively high measure of internal consistency with a Cronbach alpha of .61 (Morisky, 1986). Morisky (2008) and Krousel-Woods and colleagues (2009) validated the adapted eight-item Morisky Medication Adherence Scale with pharmacy refill data and actual blood pressure measurements, obtaining alpha coefficients of .83. The four-point scale was previously validated in HIV research (Holzemer, 1999; Pratt, et al., 2001; Corless, et al., 2005) with alpha coefficients ranging .65 to .77. Other HIV research utilizing the adapted eight-item Morisky Medication Adherence Scale has shown good internal consistency as well, with

alpha coefficients of .84 (Viswanathan, Anderson, & Thomas, 2005) and .89 in a Swedish study (Sodergard, et al., 2006). The reliability of the adapted Domestic Violence Specific Morisky Medication Adherence Scale ([Appendix D], Morisky, 2008) was not previously tested.

The HIV RNA viral load measures the amount of HIV replication that is occurring in the blood (Bartlett, 2009; Ferri, 2010). The viral load is one of the laboratory tests done approximately every three months on stable HIV-infected persons to monitor the immunologic and virologic status. The viral load laboratory test is drawn by the phlebotomist in the HIV specialty clinic; this sample is then sent to the main laboratory where the test values are determined by the reverse transcriptase-polymerase chain reaction methodology (Bartlett, 2009). The most recent two viral load measurements for the previous 12 months recorded in the medical record which were at least three months apart were collected on the Medical Record Data Collection Form (Appendix E) and were then categorized as either detectable or undetectable for viral replication for purposes of statistical analysis in this study.

Pilot Study

A pilot study was conducted to test recruitment feasibility and to determine the proportions of HIV-infected English and Spanish-speaking women at this HIV specialty clinic who did and did not report intimate partner violence. A total of 40 participants were recruited using convenience sampling. More than half (n = 23, 57.5%) of the 40 subjects reported intimate partner violence compared to those who did not report intimate partner violence (n = 17, 42.5%). The mean viral load count among women who reported

partner violence (M = 41,843.69, SD = 10,422.64) was higher than the mean viral load count for women who did not report intimate partner violence in the past 12 months (M = 25,411.67, SD = 25,807.86). However, the t test for equality of means did not find the difference significant, t = -.602, df = 20.165, p = .277. The lack of significance may have been related to the very small sample size and wide range in viral load measurements, corrected by the current study design.

The pilot study established that sufficient number of participants could be recruited at the setting and that it was likely 50% or more of the participants might report physical or sexual intimate partner violence in the past 12 months. To strengthen the study, inclusion criteria were modified to include the participant reporting and confirming an intimate partner relationship in the past 12 months and all women reporting to have been prescribed and were taking antiretroviral medications per the medical record for the past 12 months. The pilot results also revealed the need to standardize the number and spacing of viral load results to include in final analysis; this strengthening specification was detailed in the section describing instrumentation. The pilot study experience validated the individual approach and recruitment of women to be the best process to avoid selection bias, which could come with referrals from support group members or social workers who were aware of a woman's experience with intimate partner violence.

The Medical Record Data Collection Form was edited to avoid extraneous data collection that was not to be included in final analysis. Additionally and most important to a major dependent variable in this study—antiretroviral adherence—a validated instrument to measure adherence was added. The Morisky Medication Adherence Scale

(Morisky, 2008) was adapted for this study as the Domestic Violence Specific Morisky Medication Adherence Scale. This provided the researcher a valid and reliable instrument for adherence measurement rather than using the surrogate marker of the HIV RNA viral load count solely as a measure of adherence.

Data Collection

Women were invited to participate in the study while waiting in the general waiting areas to see their medical provider, waiting for discharge instructions or medication retrieval at the pharmacy, or seeking social services at the clinic. Women interested in learning more about the study were taken to a private room, where details of the study were explained by the researcher and informed consent was completed. A unique identifying number was recorded on the individual forms and entered into the researcher's participant list. Data was collected in an interview format. Following informed consent, questions from the Demographic Data Form, the Severity of Violence Against Women Scale (Marshall, 1992), the Danger Assessment (Campbell, 1986), and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) were read to the woman in her preferred language, English or Spanish. The researcher administering the questions recorded the women's responses on the specific forms.

Following the interview portion of data collection, at a later time, the researcher abstracted clinical information from the electronic medical record to complete the Medical Record Data Collection Form. Only clinical information for the past 12 months from the date of the interview was considered for the study. Recorded responses and clinical data prior to the medical record were entered into a computer database at a later

time for statistical analysis. Women who completed all the questionnaires were given ten dollars in cash along with information about a local women's shelter and support group.

Treatment of the Data

PASW Statistics 18 (SPSS, 2009) was used for data analysis. Descriptive statistics were computed for demographic data. Differences in antiretroviral adherence scores among women who did and did not report physical or sexual intimate partner violence were determined using the *t* test for significant difference in independent samples, testing hypotheses one. To test the second hypothesis, the Fisher's Exact statistic was computed for the proportions of women who had detectable viral replication among those HIV-infected women who did and did not report intimate partner violence in the past 12 months. Regarding hypotheses three and four, inverse correlations between total Severity of Violence Against Women Scale (Marshall, 1992) scores and the total Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores, and the total Danger Assessment (Campbell, 1986) scores and the total Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores, respectively, were tested using the bivariate correlation Pearson's *r*. The level of significance was set at an alpha of .0125 for testing all four hypotheses.

