# PERINATAL HUMAN IMMUNODEFICIENCY SCREENING

## IN WASHINGTON STATE

By

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The members of the Committee appointed to examine the thesis of SARAH ANNETTE WAGNER find it satisfactory and recommend that it be accepted.

Chair

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#### Abstract

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## Context

Perinatal Human Immunodeficiency Virus (HIV) transmission reduction is dependent upon the utilization of antiretroviral therapies (ART) in the pregnant women's medicinal regimen. Recent studies indicate that the uptake of HIV screening in pregnant populations is dependent on: 1) Access to a provider offering HIV perinatal screening; and, 2) Knowledge of the efficacy of ART at perinatal HIV transmission reduction. *Objective* 

To assess the association between knowledge of ART and HIV screening uptake in pregnant populations in the State of Washington.

## Design and Settings

Secondary data analysis was conducted on the 2000 and 2003 responses by pregnant individuals to the Washington State HIV/AIDS Knowledge, Attitudes and Beliefs Survey (KAB). The data obtained from this cross-sectional data collection were analyzed using bivariate and multivariate regression analyses. Variables controlled for in

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this research were: education, income, race, marital status, and susceptibility to HIV risk factors.

#### Results

The findings of this research did not provide support for the central hypothesis regarding the association between knowledge of ART and HIV screening uptake in pregnant populations in the State of Washington.

## Conclusion

One potential interpretation for the lack of support for the central hypothesis is that providers who offered the HIV test to their patients did indiscriminately of their patients' knowledge of ART, education, income, race, marital status, and susceptibility to HIV risk factors. Further research is needed to determine whether or not there is a statistically significant association between knowledge of ART and screening uptake in pregnant populations in the State of Washington.

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# Dedication

You escape from me, in giggles and glee...

Love you

Bryan George Baldwin 4-3-64 ~ 2-14-05

#### CHAPTER I

## INTRODUCTION / SIGNIFICANCE OF STUDY

This chapter will discuss the current situation surrounding perinatal HIV transmission in the United States in order to present the significance of the proposed research problem and hypothesis specific to the state of Washington.

More than twenty years ago Human Immunodeficiency Virus (HIV) was discovered and successfully isolated (Garrett, 1994). This virus (specifically a retrovirus) is the causative agent for the Acquired Immunodeficiency Syndrome (AIDS) (Garrett, 1994). The first cases of AIDS in the United States emerged in the 1980's with the opportunistic infections of Pneumoystis carinii pneumonia (previously only found in patients with weaken immune systems and concentrated exposure to immune-deficient individuals), oral Candida albicans fungi (thrush), and cytomegalovirus (CMV) infections (Garrett, 1994). Externally those afflicted with the newly emerging AIDS virus developed a rare form of cancer, Kaposi's sarcoma, which was generally isolated to certain parts of Africa (Garrett, 1994).

Since its isolation and identification, it is estimated that at least 28 million people globally have perished from the AIDS virus (British Broadcasting Company [BBC], 2004; AVERT, 2005). Worldwide, approximately 40.3 million people are living with the HIV virus (AVERT, 2005). It is estimated that globally, 1,600 infants are born daily infected with HIV; in the U.S. 280-370 cases are reported annually in neonates (Centers for Disease Control and Prevention [CDC], 2004).

The U.S.'s success at impeding perinatal HIV transmission is linked to the advent of Antiretroviral Therapies (ART) (Connor, et al., 1994). An additional important

contribution is the implementation of aggressive perinatal HIV screening policies enabling practitioners to identify and attempt prophylactic intervention with their infected pregnant patients (Kaiser Family Foundation [KFF], 2004). Timely administrations of current ART are correlated with rates of perinatal HIV transmission that are less than 1 percent (Sharland, Gibb, & Tudor-Williams, 2002).

#### Research Problem

Recent studies indicate that the uptake of HIV screening in pregnant populations is dependent on: 1) Access to a provider offering HIV perinatal screening (Anderson, Simhan, & Landers, 2004; Fernandez, et al., 2000, p. 460; Kline, O'Connor, 2005); and, 2) Knowledge of the efficacy of ART at perinatal HIV transmission reduction (Anderson, et al., 2004; Carusi, Learman, & Posner, 1998; Fernandez, et al., 2000; Ruiz, Molitor, Prussing, Peck, & Grasso, 2002).

Education, income, race, marital status, and susceptibility to HIV risk factors are additional factors contributing to screening uptake in pregnant populations (Kline, & O'Connor, 2005; Morbidity Mortality Weekly Report [MMWR], 2001). This research will control for the additional variables of: education, income, race, marital status, and susceptibility to HIV risk factors. Controlling for these variables, the knowledge of the efficacy of ART at perinatal transmission reduction and HIV screening uptake are analyzed.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Screening uptake in this study is measured by surveying the women who had access to a provider offering an HIV test during their prenatal care.

# Research Question

The key research question examined in this research is whether HIV screening uptake in the pregnant populations offered a test by their provider in the State of Washington is associated with knowledge of ART for perinatal transmission reduction?

#### CHAPTER II

#### THEORETICAL BASIS / LITERATURE REVIEW

Perinatal HIV transmission reduction is dependent upon the utilization of ART in the pregnant women's medicinal regimen (Connor, et al., 1994; Sharland, et al., 2002). In order to successfully convey the importance of ART utilization as an optimistic resolution to perinatal transmission, the history of antiretroviral (ARV) prophylactic utilization is discussed and related to the etiology of HIV.

Knowledge on the efficacy of ART impacts the policy options surrounding the HIV screening of pregnant women (Connor, et al., 1994; Sharland, et al., 2002). This impact is due to the incorporation of ART into medical practices surrounding the care and treatment of pregnant women currently infected with the virus. Race, income, and susceptibility to HIV risk factors are additional factors contributing to screening uptake in pregnant populations (MMWR, 2001).

The "Factors Attributed to HIV Testing Acceptance" section of the literature review provides a comprehensive review of the extent to which an individual's (either provider or patient) perception of the current situation regarding perinatal HIV transmission can influence their decision to consent to the screening.

#### Conceptual Model

The Health Belief Model (HBM) is utilized in order to predict the pregnant women's response to the HIV screening and a perinatal HIV transmission preventive service (Airhihenbuwa and Obregon, 2000). The HBM assesses the individual's perception of: 1) susceptibility; 2) severity; 3) benefits; and, 4) barriers (Dorr, Krueckeberg, Strathman, & Wood, 1999). A relevant example in the literature is the

positive association between women informed of the benefits of ART in improving neonate health and uptake of HIV perinatal screening (Boyd, Simpson, Hart, Johnstone, & Goldberg, 1999).