CHAPTER IV

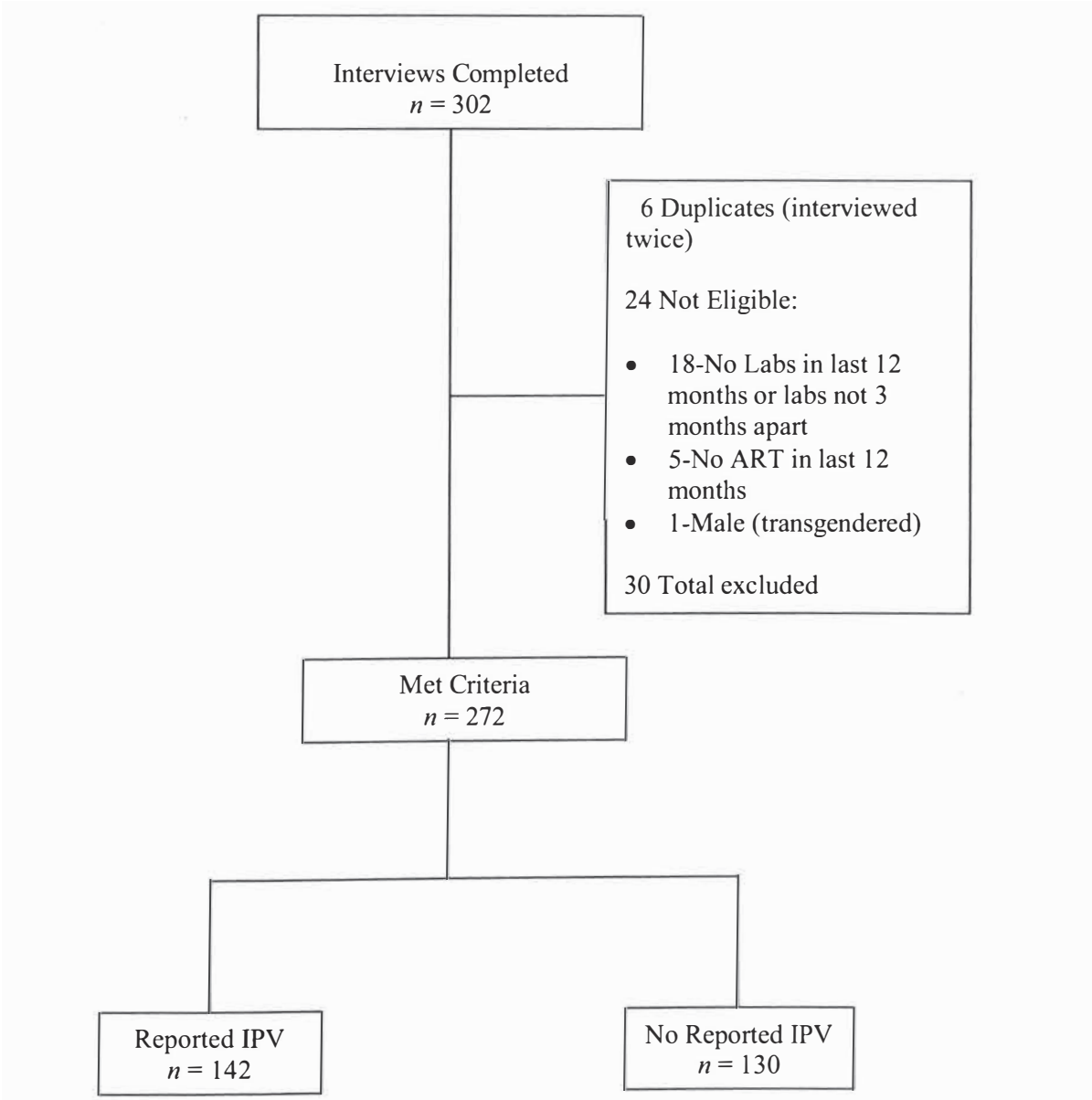
ANALYSIS OF THE DATA

A non-experimental, comparative descriptive design was used to examine the relationship between intimate partner violence, antiretroviral medication adherence and viral replication among HIV-infected women. A convenience sample of HIV-infected women from diverse ethnic backgrounds was recruited at a publically-funded HIV specialty clinic in Southeast Texas. Upon agreement to participate, the participants signed an informed consent and were interviewed using the investigator-designed Demographic Data Form, the Severity of Violence Against Women Scale (Marshall, 1992), the Danger Assessment scale (Campbell, 1986), and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008). The investigator-derived Medical Record Data Collection Form was used to abstract clinical viral load laboratory results at a later time following the interview. The experience of intimate partner violence was determined by any positive answer to questions 20 to 46 on the Severity of Violence Against Women Scale. Total scores for each of the scales were calculated for data analysis. Demographic characteristics of the participants and results of the study are presented in this chapter.

Description of the Sample

Recruitment of HIV-infected women took place in the general waiting areas of the HIV specialty clinic. The researcher approached the woman individually and invited

her to participate in the study. If the woman was interested in learning more about the study, she was taken to a private room where the study details and inclusion criteria such as receiving care at the clinic for at least 12 months and taking antiretroviral medications during the 12 months with at least two laboratory evaluations done in the year were further explained. If informed consent was obtained, the researcher administered the research instruments in an interview format in the woman's preferred language, English or Spanish. A total of 302 interviews were completed over a six week period during August and September 2010. Thirty of those interviewed were excluded from data analysis, primarily for an insufficient number of laboratory evaluations or because the participant had not been on antiretroviral treatment for the 12-month period. Six women completed the interview twice, one interview with each interviewer. Statistical analysis was performed on the remaining 272 participants who met the inclusion criteria (see Figure 2).



IPV = Intimate Partner Violence

Figure 2. Participant flowchart

Findings of the Study

The hypotheses tested in this study were:

1. HIV-infected women who report physical or sexual intimate partner violence on the Severity of Violence Against Women Scale during the previous 12 months will have significantly lower adherence to antiretroviral medications as measured by Domestic Violence Specific Morisky Medication Adherence Scale compared to women who do not report intimate partner violence in the previous 12 months.
2. HIV-infected women who report physical or sexual intimate partner violence on the Severity of Violence Against Women Scale in the previous 12 months will have a greater proportion of detectable viral replication measured by the two most recent HIV RNA viral load tests taken at least three months apart in the previous 12 months compared to women who do not report intimate partner violence in the previous 12 months.
3. HIV-infected women who report physical or sexual intimate partner violence in the previous 12 months as measured by the Severity of Violence Against Women Scale will report a Severity of Violence Against Women Scale score that is inversely correlated with the Domestic Violence Specific Morisky Medication Adherence Scale score.
4. HIV-infected women who report physical or sexual intimate partner violence in the previous 12 months on the Severity of Violence Against Women Scale will

report a score on the Danger Assessment that is inversely correlated with the Domestic Violence Specific Morisky Medication Adherence Scale score.

PASW Statistics 18 (SPSS, 2009) was used for data analysis. Frequencies and histograms were completed prior to data analysis. Descriptive statistics were computed for the demographic data. Reflective of the specialty clinic population distribution and the current HIV epidemiology in women, the largest number of women identified themselves as Black, non-Hispanic (n = 192, 70.6%) and Hispanic (n = 56, 20.1%). Ages ranged from 23 to 72, with the greatest proportion of women between ages 35 and 64. Only one woman had not received any formal education. Over half of the women had completed high school or had passed a General Education Development (GED) test (n = 148, 54.4%). One third (n = 92, 33.8%) of the women had attended some college or completed a college degree. However, the majority of this sample of women did not work outside their home for pay.

Women who reported intimate partner violence in the past 12 months were less likely to be living with a significant other than women who did not report violence. The length of time the women had been diagnosed with HIV ranged from one to 27 years, with slightly more than half (n = 139, 51.1%) being infected from one to ten years. Most women were taking two or three different antiretroviral agents (n = 194, 71.3%) with daily dosing regimens (n = 168, 61.8%). For purposes of this study, fixed dose combination medications were counted as a single antiretroviral agent. The protease inhibitor ritonavir used for boosting the pharmacokinetics of protease inhibitors was

counted as a single agent. If women took one agent once a day but another twice a day, the regimen was considered twice daily. An antiretroviral regimen was only considered a daily regimen if all agents were taken once a day and could be taken at the same time. Demographic and HIV-related characteristics of the women who did and did not report intimate partner violence are presented in Tables 1, 2 and 3.

Table 1

Language, Ethnicity and Age

	Reported IPV		Did Not Report IPV	
	n = 142		*n* = 130	
Characteristic	Number	Percentage	Number	Percentage
Language				
English	126	88.7%	106	81.5%
Spanish	16	11.3%	24	18.5%
Ethnicity/Race				
Black, non-Hispanic	107	75.4%	85	65.4%
Hispanic	24	16.9%	32	24.6%
White, non-Hispanic	7	4.9%	9	6.9%
Other	4	2.8%	4	3.1%
Age				
20-34	21	14.8%	22	16.9%
35-49	78	54.9%	65	50.0%
50-64	41	28.9%	41	31.5%
65+	2	1.4%	2	1.5%

Table 2

Living Arrangement, Education and Work

	Reported IPV (n= 142)		Did Not Report IPV (n = 130)	
Characteristic	Number	Percentage	Number	Percentage
Living With:				
Significant Other	17	12.0%	28	21.5%
Parent(s)/Children	37	26.1%	26	20.0%
Friend(s)	2	1.4%	4	3.1%
Alone	31	21.8%	31	23.8%
Other Combinations	55	38.7%	41	31.5%
Education Level				
None-8th grade	13	9.2%	19	14.6%
High School/GED	83	58.5%	65	50.0%
Some College/Graduated	46	32.4%	46	35.4%
Employed for Pay				
Yes	18	12.7%	23	17.7%
No	124	87.3%	107	82.3%

Table 3

Years Since HIV Diagnosis (DX), Antiretroviral Therapy (ART)

	Reported IPV (n = 142)		Did Not Report IPV (n = 130)	
Characteristic	Number	Percentage	Number	Percentage
Years Since HIV DX				
1-5	30	21.1%	38	29.2%
6-10	34	23.9%	37	28.5%
11-15	46	32.5%	31	23.8%
16-20	25	17.6%	16	12.3%
20+	7	4.9%	8	6.2%
Number Different ART Agents Taken Daily				
1	30	21.1%	31	23.8%
2 or 3	101	71.1%	93	71.2%
4 to 6	11	7.7%	6	4.6%
Regimen Dosing				
Daily	90	63.4%	78	60.0%
Twice Daily	52	36.6%	52	40.0%

The primary outcome measures for this study were the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores determined on the day of the interview and the two viral load measures taken at least three months apart in the past 12 months. Due to the study design and the need to utilize retrospective laboratory values, the option of standardizing and controlling the type of viral load tests and differences in lower levels of detection or sensitivity of the particular test that had been ordered by various primary care providers was not possible. Therefore, viral load results were categorized dichotomously as either detectable or undetectable for purposes of statistical analysis. If one or both of the viral load samples taken at least three months apart revealed detectable viral replication, that participant's viral load was considered detectable. Neither of the two samples for viral load, taken a minimum of three months apart, could show detectable viral replication in order for the participant's viral load to be categorized as undetectable.

The *t* test for independent samples was used to test for significant differences in the mean Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores between women who did and did not report intimate partner violence. The Fisher's Exact test was used to compare the proportions of detectable viral loads between the two groups of women. The Pearson's *r* was used to examine relationships between the Severity of Violence Against Women Scale (Marshall, 1992) and Danger Assessment (Campbell, 1986) scores with the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores.

As hypothesized in the first hypothesis, HIV-infected women who reported intimate partner violence in the past 12 months were found to have lower adherence scale scores ($M = 5.49$, $SD = 2.06$) compared to those women who did not report intimate partner violence ($M = 6.57$, $SD = 1.57$), $t(262.1) = 4.91$, $p < .001$. The assumption of homogeneity of variance was not tenable.

Regarding hypothesis two, among the group of HIV-infected women who reported violence by their partners in the past 12 months ($n = 142$, 52.2%) more than half ($n = 76$, 65.5%) had one or both viral load tests show viral replication above the limits of detection. In comparison, among the 130 HIV-infected women who did not report intimate partner violence, only 66 (42.3%) had one or both viral load tests show viral replication above the limits of detection. The Fisher's Exact test was used to test the difference in proportions of detectable viral replication among the HIV-infected women who did and did not report intimate partner violence in the past 12 months. A greater proportion of detectable viral replication was found in the women who had experienced recent intimate partner violence (Fisher's Exact $p < .001$).

Regarding hypotheses three and four, inverse correlations were hypothesized between the Severity of Violence Against Women Scale (Marshall, 1992) scores and the medication adherence scale scores, and the Danger Assessment (Campbell, 1986) scores and the medication adherence scores, respectively. Pearson's correlations for the total scale scores were computed for the HIV-infected women who reported intimate partner violence ($n = 142$). Analysis revealed there was not a relationship between the Severity of

Violence Against Women Scale (Marshall, 1992) total score and Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores, $r(138) = -.076$, $p = .185$. Also, no relationship was found between the Danger Assessment (Campbell, 1986) scores and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores, $r(138) = .000, p = .498$.

Reliability coefficients were calculated for the three scales administered to the participants. Cronbach's alpha for the instruments in this study were as follows: Severity of Violence Against Women Scale (Marshall, 1992) Cronbach's $\alpha = .98$; Danger Assessment (Campbell, 1986) Cronbach's $\alpha = .78$; and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) Cronbach's $\alpha = .73$.

Summary of the Findings

A convenience sample of 272 HIV-infected women who met the inclusion criteria participated in this non-experimental, comparative, descriptive study. The study examined the relationships between intimate partner violence, antiretroviral adherence and viral replication. Total scores from the Severity of Violence Against Women Scale (Marshall, 1992), the Danger Assessment (Campbell, 1986) and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) along with abstracted medical record values were used to examine the relationships and test the hypotheses.

Descriptive statistics were computed for demographic data. The *t* test for independent samples was used to test hypothesis one. The mean adherence scale score was significantly lower among HIV-infected women who reported intimate partner violence in the past 12 months, supporting hypothesis one. Hypothesis two was also

supported by statistical analysis. The Fisher's Exact test revealed the proportion of women with detectable viral replication was significantly greater in the women who reported intimate partner violence in the past 12 months compared to women who did not report violence. Pearson's correlation found no significant correlations between the variables of hypothesis three and hypothesis four. Neither the total Severity of Violence Against Women Scale scores nor the total Danger Assessment scores were significantly related to the medication adherence scores among the women who reported intimate partner violence in the previous 12 months.

CHAPTER V

SUMMARY OF THE STUDY

HIV infection and intimate partner violence are both recognized as global health concerns, disproportionately affecting millions of women worldwide (Afifi, 2008; UNAIDS, 2008). This intersection between HIV infection and intimate partner violence has been identified as an emerging problem with potentially devastating effects on women with HIV (Campbell, 2008), but research identifying the specific impact intimate partner violence might have on treatment adherence and viral replication has been limited. Nurses and health care providers recognize the need for evidence-based interventions that will facilitate and assist optimal adherence to HIV treatment, and more specifically, adherence by the women who are also affected by intimate partner violence. Essentially perfect adherence to antiretroviral medications is required to prevent viral replication, possible antiretroviral resistance and disease progression that can ultimately lead to AIDS and death (Paterson, 2000; Lima, 2009). Previous research has clearly shown that co-morbid predictors of nonadherence such as untreated alcohol and drug abuse, depression and mental health problems—along with fear of disclosure of HIV status and injuries resulting from violence—can also negatively impact an HIV-infected woman's adherence to antiretroviral medications (Lichtenstein, 2006; Mills, 2006; Pence, 2009). Knowledge of the effects of intimate partner violence on antiretroviral adherence

and viral replication can provide the foundation for evidence-based interventions formulated to improve adherence to treatment.

Summary

A non-experimental, comparative descriptive design was used to examine the relationship the relationship between intimate partner violence, antiretroviral medication adherence and viral replication among HIV-infected women. After approval by the university institutional review board and the agency research department, a convenience sample of 302 ethnically-diverse HIV-infected women was recruited. Women who were receiving services through a county health system HIV specialty clinic were individually approached and asked if they wanted to participate. Women who desired to participate were given an explanation of study details including inclusion criteria prior to signing informed consent.