For the purposes of this thesis, only the benefit and barrier portions of the Health Belief Model are utilized in the selection of the variables. The secondary data set utilized in this research does not allow for the testing of the susceptibility and severity factors. In addition to the limitation within the data set, testing an individual based on their perceived susceptibility to HIV infection is discouraged in the literature due to the ability to miss a diagnosis (Airhihenbuwa & Obregon, 2000; Dorr, et al., 1999).

## Literature Review Methodology

The initial article search began in Lexis Nexis with the intent to research mandatory perinatal HIV screening policy (Jayaraman, Preiksaitis, & Larke, 2003). This initial interest resulted in the understanding of the current polices practiced in the United States: 1) Opt-Out; 2) Opt-In; and, 3) Voluntary (KFF, 2004).

The opt-out policy attempts to test the pregnant women routinely (or as a component of the standard battery of prenatal tests) unless the woman specifically declines the HIV testing (CDC, 2004). The opt-in perinatal HIV testing requires specific consent of the mother to the testing (following the mandatory pre-test HIV counseling) (CDC, 2004). A voluntary test is performed from the initiation of the pregnant woman, not the provider. The literature review identified the differences between the various screening approaches is specific to pregnant women since they are the target population.

The criteria of relevance are limited to law reviews generated via Lexis Nexis, and empirical research articles found through the internet database of Google Scholar and

Medline which identify peer reviewed articles. The terms searched for generally had a combination of: "pregnant, HIV, provider, knowledge, ART/ARV, infant, etc." The primary exclusion criterion was populations other than pregnant women and infants. The exclusion criterion is particularly important since any "general" searches on HIV will return over 1,000 articles.

Careful analysis of the articles and the articles' references generated in the literature searches equates to an exhaustive description of the available secondary data pertaining to perinatal HIV screening in the U.S. Additionally the method of "Shepardizing" the legal literature was performed. Shepardizing provides the researcher with a list of all the other articles registered in its database that have referenced the specific article selected.

After the exclusion criteria are applied to the literature search, there are approximately forty relevant citations. Of these forty, seven are directly applicable to the thesis topic.<sup>2</sup> The other articles are selectively included in the literature review in order to provide the necessary background on the topic.

### Background

HIV transmits during pregnancy and delivery from an infected mother to her baby at a rate of approximately 25 percent (CDC, 2004). The Pediatric Acquired Immunodeficiency Syndrome (AIDS) Clinical Trials Group (PACTG) conducted a landmark study in 1994 (termed Protocol 076), which demonstrated that in utero administration of Zidovudine (AZT) was an effective regimen for the reduction of maternal-infant HIV transmission (Connor, et al., 1994).

<sup>&</sup>lt;sup>2</sup> "Directly applicable" refers to the seven articles used in the "Factors Attributed to HIV Testing Acceptance (U.S.)" section.

After the completion of the Protocol 076 regimen, the proportion of infected infants in the control group was 8.3%, compared to 25.5% in the placebo cohort (Connor, et al., 1994). Protocol 076 was fundamental in demonstrating that in utero administration of Zidovudine results in a significant reduction in the rates of HIV transmitted from infected women to their infants. Thus, a proven successful prophylactic treatment for perinatal HIV reduction was established.

In 2004 the Centers for Disease Control and Prevention (CDC) estimated that of the 6,000 to 7,000 HIV infected pregnant women giving birth in the United States, only 280-370 infants were born infected (CDC, 2004). For a global perspective, it is estimated that 1,600 babies are born daily infected with HIV amounting to over half a million babies infected annually by mother-infant HIV transmission (CDC, 2004). The estimated annual number of newly diagnosed AIDS cases in the U.S. for women increased from 1999 to 2003 by 15 percent (CDC, 2004).

The relatively low rate of perinatal transmission rates in the United States when compared to other developing nations, is attributed to the utilization of ART (Connor, et al., 1994). Early identification of HIV is associated with reduction of irreversible immunological damages and the opportunity to reduce HIV transmission (Sanders, Bayoumi, Sundaram, Bilir, Neukermans, Rydzak, et al., 2005).

Factors Attributed to HIV Testing Acceptance (U.S.)

There are many reasons why women either accept or decline HIV testing. In a cross-sectional study of 247 pregnant women in the state of California, testing acceptance correlated with the pregnant women's knowledge of ART and their willingness to learn of their serostatus (even if positive) (Carusi, et al., 1998). The majority of the patients

surveyed in this study supported a routine (opt-out) approach to perinatal HIV screening (Carusi, et al., 1998). A possible lack of education on the efficacy of ARV utilization was reflected in finding that only a small percentage (24%) was aware of the transmission reduction caused by the implementation of ARV (Carusi, et al., 1998).

In a survey of 850 women receiving prenatal care in the state of California, 65.9% indicated knowledge of ART for reduction of perinatal HIV transmission (Ruiz, et al., 2002). Regardless of prior knowledge of ART, when informed of the benefits of ART for reduction of perinatal HIV transmission, 78.7% of the women surveyed indicated that they were more likely to undergo the HIV screening (Ruiz, et al., 2002). In comparison to the 78.7% of women associated with a likelihood of screening and ART knowledge, 1.3% of women with knowledge of ART indicated that their likelihood of testing was reduced (Ruiz, et al., 2002).

Knowledge upon the efficacy of ARVs in perinatal transmission prevention, and the pregnant women's perception of her provider endorsing and offering the testing correlate positively to testing acceptance in a study that interviewed 1,357 pregnant women in the Miami area (Fernandez, et al., 2000). The research surrounding provider's perception of HIV screening is generally supportive. However, women who have private insurance or receive perinatal care from a private provider correlate to lower levels of HIV testing<sup>3</sup> (Troccoli, Pollard, McMahon, Foust, Erickson, & Schulkin, 2002).

Although pediatricians generally understand the role that HIV screening has on perinatal reduction, a survey conducted of members of the American Academy of Pediatrics (AAP) revealed some discrepancy. Of the 982 responding physicians'

<sup>&</sup>lt;sup>3</sup> Due to limitations in the survey questionnaire used in this thesis, this study does not control for the insurance variable.

(representing a 59.6 percent response rate) reasons for not counseling pregnant patients of unknown HIV serostatus ranged from: 1) The practice area is in a perceived "low risk"<sup>4</sup> area (65.4%); 2) The parents were not perceived as "at risk"<sup>5</sup> (56.1%); 3) Concern and/or fear of offending the patients (50.2%); 4) Lack of understanding by the patients of the importance of perinatal screening (50.1%); and, 5) Lack of sufficient HIV pre-counseling time (44.4%) (Kline & O'Connor, 2005).