Upon informed consent, the research instruments were administered. The investigator-designed Demographic Data Form, the Severity of Violence Against Women Scale (Marshall, 1992), the Danger Assessment (Campbell, 1986), and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) were administered in the language preferred by the participants—English or Spanish—by the investigator in an interview format. Clinical data was obtained from the electronic medical record at a later time after the interview, guided by the investigator-derived Medical Record Data Collection Form. Experience of intimate partner violence was determined by a positive response to any questions numbered 20 to 46 of the Severity of Violence Against Women Scale (Marshall, 1992). A total of 302 interviews were

completed. Data analysis was performed on 272 participants who met the inclusion criteria based on clinical data verification. Data from thirty interviews were excluded: 18 did not have the required amount of laboratory values available for analysis; five had not been prescribed antiretrovirals; and one was biologically male. Additionally, six women completed the interview twice, once with each interviewer.

Primary outcome measures examined on the 272 participants were the total adherence scale scores and the categorization of viral replication, detectable or undetectable, among the HIV-infected women who did and did not report intimate partner violence. The difference in mean adherence scale scores was compared between the women who did and did not report intimate partner violence using the *t* test for independent samples. The Fisher's Exact test compared the proportions of detectable viral loads among the two groups of HIV-infected women. Total violence scale and danger assessment scores for the HIV-infected women who reported intimate partner violence were also examined for relationship to total adherence scale scores using the Pearson's *r* correlation. All statistical analysis was computed using PASW 18 (SPSS, 2009).

Discussion of the Findings

Prevalence of Intimate Partner Violence

Fifty-two percent of HIV-infected women who were established patients within a HIV specialty clinic for at least the past 12 months and who had been prescribed antiretroviral medications during that time reported physical or sexual intimate partner violence during the same 12 month period. The prevalence of partner violence found in

this study (n = 142, 52%) is slightly higher than the 47% (n = 44) reported by Lopez (2010) among a group of 94 HIV-infected women. It should be noted that the Lopez study measured violence with the Conflict Tactics Scale, which considers any past threat or act of violence by a male partner across the lifespan as partner violence. Therefore the findings of this current study could be interpreted as stronger, due to the larger sample and the more specific measurement of partner violence in the recent 12 months.

Medication Adherence and Intimate Partner Violence

Regarding medication adherence, this study used the Morisky Medication Adherence Scale for measurement. Scores using this scale have been reported in other studies, with scores of eight indicating "high" or near perfect adherence and scores of 6 or less as poor or inadequate adherence (Morisky, 2008). The adapted Domestic Violence Specific Morisky Medication Adherence Scale for this study revealed mean total adherence scale scores for this sample of HIV-infected women were significantly lower among the women who reported intimate partner violence (M = 5.49, SD = 2.06) compared to those women who did not report violence (M = 6.57, SD = 1.57), $t(262.1)$ = 4.91, $p < .001$. No studies, except the one by Lopez (2010), were identified in the literature that specifically measured antiretroviral medication adherence in relationship to reports of partner violence.

Viral Replication and Intimate Partner Violence

A larger proportion of women who reported physical or sexual violence had detectable viral replication compared to women who did not report violence. Viral replication was not compared with specific total adherence scale scores for these women.

However, a well documented reason for viral replication detected by the viral load is lack of optimal adherence to antiretroviral medication (Bartlett, 2009; Ferri, 2010; Saag, 2008). Among the 142 women who reported physical or sexual violence by their partners in the past 12 months, two-thirds (n = 76, 66%) had one or both viral load tests show viral replication above the limits of detection. In comparison, among the 130 HIV-infected women who did not report intimate partner violence, only one-third (35%) or 40 women had one or both viral load tests show viral replication above the limits of detection. Once again, no literature was identified that measured viral detection for a group of HIV-infected women who did and did not report partner violence.

Medication Adherence, Viral Replication and Violence Severity

It was hypothesized that higher violence scale and danger assessment scores would be associated with lower adherence scale scores. However, there was not a relationship between the Severity of Violence Against Women Scale (Marshall, 1992) total score $r(138) = -0.76$, $p = .185$ and Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores or the Danger Assessment (Campbell, 1986) scores $r(138) = .000$, $p = .498$ and the Domestic Violence Specific Morisky Medication Adherence Scale (Morisky, 2008) scores, respectively. This lack of an association may be due to a smaller than desired sample size. Again no literature studying an association of severity of violence or danger level associated with violence and concurrent antiretroviral medication adherence among HIV-infected women was found in the literature.

Finally, the literature review concerning HIV-infected women and intimate partner violence found no reports examining antiretroviral adherence and viral replication

in women who report recent acts of intimate partner violence, similar to this study. One recent report was found in which intimate partner violence and antiretroviral adherence was examined in both seroconcordant and serodiscordant heterosexual couples who were participating in a group-based intervention to increase coping skills. Lopez (2010) found extreme intimate partner violence was correlated with decreased antiretroviral adherence as measured by four day recall in women, $r(42) = -0.26$, $p = .026$. Extreme violence was the only variable of all variables measured that was found to contribute to adherence (Lopez, 2010). Mean adherence reported for the 94 women was 87.77% ($SD = 24.60\%$). Viral replication or viral loads were not reported for the Lopez study (2010). The current study reported here found that physical or sexual intimate partner violence in the past 12 months was associated with significantly less antiretroviral adherence and a greater proportion of detectable viral replication among HIV-infected women. Extreme violence, which would have been reflected by higher Severity of Violence Against Women Scale (Marshall, 1992) scores and Danger Assessment (Campbell, 1986) scores, as hypothesized in this study and as found in the Lopez (2010) study, was not inversely correlated with total adherence scale scores.

Barriers to Adherence and Neuman Systems Model

Barriers to antiretroviral adherence identified by the Mills (2006) systematic review included fear of disclosure, feelings of stress, depression, hopelessness and stress, concomitant substance abuse, forgetfulness, suspicions of treatment and complicated antiretroviral regimens, including the number of pills required to take for treatment. Most of the studies included in the Mills systematic review were completed and reported prior

to availability of the newer antiretrovirals that are co-formulated, such as two or three medications in one pill that may reduce pill burden and allow once or twice daily dosing. In this study sample, 61.2% of the women were able to take their antiretrovirals once daily and only 17 women (6.25%) took more than three different antiretroviral agents daily. While it was not analyzed in relationship to adherence for this study, complicated regimens most likely did not contribute to lack of adherence among these women. Co-morbid conditions such as psychiatric illness and concomitant substance abuse were not variables investigated in this study, but the investigator did note during chart abstraction that many of the women participating did have these diagnoses noted in their records. Partner violence was not cited as a barrier to drug adherence for HIV-infected women.

The Neuman Systems Model framework was ideal for this study and helps illustrate how the stressors of HIV and intimate partner violence contribute to vulnerability of the woman's core stability. While antiretroviral medications are prescribed for women to assist their immune system in controlling viral replication, compounding stressors may allow penetration of lines of defense and her reaction may be to forget to take the medication or simply not prioritize it over other conditions and situations with which she may be dealing. Co-morbid conditions such as substance abuse and psychiatric illnesses could certainly add additional stress to the woman's lines of defense, causing further instability and inability to adequately manage her HIV infection through consistent antiretroviral adherence.

Limitations

Interpretations of this study must be considered with identified limitations. The study results are reflective of this sample but may not be generalized to other populations of HIV-infected women who experience intimate partner violence. The sample size may not have been large enough to test for significance in the correlations between severity of violence and adherence. Additionally, the convenience sample of participants for this study were all recruited from one large, urban, publically-funded HIV specialty clinic and was limited to only women who were willing to be interviewed and who might have been at the clinic during the time period in which recruitment occurred. Finally, violence was limited to physical and sexual acts and did not include aspects of spiritual, mental or emotional abuse which women may have experienced.

Conclusion and Implications

The results of this study examining the relationship of intimate partner violence, antiretroviral adherence and viral replication contributed to the following conclusion: HIV-infected women who reported intimate partner violence in the recent 12 months had significantly lower antiretroviral adherence and a greater proportion of detectable viral replication compared to women who did not report intimate partner violence.

Implications for the health care of HIV-infected women which can be drawn from this study are as follows:

1. Participation indicated that HIV-infected women who experienced intimate partner violence are willing to disclose their experiences and their lack of adherence to their medication regimens.
2. Fifty-two percent of HIV-infected women in this study reported intimate partner violence and had associated lower antiretroviral medication adherence with the greater likelihood of detectable viral replication.
3. Antiretroviral treatment guidelines now recommend earlier and more aggressive initiation of antiretroviral medications. Antiretroviral medications are most effective if taken on schedule. Potential barriers to antiretroviral treatment, such as partner violence, should be acknowledged and all HIV-infected women regularly assessed for intimate partner violence and offered safety and resource information.

Recommendations for Further Study

The results of this study confirmed the need for additional research regarding intimate partner violence among HIV-infected women. Recommendations for future studies include:

1. Research that extends the definition of intimate partner violence to include emotional, verbal, and spiritual in addition to physical and sexual violence.

2. Evidence-based research using the Neuman Systems Model framework as the basis for testing nursing interventions to reduce the stress of violence and strengthen the woman's lines of resistance and defense to promote antiretroviral adherence in HIV-infected women.
3. Replication research that includes a larger sample size of HIV-infected women from diverse clinical care settings and geographic areas.

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APPENDIX A

Demographic Data Forms

Demographic Data Form (English)

Date_____ Code # _____

Ask the woman the following questions:

1. What is your date of birth? _____

2. What is your Race/ethnicity?
   - ☐ White
   - ☐ Black
   - ☐ Hispanic
   - ☐ Asian
   - ☐ American Indian
   - ☐ Pacific Islander
   - ☐ Other, please specify _____

3. Who do you live with? (Mark all that apply)
   - ☐ Spouse/boyfriend
   - ☐ Children
   - ☐ Parents
   - ☐ Friends
   - ☐ Alone
   - ☐ Other

4. What is the highest grade or level of education you completed?
   - ☐ Never attended school or kindergarten only
   - ☐ Elementary school (grades 1 through 8)
   - ☐ Some high school (grades 9 through 11)
   - ☐ High school graduate (grade 12 or GED)
   - ☐ Some college (1 to 3 years of college)
   - ☐ College graduate (4 years or more of college)
   - ☐ Other, please specify _____

5. Are you working outside of your home (Employment status) ☐ Yes ☐ No

6. Distance from facility (in time and distance)_____

7. What year were you first diagnosed with HIV? _____

8. What HIV medications are you currently taking?

_____

When did you start the current medications? Date_____

Demographic Data Form (Spanish)

Date_____ Code # _____

Haga las siguientes preguntas a la mujer:

1. ¿Cual es la fecha de su cumpleaños? _____

2. ¿Cual es su raza/grupo étnico?
   - ☐ Blanco
   - ☐ Afroamericano
   - ☐ Hispano
   - ☐ Asiático
   - ☐ Indio Americano
   - ☐ Isleno Pacifico
   - ☐ Otro, por favor especifique _____

3. ¿Con quien vive? (Marque todas las opciones que apliquen)
   - ☐ Esposo/novio
   - ☐ Hijos
   - ☐ Papas
   - ☐ Amigos
   - ☐ Sola
   - ☐ Otro

4. ¿Cual es su nivel de educación mas alto?
   - ☐ Nunca fue a la escuela o preescolar solamente
   - ☐ Escuela primaria (grados 1 al 8)
   - ☐ Algo de preparatoria (grados 9 al 11)
   - ☐ Graduado de preparatoria (grado 12 o su equivalente)
   - ☐ Algo de universidad (1 a 3 años de universidad)
   - ☐ Graduado de universidad (4 años o más de universidad)
   - ☐ Otro, por favor especifique _____

5. ¿Trabaja fuera de su casa? ☐ Si ☐ No

6. ¿Que tan retirado vive de la clínica (tiempo y distancia)?

7. ¿En que año fue diagnosticada con VIH? _____

8. ¿Cuál medicamento antirretroviral esta usted tomando actualmente?

_____

_____

¿Cuando empezó a tomar los medicamentos que esta tomando ahora?_____

APPENDIX B

Severity of Violence Against Women Scale

Severity Violence Against Women Scale (English)

Date _____ Code _____

DURING THE LAST 12 MONTHS, how often has :	NEVER	ONCE	2-3 TIMES	4 OR MORE TIMES
1. Hit or kicked a wall, door or furniture?	1	2	3	4
2. Threw, smashed or broke an object?	1	2	3	4
3. Drove dangerously with you in the car?	1	2	3	4
4. Threw an object at you?	1	2	3	4
5. Shook a finger at you?	1	2	3	4
6. Made threatening gestures at you?	1	2	3	4
7. Shook a fist at you?	1	2	3	4
8. Acted like a bully toward you?	1	2	3	4
9. Destroyed something belonging to you?	1	2	3	4
10. Threatened to harm or damage things you care about?	1	2	3	4
11. Threatened to destroy property?	1	2	3	4
12. Threatened someone you care about?	1	2	3	4
13. Threatened to hurt you?	1	2	3	4
14. Threatened to kill himself/herself?	1	2	3	4
15. Threatened you with a club-like object?	1	2	3	4
16. Threatened you with a knife or gun?	1	2	3	4
17. Threatened to kill you?	1	2	3	4
18. Threatened you with a weapon?	1	2	3	4
19. Acted like he wanted to kill you?	1	2	3	4
20. Held you down, pinning you in place?	1	2	3	4
21. Pushed or shoved you?	1	2	3	4
22. Shook or roughly handled you?	1	2	3	4
23. Grabbed you suddenly or forcefully?	1	2	3	4
24. Scratched you?	1	2	3	4
25. Pulled your hair?	1	2	3	4
26. Twisted your arm?	1	2	3	4
27. Spanked you?	1	2	3	4
28. Bit you?	1	2	3	4
29. Slapped you with the palm of his hand?	1	2	3	4
30. Slapped you with the back of his hand?	1	2	3	4
31. Slapped you around your face and head?	1	2	3	4
32. Kicked you?	1	2	3	4
33. Hit you with an object?	1	2	3	4
34. Stomped on you?	1	2	3	4
35. Choked You?	1	2	3	4
36. Punched you?	1	2	3	4
37. Burned you with something?	1	2	3	4
38. Used a club-like object on you?	1	2	3	4
39. Beat you up?	1	2	3	4
40. Used a knife or gun on you?	1	2	3	4
41. Demanded sex whether you wanted to or not?	1	2	3	4
42. Made you have oral sex against your will?	1	2	3	4
43. Made you have sexual intercourse against your will?	1	2	3	4
44. Physically forced you to have sex?	1	2	3	4
45. Made you have anal sex against your will?	1	2	3	4
46. Used an object on you in a sexual way?	1	2	3	4

Severity Violence Against Women Scale (Spanish)