A study in 2001 conducted by the American College of Obstetricians and Gynecologist sought to evaluate the effectiveness of the implementation of a routine screening program at a maternity clinic in Birmingham, Alabama (Stringer, Stringer, Cliver, Goldenberg, & Goepfert, 2001). This study placed 3,415 pregnant women in an intervention group that fostered HIV testing into the routine battery of perinatal diseases screened for (opt-out), and compared this group to 3,778 pregnant women in the control group who received only HIV pretest counseling and voluntary HIV testing (Stringer, et al., 2001).

All of the women in the study had similar demographic and risk factors to HIV<sup>6</sup>, and of the population of women that received the routine screening methodology (intervention group), the overall percentage of women consenting to the HIV testing rose from 75% to 88%. (Stringer, et al., 2001). This study demonstrated that routine perinatal

<sup>&</sup>lt;sup>4</sup> "Low Risk" is defined as "having a low prevalence of HIV in the pediatrician's practice area" (Kline & O'Connor, 2005, p. e367).

<sup>&</sup>lt;sup>5</sup> "At Risk" is not specifically defined in the literature; pediatricians response to questioning regarding whether the "parents do not fit the profile of those "at risk" for HIV infection" is recorded in this article (Kline & O'Connor, 2005, p. e369).

<sup>&</sup>lt;sup>6</sup> Defined as "including maternal age, proportion who were primiparous, self-reported smoking and substance abuse (alcohol and illicit drug) history, and proportion diagnosed with a sexually transmitted disease (syphilis, gonorrhea, Chlamydia, hepatitis B) during the index pregnancy" (Stringer, et al., 2001, p. 1105).

HIV screening resulted in an increase in HIV testing among women in an urban obstetric clinic environment (Stringer, et al., 2001).

A study similar to the previous study utilized an education intervention<sup>7</sup> on 206 pregnant women seeking prenatal care in Pennsylvania (Anderson, et al., 2004). HIV test acceptance rate increased from 74.8% to 84.3% in the pregnant women who underwent the educational intervention (Anderson, et al., 2004).

In a fourteen state study of pregnant women voluntarily testing for HIV, counseling and testing correlated<sup>8</sup> with women of African-American descent and with women who received less than a high school education (MMWR, 1999; MMWR, 2001). Additional HIV counseling and testing correlations in the pregnant women studied were demonstrated in individuals less than 25 years of age<sup>9</sup>, recipients of Medicaid<sup>10</sup>, and individuals who sought prenatal care in public health care settings (MMWR, 1999;

## MMWR, 2001).

The factors of education, income, race, Hispanic ethnicity, marital status, and risk factors are controlled for in the statistical analysis due to the historical support in the literature describing these variables as correlates with HIV screening offering (MMWR, 1999; MMWR, 2001). Since the purpose of this research is to describe the acceptance of HIV screening in a population of women offered the HIV test by their provider, the key

<sup>&</sup>lt;sup>7</sup> "The intervention involved a brief standardized educational program provided by the intervention nurse and focused on the importance of universal screening for HIV as well as non-confrontational methods of patient education and counseling, with the goal of improving acceptance rates of testing in the clinic." (Anderson, Simhan, Landers, 2004, p. 116).

<sup>&</sup>lt;sup>8</sup> "In most states, black race, type of prenatal health-care provider, education level, age, and receipt of Medicaid benefits were associated significantly with maternal HIV testing." (MMWR, 1999, p. 401); the women survey with the above correlates were "significantly more likely to recall a discussion about testing." (MMWR, 1999, p. 401).

<sup>&</sup>lt;sup>9</sup> Due to limitations in the survey questionnaire used in this thesis, this study does not control for the age of the woman at the time of the pregnancy.

<sup>&</sup>lt;sup>10</sup> Due to limitations in the survey questionnaire used in this thesis, this study does not control for the insurance variable.

variable of interest is the knowledge of ART in perinatal transmission reduction supported in the literature as associated with uptake rates in pregnant populations (Carusi, et al., 1998; Fernandez, et al., 2000; Ruiz, et al., 2002).

Importance of Highly Active Antiretroviral Therapy (HAART) Regimens

There are four classifications of Antiretrovirals (ARVs): 1) Entry Inhibitors (EI); 2) Protease Inhibitors (PI); 3) Nucleoside/Nucleotide Analog Reverse Transcriptase Inhibitors (NRTI); and, 4) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) (The Body, 2004).

Current ARV regimens for HIV prevention and treatment incorporate a combination of at least two different types of the four ARVs in order to increase the ability of the treatment to impede viral replication (The Body, 2004). An ARV regimen that contains multiple types of ARVs, particularly a PI, is termed a Highly Active Antiretroviral Therapy (HAART), and is more successful than a monotherapy (single type of ARV utilized; i.e. Zidovudine) approach (BBC, 2004).

The addition of a PI to an ARV regimen (thus becoming a HAART regimen) is beneficial due to the PI's ability to inhibit the protease enzyme which catalyzes the virus's replication (National Institute of Health [NIH], 2005). When viral replication is impeded mutational probabilities are reduced, and the infected individual's viral load level plummets to an "undetectable level" when assayed (NIH, 2005).

In addition to the viral load reduction, an HIV infected patient receiving the ARV intervention should gain an increase in the lymphocyte count (specifically counted by the presence of the CD4 receptor site of the T-lymphocyte per mm<sup>3</sup> aliquot of sampled blood) (BBC, 2004). A person with a CD4 count of 200 cells per mm<sup>3</sup> or less is

classified as having the AIDS which is potentially fatal as it compromises the individual's immune system to the point where mortality is linked to opportunistic infections (resulting in co-morbidities) (BBC, 2004).

HAART regimens are an improvement upon the Zidovudine monotherapy approach due to their ability to reduce the risk of mother-infant transmission to approximately 2 percent (Watts, 2002). Additional research indicates that transmission rates below 1 percent are reported among women utilizing HAART and presenting with an undetectable HIV viral load at the time of delivery (Sharland, et al., 2002).

Since HAART regimens utilize multiple drugs that target varying sites of the HIV replication process, the potential for mutational resistance is minimized (Watts, 2002). ARV therapies that reduce the HIV viral load levels are correlated to reducing the risk of perinatal transmission while improving maternal health (Mofenson, Lambert, Stiehm, Bethel, Meyer, Whitehouse, et al., 1999).