Fecha _____ Code _____

EN LOS ULTIMOS 12 MESES, cuan a menudo el hombre que la maltrato:	NUNCA	UNA VEZ	2-3 VECES	4 O MAS VECES
1. ¿Le ha dado o pateado a una pared, una puerta, o un mueble?	1	2	3	4
2. ¿Ha tirado, destruido o roto un objeto?	1	2	3	4
3. ¿Ha manejado (conducido) peligrosamente; con usted en el carro (auto)?	1	2	3	4
4. ¿Le ha tirado un objeto?	1	2	3	4
5. ¿Le ha apuntado (señalado) con un dedo (meneándolo)?	1	2	3	4
6. ¿Le ha hecho gestos amenazantes?	1	2	3	4
7. ¿Le ha mostrado el puño, de forma amenazante?	1	2	3	4
8. ¿La ha intimidado?	1	2	3	4
9. ¿Ha destruido algo que le pertenecía a usted?	1	2	3	4
10. ¿La ha amenazado con dañar o destruir cosas que usted estima?	1	2	3	4
11. ¿La ha amenazado con destruir la propiedad?	1	2	3	4
12. ¿Ha amenazado a alguien que usted estima (aprecia)?	1	2	3	4
13. ¿La ha amenazado con hacerle daño?	1	2	3	4
14. ¿La ha amenazado con quitarse la vida?	1	2	3	4
15. ¿La ha amenazado con un palo, macana, bate, o un objeto parecido?	1	2	3	4
16. ¿La ha amenazado con cuchillo o pistola?	1	2	3	4
17. ¿La ha amenazado con matarla?	1	2	3	4
18. ¿La ha amenazado con un arma?	1	2	3	4
19. ¿ Ha actuado como si la quisiera matar?	1	2	3	4
20. ¿La ha tirado al piso y la ha mantenido inmovilizada?	1	2	3	4
21. ¿La ha empujado?	1	2	3	4
22. ¿La ha sacudido fuertemente (menearla)?	1	2	3	4
23. ¿La ha agarrado súbitamente (repentinamente) o con fuerza?	1	2	3	4
24. ¿La ha arañado?	1	2	3	4
25. ¿La ha halado (jalado) el pelo?	1	2	3	4
26. ¿Le ha torcido (doblado) un brazo?	1	2	3	4
27. ¿Le ha dado unas nalgadas?	1	2	3	4
28. ¿La ha mordido?	1	2	3	4
29. ¿La ha abofeteado (cacheteado) con la palma de su mano?	1	2	3	4
30. ¿La ha abofeteado (cacheteado) con la parte de atrás de su mano?	1	2	3	4
31. ¿Le ha dado alrededor de la cara y en la cabeza?	1	2	3	4
32. ¿La ha pateado?	1	2	3	4
33. ¿Le ha dado con un objeto?	1	2	3	4
34. ¿La ha pisoteado?	1	2	3	4
35. ¿La ha tratado de estrangular?	1	2	3	4
36. ¿Le ha dado un puño?	1	2	3	4
37. ¿La ha quemado con algo?	1	2	3	4
38. ¿Ha utilizado un objeto parecido a un palo, macana, o un bate?	1	2	3	4
39. ¿Le ha dado una paliza (zurra)?	1	2	3	4
40. ¿Ha utilizado un cuchillo o revólver?	1	2	3	4
41. ¿Le ha exigido tener sexo a pesar de que usted no quería?	1	2	3	4
42. ¿La ha obligado a tener sexo oral?	1	2	3	4
43. ¿La ha obligado a tener relaciones sexuales?	1	2	3	4
44. ¿La ha obligado a tener relaciones sexuales, por la fuerza?	1	2	3	4
45. ¿La ha obligado a tener relaciones sexuales por el ano (anales)?	1	2	3	4
46. ¿Ha utilizado un objeto, con usted, de una forma sexual?	1	2	3	4

APPENDIX C

Danger Assessment

Danger Assessment (English)

Date_____ Code_____

Several risk factors have been associated with increased risk of homicides (murders) of women and men in violent relationships. We cannot predict what will happen in your case, but we would like you to be aware of the danger of homicide in situations of abuse and for you to see how many of the risk factors apply to your situation.

The following question place women at higher risk of violence

1. Has the physical violence increased in severity or frequency over the past year?	Yes	No
2. Does he own a gun?	Yes	No
3. Have you left him after living together during the past year? 3a. (If have *never* lived with him, check here___)	Yes	No
4. Is he unemployed?	Yes	No
5. Has he ever used a weapon against you or threatened you with a lethal weapon? 5a. (If yes, was the weapon a gun?____)	Yes	No
6. Does he threaten to kill you?	Yes	No
7. Has he avoided being arrested for domestic violence?	Yes	No
8. Do you have a child that is not his?	Yes	No
9. Has he ever forced you to have sex when you did not wish to do so?	Yes	No
10. Does he ever try to choke you?	Yes	No
11. Does he use illegal drugs? By drugs, I mean "uppers" or amphetamines, speed, Angel dust, cocaine, "crack", street drugs or mixtures.	Yes	No
12. Is he an alcoholic or problem drinker?	Yes	No
13. Does he control most or all of your daily activities? (For instance: does he tell you who you can be friends with, when you can see your family, how much money you can use, or when you can take the car? (If he tries, but you do not let him, check here: ____)	Yes	No
14. Is he violently and constantly jealous of you?	Yes	No
15. Have you ever been beaten by him while you were pregnant? (If you have never been pregnant by him, check here: ____)	Yes	No
16. Has he ever threatened or tried to commit suicide?	Yes	No
17. Does he threaten to harm your children?	Yes	No
18. Do you believe he is capable of killing you?	Yes	No
19. Does he follow or spy on you, leave threatening notes or messages on answering machine, destroy your property, or call you when you don't want him to?	Yes	No
20. Have you ever threatened or tried to commit suicide?	Yes	No

Danger Assessment (Spanish)

Date_____ Code_____

Se ha asociado la presencia de varios factores de riesgo con un aumento en el riesgo de homicidio (o asesinato) de mujeres y hombres con relaciones violentas. No puede predecirse qué pasará en su caso, pero nos gustaría que se mantuviera atenta al riesgo de homicidio en situaciones de maltrato, y que compruebe cuantos y cuales son los factores de riesgo que se dan en su caso.

Las siguientes preguntas ponen en un riesgo de violencia mas alto

1. ¿Ha aumentado la violencia física en severidad o frecuencia, en el último año?	Si	No
2. ¿Tiene él algún arma?	Si	No
3. ¿Le ha dejado usted, después de vivir juntos, en el último año? 3a. [Si nunca ha vivido con él, señálelo aquí ____]	Si	No
4. ¿Está él en paro actualmente?	Si	No
5. ¿Ha usado algún arma contra usted o le ha amenazado con algún arma? 5a. [en caso afirmativo, ¿fue con una pistola? _____]	Si	No
6. ¿Le ha amenazado con matarla?	Si	No
7. ¿Ha evitado él ser arrestado por violencia doméstica?	Si	No
8. ¿Tiene usted algún niño/hijo que no es de él?	Si	No
9. ¿Le ha forzado a mantener relaciones sexuales cuando usted no lo deseaba?	Si	No
10. ¿Ha intentado alguna vez estrangularla?	Si	No
11. ¿Toma él drogas?, como por ejemplo anfetaminas, cocaina, heroína, crack u otras drogas.	Si	No
12. ¿Es alcohólico o tiene problemas con el alcohol?	Si	No
13. ¿Le controla él la mayoría de sus actividades diarias? Por ejemplo, le dice con quién puede hacer amistades, cuándo puede ver a su familia, cuánto dinero puede usar/ gastar, o cuándo puede coger el coche? [Si lo intenta pero usted no le deja, señálelo aquí _____] ¿ Es celoso con usted constante y violentamente?	Si	No
14. (Por ejemplo, dice "si no puedo tenerte, nadie podrá") ¿ Le ha golpeado alguna vez estando embarazada?	Si	No
15. [Si no ha estado nunca embarazada de él, señálelo aquí ____]	Si	No
16. ¿ Alguna vez él ha amenazado con suicidarse o lo ha intentado?	Si	No
17. ¿ Amenaza él con hacer daño a sus hijos?	Si	No
18. ¿ Cree usted que es capaz de matarla?	Si	No
19. ¿ La persigue o espía, le deja notas amenazantes o mensajes en el contestador, destruye sus cosas o propiedades, o le llama cuando usted no quiere?	Si	No
20. ¿ Alguna vez ha amenazado usted con suicidarse o lo ha intentado?	Si	No