Zidovudine monotherapy approaches, although successful at substantially reducing perinatal transmission, are suboptimal when compared to the current combination drug regimens (NIH, 2005). Aggressive combination antiretroviral regimens are the standard of care for prophylactic perinatal HIV transmission reduction due to their ability to maximize the suppression of viral replication (thus reducing the development of viral drug resistance) which enhances immune functioning (NIH, 2005). *Current Medical Care Regarding Pregnant HIV Positive Women* 

The U.S. Department of Public Health's recommendations for pregnant women infected with HIV-1 (HIV-1 is the predominate strain in the United States) are premised on the belief that therapies of known benefit to women are proscriptive during pregnancy

only when: 1) the adverse effects of the therapy are greater than the benefits to the pregnant woman; and, 2) there are known adverse effects on the fetus, infant, or mother (NIH, 2005).

In addition to implementation of HAART, management of HIV infection during pregnancy for developed nations recommends scheduled cesarean deliveries and formula milk feedings (Watts, 2002). This is due to the fact that perinatal HIV transmission can occur at three points: 1) During pregnancy (intrauterine); 2) During labor and delivery (intrapartum); or, 3) Post delivery via breast-feeding (postpartum) (MMWR, 2001) A successful reduction in perinatal HIV transmission is beneficial to not only the mother and infant involved in the process, but to the public in that the epidemic's prevalence is reduced (Sanders, et al., 2005).

#### Policy Analysis

With the 1996 reauthorization of the Federal Ryan White CARE Act,

amendments were made in an attempt to improve program spending priorities by creating legislation which required the adoption of the CDC guidelines<sup>11</sup> on HIV counseling and voluntary testing for pregnant women by the states (Lazzarini, 2002). Failure to adopt the CDC guidelines resulted in a loss of the federal funds allotted under the Ryan White

- recommend simplifying the testing process so that pretest counseling is not a barrier to testing,
- increase the flexibility of the consent process to allow for various types of informed consent,
- recommend that providers explore and address reasons for refusal of testing, and
- emphasize HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and chemoprophylaxis.

<sup>&</sup>lt;sup>11</sup> MMWR's "Revised Recommendations for HIV Screening of Pregnant Women" (2001) specified: The resulting guidelines are presented in this document. They differ from the 1995 guidelines in that they:

<sup>•</sup> emphasize HIV testing as a routine part of prenatal care and strengthen the recommendation that all pregnant women be tested for HIV,

These guidelines maintain a voluntary approach to HIV testing. This voluntary approach preserves a woman's right to make decisions regarding testing and supports a woman's right to refuse testing if she does not think it is in her best interest. (p. 66)

Comprehensive AIDS Resources Emergency (CARE) Act. (Lazzarini, 2002). As an incentive, states with the highest rate of HIV infection among their pregnant population that were compliant with the legislation received priority for the funding (Lazzarini, 2002). The Ryan White CARE Act is designed to finance the unmet health needs of individuals living with HIV (U.S. Department of Health and Human Services: Health Resources and Services Administration [HRSA], 2005).

In 1999 the Institute of Medicine (IOM) issued a report that correlated the lack of adequate perinatal HIV testing and treatment to the lack of universal screening practices (Lazzarini, 2002). The IOM highlighted the discrepancy in the current practice that allowed for the provider's perception of their patient's risk level to govern the implementation of the HIV testing (Lazzarini, 2002). An additional assertion was made that challenged the testing rates due to the providers either having too little time to administer the pre-test counseling, or the perception of the pretest counseling requirements as burdensome (Lazzarini, 2002). From these findings the IOM recommended the adoption of universal HIV testing, with patient notification, as a component of routine prenatal screening preventive care (Wolf, Lo, & Gostin, 2004).

Following the IOM's recommendation in 1999, the CDC in 2002 revised its recommendations for HIV counseling and testing of pregnant women, to include routine perinatal HIV screening with an additional simplification<sup>12</sup> on the informed consent requirements (Wolf, et al., 2004). Following the revised CDC recommendations, the American College of Obstetricians and Gynecologists (ACOG) and the American

<sup>&</sup>lt;sup>12</sup> An Opt-Out policy generally requires less pre-test counseling and informed consent requirements than an Opt-In policy (Wolf, et al., 2004, pp. 139-140; KFF, 2004, p.1). What is commonly described in the analyses of the Codes and Regulations (variations between the state, territory, and the District of Columbia) is a "notice" (versus an "offering" of the test; more often accompanied with counseling on the benefits of screening) of the HIV testing as a component of the routine battery of prenatal tests (Wolf, et al., 2004, pp. 139-140).

Academy of Pediatrics (AAP) recommended HIV testing as a routine part of prenatal care (American College of Obstetricians and Gynecologists [ACOG], 1999, p. 128; Wolf, et al., 2004). The ACOG is currently one of the largest proponents of a routine perinatal HIV screening policy (ACOG, 1999; Lazzarini, 2002).

#### Perinatal HIV Screening Methodologies: Opt-Out, Opt-In, Voluntary

When comparing the various perinatal HIV screening approaches, the decision to undergo testing is at the discretion of the pregnant woman. The Opt-Out policy attempts to test the pregnant women routinely (or as a component of the standard battery of prenatal tests) unless the woman specifically declines the HIV testing (CDC, 2004). The Opt-In perinatal HIV testing requires specific consent of the mother to the testing (following the mandatory pre-test HIV counseling (CDC, 2004). A voluntary test is at the initiation of the pregnant women not the provider. Two states, New York and Connecticut, have required mandatory newborn testing, but none of the states have required mandatory HIV testing of pregnant women<sup>13</sup> (MMWR, 2001).

The opt-out approach is demonstrated more effective at screening pregnant women for HIV when compared to an opt-in approach (MMWR, 2002). In the most recent comparison of the varying policies adopted by the states by The Kaiser Family Foundation, Opt-Out (where the providers are required to test for HIV unless refused by the pregnant woman) states encompassed only Arkansas, Tennessee, and Texas (KFF, 2004). Opt-In (where the providers are required to offer an HIV test to the pregnant woman) states encompassed California, Florida, Indiana, Iowa, Kentucky, Louisiana, Maryland, Michigan, New Jersey, Rhode Island, Virginia, and Washington (KFF, 2004).

<sup>&</sup>lt;sup>13</sup> Hodge, Gostin, Gebbie and Erickson (2006), note that "modern developments in constitutional (e.g., due process and equal protection) and statutory (e.g., disability discrimination) laws" preclude "unfettered…public health powers" like mandatory HIV testing (p. 79).