APPENDIX D

Domestic Violence Specific Morisky Medication Adherence Scale

The Domestic Violence Specific Morisky-Medication Adherence Scale 8 Items (English)

Date_____ Code_____

Questions	Response Options	
1. Do you sometimes forget to take your HIV pills?	Yes	No
2. Over the past two weeks, were there any days when you did not take your HIV medicine?	Yes	No
3. Have you ever cut back or stopped taking your HIV medications without telling your doctor because you felt worse when you took them?	Yes	No
4. When you travel or leave home, do you sometimes forget to bring along your HIV medications?	Yes	No
5. Did you take your HIV medicine yesterday?	Yes	No
6. When you feel like your HIV is under control, do you sometimes stop taking your HIV medicine?	Yes	No
7. Taking medication everyday is a real incovenience for some people. Do you ever feel hassled about sticking to your HIV treatment plan?	Yes	No
8. How often do you have difficulty remembering to take all your HIV medication?	Never Almost Never Sometimes Quite Often Always	

The Domestic Violence Specific Morisky-Medication Adherence Scale 8 Items (Spanish)

Date_____ Code_____

Preguntas	Opciónes de Respuestas	
1. ¿Olvida tomar su medicina para el VIH algunas veces?	Si	No
2. Algunas veces las personas no se toman su medicina por razones diferentes al olvido. Piense en las dos semanas pasadas ¿dejó de tomar su medicina para el VIIH algún día?	Si	No
3. ¿Alguna vez ha reducido o dejado de tomar por completo sus medicamentos para la el VIH sin haberle dicho a su medico, debido a que se sentio peor al tomarlos?	Si	No
4. ¿Cuando viaja o sale de casa olvida llevar sus medicinas para el VIH algunas veces?	Si	No
5. ¿Se tomó sus medicinas para el VIH ayer?	Si	No
6. ¿Cuando siente que sus síntomas están bajo control deja de tomar su medicina para el VIH algunas veces?	Si	No
7. Tomar medicina para el VIH todos los dias es realment incomodo para algunas personas ¿siente usted que es un fastidio lidiar con su plan de tratamiento?	Si	No
8. ¿Con qué frecuencia le es dificil recordar que debe tomar todas sus medicinas para el VIH?		Nunca Casi Nunca Algunas Veces Muy Seguido Siempre

APPENDIX E

Medical Record Data Collection Form

Medical Record Data Collection Form

Date of enrollment and interview _____ Code # _____

Date of initiation of current regimen_____

CD4 results	Dates			
	Values			
Viral Load results	Dates			
	Values			
Opportunistic infections	Name of OI			
	Date of diagnosis			
Hospitalizations	Dates of inpatient stay			

APPENDIX F

Institutional Review Committee Approval

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

July 28, 2010

Ms. Debra Trimble
College of Nursing - Judith McFarlane Faculty Advisor
6700 Fannin Street
Houston, TX 77030

Dear Ms. Trimble:

Re: HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence

The request for an extension of your IRB approval for the above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and appears to meet our requirements for the protection of individuals' rights.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. A copy of all signed consent forms and an annual/final report must be filed with the Institutional Review Board at the completion of the study.

This extension is valid one year from July 8, 2010. According to regulations from the Department of Health and Human Services, another review by the IRB is required if your project changes in any way. If you have any questions, feel free to call the TWU Institutional Review Board.

Sincerely,

Carolyn Kelley

Carolyn Kelley, PT, DSc, NCS
Institutional Review Board - Houston

APPENDIX G

Agency Approval

Harris County Hospital District

service FIRST

We will create a healthier community and be one of America's best community-owned healthcare systems.

Research and Sponsored Programs
2525 Holly Hall, Room 187E
Houston, Texas 77054
Tel: 713.566.6914
Fax: 713.440.1384
research@hchd.tmc.edu

August 18, 2010

Debra Trimble, RN, MSN
Texas Woman's University
College of Nursing

RE: **No Number Used: HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence**

APPROVAL VALID FROM 8/18/10 TO 7/28/11

Location: Thomas Street Clinic

Dear Ms. Trimble:

The Harris County Hospital District is pleased to inform you that the research protocol named above has been approved for implementation. The study may not continue after the approval period without additional IRB and HCHD review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

The Principal Investigator must received approval from the IRB and HCHD before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the IRB and HCHD.

Attached is the approved and validated consent form. You must discard all previous informed consent documents being used and replace them with this stamped validated version. **Please be aware that only copies of the appropriately dated, stamped IRB and HCHD approved informed consent form can be used when written informed consent is required.**

Sincerely,

Diana Mouton

Diana Mouton, MHA, RN, CIP
Manager, Research & Sponsored Programs
Harris County Hospital District

xc: Dana Bjarnson, CNO
Margery Watt, Interim CNO
Pete Rodriguez, Director
Sandra Byrd, Associate Administrator
Research Office

APPENDIX H

Informed Consent Form

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Nelda C. Stark College of Nursing
Houston Center
6700 Fannin Street
Houston, TX 77030-2343
713-794-2100 713-794-2103

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TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence

Investigators: Ma. de los Angeles Nava.....713-254-0961
Debra Trimble.....832-423-4486
Advisor: Judith McFarlane.....713-794-2138

Explanation and Purpose of the Research

You are being invited to be part of a study. The study is going to be done with women who have HIV. Ms. Nava and Ms. Trimble are going to be doing the study. They are nurse researchers at Texas Woman's University. This project is part of their doctoral degree. The purpose of this study is to find out if there is any relationship between abuse, and how HIV progresses. This study is expected to be done by May 2011.

Research Procedures

About 400 women receiving care at this center will be part of the study. This study may help women infected with HIV who are also abused.

Your interview will be done in private in the center. The interview will take about 27 minutes of your time. You will first sign the consent to be in the study. Then you will be asked questions from four surveys. This study uses these surveys: 1) Demographic Data Form; 2) the Danger Assessment Scale; 3) the Severity of Violence Against Women Scale; and the Domestic Violence Specific Morisky Medication Adherence Scale, 8 items. After you complete the interview, the nurse researcher will review your medical records at the clinic as part of the study.

Potential Risks

You may feel tired and physical or emotional discomfort from being in the study. Physical risk from participating in the study is probably minimal. You may take breaks during the interview to decrease fatigue. You may stop the interview at any time if you feel physical or emotional discomfort. The nurse researcher will give you names and numbers for people you can talk to if you need.