The rest of the states and Puerto Rico were classified as Voluntary (where the law surrounding perinatal HIV testing is not specified) (KFF, 2004). These data were based on 2002 legislation and conflicts with existing primary legal specification of the law (e.g. Washington is now Opt-Out<sup>14</sup>) which are not included in this literature review.

Concern is raised for the possibility of routine HIV testing placing pregnant women at a greater risk of harm due to: 1) HIV infection still presenting a greater risk of discrimination and other harms; and, 2) Pregnant women are more vulnerable because many women first learn of their HIV infection during pregnancy, disclosure of HIV status may trigger domestic violence, and pregnancy is a high risk period for abuse (Wolf, et al., 2004). Although these concerns have some validity, a greater concern with respect to an HIV positive individual is in their lack of knowledge about their condition (primarily for their own health implications).

#### Cost-Effectiveness of Perinatal Screening

In response to Protocol 076, an experiment was conducted to compare the costs incurred from the HIV screening and Zidovudine treatment of pregnant women to the decrease in expenditure resulting from the reduction in cases of pediatric HIV infection (Mauskopf, Paul, Wichman, & Tilson, 1996). From this analysis, it was concluded that the reduction in pediatric HIV cases reduced health care expenditures, but that the reduction in cost was dependent on the HIV prevalence rate and the costs of the screening program (Mauskopf, et al., 1996).

Historically, HIV screening has consisted of practitioners selectively targeting individuals (still subject to the individual's informed consent to the screening) based on the patient's responses to their involvement in "high-risk" behavioral activities. High

<sup>&</sup>lt;sup>14</sup> (246-100-208: Counseling Standard – AIDS Counseling, 2005).

risk behaviors were classified as: 1) Admission of injectable substance abuse; 2) Confounding medical treatment (i.e. blood or body transfusion); or, 3) Inhabiting an urban area (Lewis, O'Brien, Ray, Sibai, 1995). However, the offering of voluntary HIV screening to all pregnant patients is demonstrated as both cost effective and medically beneficial in an urban setting (Lewis, et al., 1995).

Targeted HIV screening to only those individuals perceived at a high risk increases the probability of missed diagnoses to a significant portion of the infected pregnant population (Lewis, et. al., 1995). These missed diagnoses allow for a preventable increase in the rate of perinatal transmission due to the failure of health care practitioners to administer ARVs (Lewis, et al. 1995).

The Department of Pediatrics at the University of Illinois in Chicago studied both direct and indirect costs attributed to the identification of both the HIV infected pregnant woman and the prevention and treatment of the infection to the newborn (Immergluck, Cull, Schwartz, & Elstein, 2000). This study indicated that universal (routine or Opt-Out) perinatal screening is more cost effective than a voluntary screening approach (Immergluck, et al., 2000).

For an international comparison, studies in the United Kingdom support Opt-Out screening policies (over Opt-In and Voluntary) due to their effectiveness at screening women for HIV and providing the most cost effective policy option (Ades, Sculpher, Gibb, Gupta, & Ratcliffe, 1999; Postma, Beck, Hankins, Mandalia, Jager, & De, 2000; Postma, Beck, Mandalia, Sherr, Walters, Houweling, et al., 1999; Simpson, Johnstone, Goldberg, Gormley, & Hart, 1999).

#### HIV Impacts on Neonates

In 1997 PACTG started a prospective study of the infants who were exposed to the zidovudine treatments in the PACTG 076 study (Culane, Fowler, Lee, McSherry, Brady, O'Donnell, et al., 1997). This study could not find a significant difference in the children exposed to antiretrovirals in utero when compared to the children who received the placebo (and did not transmit HIV) (Culane, et al., 1997). The children were compared in the areas of growth, development, and immune functioning (Culane, et al., 1997). Current studies are conducted by the National Institute of Allergy and Infectious Diseases (NIAID) to test the effects that ARVs, other than the AZT used in the PACTG 076 study will have on the growth and development of the neonates exposed.

For infants that are born infected with HIV, the higher viral load levels are associated with an increasing risk for the rapid progression of disease, which indicates that early ARV treatment is advantageous (Shearer, Quinn, LaRussa, Lew, Mofenson, et al., 1997). The necessity to treat neonates prophylactically with ARV is imperative.

For infants who are perinatally infected with HIV, the outlook is inconclusive and pessimistic. Obstacles impeding the long term success of the ARV treatment include: 1) Poor adherence due to the unpleasant taste, size, or amount of the ARV tablets; 2) Adverse effects of the regimen, both long and short term (example: abnormal lipid, glucose, and bone metabolism); and, 3) Lack of a family or a caregiver routine to monitor and assist with compliance (Sharland, et al., 2002). The global dilemma with perinatal transmission is that only 1% of the children living with HIV are living in Europe and the U.S. Developing nations face many problems including (but not limited to) the accessibility and affordability of efficacious ARVs (Sharland, et al., 2002).

## Summary of Key Findings

This literature review highlights the efficacy of ARV utilization in perinatal HIV transmission reduction. The literature supports the strong influence of the provider's discretion and counseling of the pregnant woman on her decision regarding the HIV screening. This creates a necessity for additional study in the area of access to providers that offer HIV testing to their pregnant patients, and the impact of ARV knowledge on HIV screening uptake in pregnant populations.

In addition to the offering of a test by a provider and the knowledge of ARVs, the literature indicates that HIV testing varies with education, income, race, marital status, and engagement in risk factors. These factors are controlled for in order to test the key hypothesis of knowledge of ART in the reduction of perinatal HIV transmission as indicated in the literature in order to contribute further research on the associations with perinatal HIV screening.

## CHAPTER III

## STUDY DESIGN /EVALUATIVE COMPONENET

This chapter introduces the key hypothesis tested from the survey data collected by the Washington State Department of Health. The data collection process by the Washington State Department of Health is described. From this data collection process, the population of interest is analyzed and the independent and dependent variables are operationally defined. The final portion of this section discusses the bivariate and multivariate regression analyses utilized to measure the association between the dependent variable of HIV screening uptake and the key independent variable of knowledge of ART.

#### Hypothesis Description

Based on the completed literature review, this study will examine the association between screening uptake in pregnant populations in the State of Washington and the knowledge regarding the efficacy of ART in perinatal HIV transmission reduction. *Key Hypothesis* <sup>15</sup>

HIV perinatal screening uptake in the State of Washington is positively associated with knowledge regarding the efficacy of ART in perinatal HIV transmission reduction. *Data Source* 

The 2000 and 2003 responses by pregnant individuals to the Washington State HIV/AIDS Knowledge, Attitudes and Beliefs Survey (KAB) were obtained from the Department of Health. The KAB data set is based on the data collected from random-

<sup>&</sup>lt;sup>15</sup> Controlling for the variables of: education, income, race, Hispanic ethnicity, risk factors, and marital status.

digit-dial telephone surveys of Washington State residents of 18 years or older (Rime, Courogen, & Peppert, 2001).

The KAB data samples selected by the random-digit-dial telephone surveys are collected from different counties that are aggregated into strata (Rime, 2004; Rime, et al., 2001). The strata were defined as<sup>16</sup>: 1) King county; 2) Other Western Washington counties; and, 3) Eastern Washington counties (Rime, 2004; Rime, et al., 2001). The "stratified equal quota sampling design" was utilized for the KAB in order to produce equal samples proportionate to the populations within the strata (Rime, 2004, p. 1; Rime, et al., 2001, p. 2)

The sample size for the 2000 survey was 800, of which 87 of the total 437 females surveyed were pregnant (Rime, et al., 2001). The sample size for the 2003 survey was 1,223, of which 146 of the total 762 females surveyed were pregnant (Rime, 2004). The survey years of 2000 and 2003 were selected as the questionnaire for these years contained the question regarding a pregnant woman's knowledge of ART (the 1995 and 1998 surveys did not contain the knowledge question) (Gilmore Research Group, 2003). The survey years of 2000 and 2003 were combined in order to provide a larger sample for the statistical analysis.

#### Analytical Approach and Methods

The statistical analyses were performed on the combined 2000 and 2003 data sets. These analyses constitute secondary data analyses as the primary data collection was performed by the Washington State Department of Health.

<sup>&</sup>lt;sup>16</sup> The strata for the 2000 KAB survey was reduced to two groups (Eastern and Western Washington Counties) due to a reduction in sample size; sampling design remained the same ensuring equal quotas represented within each strata (Rime, et al., 2001, p. 1).

The dependent variable used in this research is HIV screening uptake. The key independent variable used in this research is knowledge of ART efficacy in perinatal transmission reduction. Consistent with the existing literature, the control variables used in this research are: 1) Education Level; 2) Income Level; 3) Race (White vs. Non-White); 4) Hispanic Ethnicity; 5) Engagement in Risk Factors; and, 6) Marital Status. *Operational Definitions* 

The statistical frequencies for the dependent and independent variables were analyzed in order to determine if the variables of interested needed recoding prior to performing the bivariate and multivariate analyses. This process of recoding the variables according to the descriptive statistical frequency data also allowed for consistent variable labeling.

The dependent variable is operational defined as follows: The recollection of consent or refusal to a provider's HIV test offering while pregnant (e.g., 0=not tested; 1=tested).

The key independent variable is operationally defined as follows<sup>17</sup>: The documented verbal response of either having or not having knowledge of ART efficacy in perinatal transmission reduction (e.g., 0=No; 1=Yes).

Consistent with the existing literature, the independent variables controlled for in the multivariate analysis are operationally defined as follows<sup>18</sup>: 1) The documented verbal response of level of education completed (e.g., 0=High school or less; 1=Greater than high school); 2) The documented verbal response of the amount of annual household

<sup>&</sup>lt;sup>17</sup> Survey question stated as: "Are there medical treatments available that reduce the chance that a woman with HIV will pass on the virus to her baby?" (Gilmore Research Group, 2003, p. 4).

<sup>&</sup>lt;sup>18</sup> Education was collapsed from five categories; income was collapsed from 8 categories; race was collapsed from 5 categories (Gilmore Research Group, 2003, pp. 22-23).

income earned before taxes (e.g., 0=Less than \$35,000; 1=More than \$35,000); 3) The documented verbal response of the race classification (e.g., 0=White; 1=Non-White); 4) The documented verbal response to Hispanic ethnicity classification (e.g., 0=Yes; 1=No); 5) The documented verbal response to a list of risk factors (e.g., 0=Yes to at least one of the statements; 1=No to all the statements); 6) The documented verbal response to marital status (e.g., 0=Married; 1=Not Married).

## Bivariate and Multivariate Analyses

Bivariate (Chi-square) analyses are conducted to test the hypothesized associations between the independent and dependent variables (Kuzma & Bohnenblust, 2001). A multivariate logistic regression analysis is conducted to measure the association between the key independent and dependent variable while controlling for the additional independent variables (Kuzma & Bohnenblust, 2001). The statistical methodology is analytic in nature and the data are binary for all the variables analyzed (Kuzma & Bohnenblust, 2001).

The Chi-square analysis determines the association between the independent and dependent variables by comparing the observed and expected frequencies (Kuzma & Bohnenblust, 2001). The hypothesis was tested at the P  $\leq$  0.5 level of significance. If the results of the Chi Square analysis are a P  $\leq$  0.5 then the research could state that the associations observed are "unlikely to occur by chance except in rare instances; less than 5 percent of the time." (Kuzma & Bohnenblust, 2001, p. 188).

#### CHAPTER IV

#### RESULTS

This chapter discusses the results of the statistical analyses performed on the data from the Washington State Department of Health. The dependent variable (screening uptake) was tested against the independent variables of knowledge of ARVs, education, income, race, Hispanic ethnicity, marital status, and risk factors.

Table 1 displays the descriptive statistics of the survey respondents for the combined survey years of 2000 and 2003. The sample sizes and the percentages associated with the dependent variable, key independent variable, and other independent variables (controlled for in the multivariate regression analysis) are listed.

#### --- Insert Table 1 about here ---

Figure 1 demonstrates the percentage of women screened for HIV for the years of 1995, 1998, 2000, and 2003 (Rime, 2004, p. 1). The Appendix displays the results provided from the Washington State Department of Health detailing the numbers and percentages for the four survey years of: 1) Receiving of prenatal care; 2) Offering of an HIV test by the prenatal care provider; and, 3) HIV screening uptake (Rime, 2004, p. 1).

#### --- Insert Figure 1 about here ---

The percentages of women screened for HIV after receiving a test offering from a provider is the dependent variable analyzed for the combined years of 2000 and 2003 in this thesis. The percentage of women offered an HIV test by their provider increased by 19 percent in the survey respondents from 1995 to 2000. Of the percentage of women offered an HIV test by their provider, screening uptake increased in the survey respondents from 1995-2000 by 9 percent. A slight decrease is noticed in both the

percentage of women offered an HIV test by their provider, and the screening uptake between the survey years of 2000 and 2003. Although lower than the reported percentages for 2000, the 2003 percentages remain higher than the previously surveyed years of 1995 and 1998.