Participant Initials

Title: HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence

Release of private information could happen by accident in research. Your confidentiality will be protected to the extent that is allowed and required by law. You will not be identified by name. A number will be assigned to your name. Only Ms. Nava, Ms. Trimble, and their advisor will have access to your information in paper and in computer devices. Only you and the nurse researcher will be present during the interview. Your answers to the questions will be kept safe and confidential.

All your information on paper and on computer devices will be placed in a locked file. The file will be behind locked doors in the researchers' office. All your information on paper will be torn and all your information on computer devices will be erased by 2016. The information gathered in this project will be included in the researchers' dissertations. The information may also be published in other documents. Your name or other information that could identify you will not appear in any publications.

The researchers will try to prevent any problem that could happen because of this research. You should let the researcher(s) know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Being part of this study is voluntary. If you decide to not participate, your care at the clinic will not be affected in any way. You may stop the interview at any time. There will not be penalties if you do this. You will receive $10 cash for your time spent completing all the portions of the interview. You will be given information on available resources for women who have experienced intimate partner violence. At the end of the study, a report of the results will be mailed to you upon request.*

Participant Initials

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Nelda C. Stark College of Nursing
Houston Center
6700 Fannin Street
Houston, TX 77030-2343
713-794-2100 713-794-2103

Pioneering Nursing's Future:
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Title: HIV-Infected Women Who Do and Do Not Report Intimate Partner Violence

Questions Regarding the Study

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you should ask the researchers; their phone numbers are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research at 713-794-2480.

_____ _____
Signature of Participant Date

The above consent form was read, discussed, and signed in my presence. In my opinion, the person signing said consent form did so freely and with full knowledge of it contents.

_____ _____
Signature of Investigator Date

* If you would like to obtain a report of the results of this study, please provide an address to which the report can be sent:

_____

_____

_____

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Houston, TX 77030-2343
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CONCENTIMIENTO PARA PARTICIPAR EN UNA INVESITGACION DE
TEXAS WOMAN'S UNIVERSITY

Titulo: Mujeres Infectadas Con VIH Quienes Reportan y Quienes No Reportan Violencia Provocada Por la Pareja Intima

Investigadores: Ma. de los Angeles Nava.....713-254-0961
Debra Trimble.....832-423-4486
Consejera: Judith McFarlane.....713-794-2138

Explicación Y Propósito de la Investigación

La estamos invitando a participar en un estudio. El Studio se hará con mujeres que tienen el VIH. La señora Nava y la señora Trimble estarán llevando acabo este estudio. Ellas son enfermeras e investigadoras de la escuela Texas Woman's University. El propósito de esta investigación es para averiguar la relación que pueda haber entre el abuso, como las mujeres toman su medicamento, y el avance del VIH. La fecha aproximada de terminación de este estudio es Mayo del 2011.

Procedimientos de la Investigación

Aproximadamente 400 mujeres recibiendo atención médica en este clínica participaran en esta investigación. Este proyecto pudiera ayudar a mujeres con VIH quienes también son abusadas.

La entrevista se le hará en privado en esta clínica. La entrevista durara aproximadamente 27 minutos. Antes de la entrevista usted firmara la forma de consentimiento para participar en el estudio. Después se le harán preguntas de estos cuatro cuestionarios: 1) Demographic Data Form; 2) Danger Assessment; 3) Severity of Violence Against Women Scale; y the Domestic Violence Specific Morisky Medication Adherence Scale, 8 Items. Una vez que la entrevista termine, las investigadoras revisaran su archivo medico como parte de este estudio.

Posibles Riesgos

Usted pudiera sentir cansancio, molestia fisica, o emocional por su participación en la entrevista. Los riesgos de sentir molestia fisica son minimos. Usted podrá tomar descansos para reducir el cansancio. Usted tendrá la libertad de suspender la entrevista en cualquier momento en caso

Iniciales del Participante

de sentir molestias fisicas o emocionales. La enfermera investigadora le va a proporcionar nombres y números de teléfono de personas que le podrán ayudar en caso que usted lo necesite.La difusión de información confidencial puede pasar por accidente en una investigación. Se
proveerá protección a su información confidencial tanto como la ley lo permita y lo requiera. Se le asignara un numero a usted y ese numero será usado en lugar de usar su nombre. Solo la señora Nava, la señora Trimble, y su consejera tendrán acceso a su información en papel, en computadora, o memorias removibles. Solo usted y la investigadora estarán presentes en el cuarto privado donde usted responderá a los cuestionarios.

La información que usted nos proporcione será confidencial y se mantendrá en un lugar seguro. Toda su información en papel y en equipo de computadora se mantendrán asegurados en un archivo bajo llave en la oficina de las investigadoras. Toda su información que aparezca en papel se romperá y toda su información en equipo de computadora se borrara a más tardar en el año 2016. La información recopilada en este proyecto será incluida en la disertación de las investigadoras. Esta información también pudiera ser publicada en otros trabajos de las investigadoras. De cualquier manera su nombre ú otra información que pueda identificarla a usted no será incluida en ninguna publicación.

Las investigadoras harán todo lo posible para prevenir cualquier problema que pudiera pasar como resultado de esta investigación. Usted deberá avisarle a la investigadora inmediatamente si acaso algún problema se presenta y ellas le ayudaran. De cualquier manera, Texas Woman's University no proporciona servicios médicos ni ayuda financiera para cubrir daños causados por participar en esta investigación.

Participación y Beneficios

Su participación en esta investigación es completamente voluntaria. Si usted decide no participar, los servicios de la clínica no serán afectados de ninguna manera. Usted puede suspender la entrevista en cualquier momento y no se le dará ningún castigo. Usted recibirá $10 dólar en efectivo por el tiempo que usted tomo en contestar todas las preguntas. También se le dará información de recursos disponibles para mujeres que sufren violencia domestica. Al final de la investigación, usted tendrá la oportunidad de recibir una copia de los resultados de esta investigación si usted lo desea.*

_____
Iniciales del Participante

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DENTON DALLAS HOUSTON

Nelda C. Stark College of Nursing
Houston Center
6700 Fannin Street
Houston, TX 77030-2343
713-794-2100 713-794-2103

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Titulo: Mujeres Infectadas Con VIH Quienes Reportan y Quienes No Reportan Violencia Provocada Por la Pareja Intima.

Preguntas Sobre la Investigación

Una vez que este consentimiento para participar en la investigación sea leído y firmado, se le dará una copia a usted para que la conserve. En caso de que usted tenga cualquier pregunta sobre la investigación, usted es completamente libre de hacerle las preguntas a las investigadoras; sus números de teléfono se encuentran en la parte de arriba de la primera hoja de este documento. Si usted tiene preguntas sobre sus derechos como participante en esta investigación, o si tiene preguntas sobre la forma en que esta investigación se esta llevando acabo, usted puede contactar a la oficina de investigaciones en Texas Woman's University al 713-794-2480.

Firma del Participante _____ Fecha _____

El presente consentimiento fue leído, explicado, y firmado en mi presencia. En mi opinión, la persona que firmo dicho consentimiento lo hizo sin que nadie la forzara y con pleno conocimiento de su contenido.

Firma de la Investigadora _____ Fecha de Hoy _____

*Si usted desea una copia de los resultados de esta investigación, por favor proporcione una dirección a la cual se le pueda enviar:

_____

_____

_____

Approved by the Texas Woman's University Institutional Review Board
Date: 7/13/2010

DECADE OF ACHIEVEMENT
1999 - 2009

Harris County Hospital District
Protocol Number: No Number Used
Approval Date: 08-18-10
Expiration Date: 7-28-11