#### Chi Square Analyses

The Chi Square analyses were performed on the survey years of 2000 and 2003 for a total sample size of 162 women offered an HIV test, of which 126 women were screening for HIV while pregnant. Table 2 presents the finding of the Chi Square test for the association between the key independent variable (knowledge of ART) and the dependent variable (HIV screening uptake).

#### --- Insert Table 2 about here ---

Table 3 presents the findings of the Chi Square results for the associations between the independent variables (e.g., education, income, race, Hispanic descent, marital status, and risk factors) and the dependent variable (HIV screening uptake).

#### --- Insert Table 3 about here ---

Table 3 demonstrates that the key independent variable examined is not significantly associated with the dependent variable of screening uptake.

## Key Hypothesis

HIV perinatal screening uptake in the State of Washington is positively associated with knowledge regarding the efficacy of ART in perinatal HIV transmission reduction.

Table 3 demonstrates that none of the independent variables examined are significantly associated with the dependent variable of screening uptake. This

determination is primarily based on the P-Value, as a value of  $P \le 0.5$  is statistically significant (Kuzma & Bohnenblust, 2001).

The lack of statistical significance between the key independent variable and the dependent variable indicates that there is no evidence for the hypothesized relationship. The lack of statistical significance indicates that the associations between the dependent variable and each independent variable are inconclusive. The association between income and screening uptake is marginally significant at a p-value of 0.087 or slightly above the 0.05 significance level. This marginal level of significance indicates that there is a marginal association between income and screening uptake.

## Key Result

Based on the results of the bivariate Chi Square analysis, this hypothesis is inconclusive due to the lack of statistical significant association between perinatal screening uptake and knowledge regarding the efficacy of ART in perinatal HIV transmission reduction based on the current data set used in this research.

### Multivariate Analysis

A multivariate logistic regression analysis was performed in order to test the association between the key independent variable (knowledge) and the dependent variable (screening uptake) while controlling for the other independent variables (Kuzma & Bohnenblust, 2001). In the previous bivariate model, the analyses were performed between each independent and dependent variable without controlling for the additional independent variables (Kuzma & Bohnenblust, 2001). Since the confidence intervals are

wide (the odds ratio includes 1 between the lower and upper levels) the associations are insignificant<sup>19</sup> (Kuzma & Bohnenblust, 2001).

Table 4 displays the results of the multivariate logistic regression analysis. The variable controlled for in this analysis are: 1) Education level; 2) Income level; 3) Race (White vs. Non-White); 4) Hispanic ethnicity; 5) Engagement in Risk Factors; and, 6) Marital Status. The results of the multivariate regression analysis indicate that there is no statistical support for the key hypothesis tested. Those pregnant women who reported that they have knowledge of ART efficacy in perinatal transmission reduction were 35 percent less likely to undergo screening for HIV (OR = .647; CI = [.126; 3.315]), but this association is not statistically significant.

## --- Insert Table 4 about here ---

<sup>&</sup>lt;sup>19</sup> Odds ratios are not provided in Tables 2 and 3.

### CHAPTER V

#### CONCLUSIONS / LIMITATIONS OF THE STUDY

The purpose of this thesis was to test the associations between perinatal HIV screening uptake and knowledge of ARVs at perinatal transmission reduction. The results of the statistical analyses indicated inconclusive results for the support of the hypothesis. The independent variables controlled for in this research are: 1) Education; 2) Income; 3) Race; 4) Hispanic ethnicity; 5) Marital Status; and, 6) Risk factors. When tested in the Chi Square analysis, only the independent variable of income is marginally associated with screening uptake. This section will focus on the study limitations, policy implications and recommendations, and future research implications and recommendations.

#### Study Limitations

The first limitation in this study is the lack of statistical description on the cohort of women within the survey years that were not offered a HIV test by their provider. This portion was excluded from the analysis as only women offered a HIV test had the option to accept of decline the test. The acceptance or refusal of the test is utilized as the dependent variable of interest.

The second limitation with this study is in regards to the questionnaire design. Some of the questions regarding the variables were broadly stated and did not properly isolate the variable of interest (e.g. risk factors).<sup>20</sup> Other variables highlighted in the literature were not contained in the questionnaire (e.g., insurance coverage). The

<sup>&</sup>lt;sup>20</sup> The risk factors are: 1) You have hemophilia and have received clotting factor concentrates between

<sup>1977</sup> and 1985; 2) You are a native of Central or East Africa who has entered the United States since 1977; 3) Since 1977 you are or have been the sex partner of a man who had sex with another man even one time; 4) You have taken illegal drugs by needle at any time since 1977; 5) You have had sex for money or drugs at any time since 1977; 6) Since 1977, you are or have been the sex partner of any person who would answer yes to any of the items previously listed (Gilmore Research Group, 2003, p. 19)

question capturing the key independent variable is problematic in that it is specifically inquiring on the availability of the ART for pregnant individuals who are HIV positive.<sup>21</sup> A more refined definition for the operational definition of the knowledge of ART is necessary to avoid this limitation in future research.

The third limitation was related to the random-digit-dial telephone survey primary collection technique implemented by the Washington State Department of Health (Rime, 2004; Rime, et al., 2001). While the random-digit-dialing does allow for equal selection of unlisted numbers it is limited to only those households utilizing telephone land lines as a form of communication<sup>22</sup> (Shi, 1997).

The cross-sectional research design was utilized in order to describe the data extracted from the KAB survey (Aday, 1996; Hoyle, Harris, & Judd, 2002). The data extracted from these descriptive statistical analyses allow for analyses on the frequencies or the likelihood of certain associations to generalize to a larger population (Hoyle, et al., 2002). The associations in this research are inconclusive due to the lack of statistical significance between the key independent and dependent variables; these inconclusive results are not representative of a larger population until an association is statistically supported.

Based on the lack of statistical significance found in this research, a Power analysis was performed in order to determine if the inconclusive results (as measured by a p-value < 0.05) were a function of the small sample size (Aday, 1996). Using the

<sup>&</sup>lt;sup>21</sup> Survey question stated as: "Are there medical treatments available that reduce the chance that a woman with HIV will pass on the virus to her baby?" (Gilmore Research Group, 2003).

<sup>&</sup>lt;sup>22</sup> While not indicated in the literature, the recent increase in cellular phone utilization could potentially pose another limitation to the random-digit-dialing sampling validity.

observed effect size of 3 percent<sup>23</sup>, the alpha level of 0.05, and the total sample size of 121 <sup>24</sup>, the power level for this analysis is approximately 6 percent. Post hoc power analyses seek to achieve a large effect size of greater than 80 percent (Buchner, Faul, & Erdfelder, 2006). The effect size is designed to measure the proportion between the null and the alternative hypotheses (Buchner, et al., 2006). The forth limitation is that no estimation is available from the reviewed literature regarding the effect size (Anderson, et al., 2004; Carusi, et al., 1998; Fernandez, et al., 2000; Ruiz, et al., 2002).

When utilizing the Priori analysis with an adjusted power of 80 percent (actual power for this research is approximately 6 percent), it is determined that a sample size of 8,771 pregnant women is needed to significantly test the association between the key independent and dependent variables isolated from the KAB survey. This sample size determination is based on the 3 percent effect size, a 0.05 alpha level, and the adjusted power of 80 percent. If the assumed effect size is larger than 3 percent (i.e., 30 percent), the required sample size used to detect any potential associations between the key independent variable and the dependent variable is much smaller<sup>25</sup>.

Based on the findings of the Power and Priori analyses, the fifth and final limitation to this research is the small sample size. Due to this limitation, the statistical significance between the key independent variable and the dependent variable is measurable if the sample size is large (n = 8,771). If this experiment were replicated, a much larger sample size is required to achieve statistical significance.

<sup>&</sup>lt;sup>23</sup> The effect size is calculated by determining the difference in the proportions observed between the key independent variable and the dependent variable (the true observed difference).

<sup>&</sup>lt;sup>24</sup> The total sample size represents the sample size used in the Chi Square analysis between the key independent variable and the dependent variable.

<sup>&</sup>lt;sup>25</sup> The Priori analysis with an effect size of 30 percent results in a sample size of 88 pregnant individuals.

## Policy Implications and Recommendations

Effective July of 2002, the Washington Administrative Code regarding HIV/AIDS testing for pregnant women by their principal health care provider changed from an Opt-In policy to an Opt-Out policy<sup>26</sup> (246-100-208: Counseling Standard – AIDS Counseling, 2005). One interpretation of the lack of significance between the independent variables and pregnant screening uptake (dependent variable) in the women surveyed is that providers were encouraging screening of their pregnant patients regardless of the current policy and the associated factors examined in this research. This interpretation would emphasize that there is a standard of clinical practice not reflective of the current policy.<sup>27</sup>

As indicated in the literature review, perinatal HIV screening is not universally accepted and implemented across the United States (KFF, 2004; MMWR, 2002). Major questions remain as to the effectiveness of an Opt-In policy versus and Opt-Out policy. Targeted HIV screening practices of pregnant populations are discouraged as it increases the chance of missed diagnoses which delays the administration of prophylactic HAART regimens (Immergluck, et al., 2000; Lewis, et al. 1995). The CDC, IOM, ACOG, and

<sup>&</sup>lt;sup>26</sup> Principal health care providers shall counsel or ensure AIDS counseling for each pregnant woman continuing the pregnancy. This subsection shall not apply when health care is sought in order to terminate a pregnancy or as a result of a terminated pregnancy. AIDS counseling for a pregnant woman means: (d) Providing HIV testing unless the pregnant women refused to give consent.

<sup>&</sup>lt;sup>27</sup> However, Figure 1 does indicate that between the survey years of 2000 (Opt-In policy) and 2003 (Opt-Out policy) a slight decline in the percentage of providers offering the test and the screening uptake. What is unclear and cannot be measured in this study is whether the declines were reflective of the current policy or a lack of implementation of the policy. The change from the Opt-In policy to the Opt-Out policy could have reduced the "AIDS counseling" thus impacting the recall by the survey respondents of the "offering" of the test by the provider (Wolf, et al., 2004, p. 139; KFF, 2004, p.1).

AAP all recommend an Opt-Out perinatal screening policy<sup>28</sup> (ACOG, 1999; Wolf, Lo, and Gostin, 2004).

#### Future Implications and Recommendations

The literature is most supportive of educational interventions regarding the efficacy of HAART regimens for perinatal transmission reduction and the perception by the pregnant woman of her provider to endorse HIV testing (Anderson, et al., 2004; Carusi, et al., 1998; Fernandez, et al., 2000; Stringer, et al., 2001).

The Opt-Out policy is more effective than the Opt-In policy as measured by rates of women screening during pregnancy (MMWR, 2002; Stringer, et al., 2001). For comparative purposes, studies in the United Kingdom support Opt-Out screening policies as not only more effective at screening women for HIV, but also more cost effective (Ades, et al., 1999; Postma, et al., 2000; Postma, et al., 1999; Simpson, et al., 1999).

This comparison to the U.K. highlights the lack of emphasis on preventative care practices in the United States. What needs determination regarding perinatal HIV screening policies in the United States is whether the standard of care practiced by the principal health care provider is reflective of the policy. Research based on primary data collection of medical charts for pregnant women in states with varying screening policies as previously demonstrated in the MMWR's "HIV testing among pregnant women – United States and Canada, 1998 – 2001" is recommended (MMWR, 2002).

<sup>&</sup>lt;sup>28</sup> "We therefore support the recommendation of the IOM for universal HIV testing with patient notification as a routine component of prenatal care." (ACOG, 1999, p. 128). This utilization of the word "universal" with respect to "routine component of prenatal care" indicates support for an Opt-Out approach as the testing will not continue if refused by the pregnant patient; the U.S. does not allow HIV testing of non-incarcerated pregnant patients if a refusal is given (Wolf, et al., 2004, p. 139; KFF, 2004, p.1).

Descriptive Statistics of Survey Respondents (2000 and 2003)

Dependent Variable	Percentage				
HIV Screening in Pregnant Women					
Yes	80% <sup>a</sup>				
No	20% <sup>b</sup>				
Key Independent Variable & Controls	Sample Size (%)				
Knowledge of ARVs					
Yes	99 (82%)				
No	22 (18%)				
Education					
High School or less	55 (35%)				
	101 (65%)				
Income					
\$35,000 or less	55 (38%)				
\$35,000 or greater	90 (62%)				
Race					
White	147 (97%)				
Non-White	5 (3%)				
Hispanic Ethnicity					
Yes	15 (9%)				
No	143 (91%)				
Marital Status					
Married	112 (71%)				
Not Married	45 (29%)				
Risk Factors <sup>29</sup>	× /				
Yes to at least one	12 (8%)				
No to all	146 (92%)				

<sup>&</sup>lt;sup>a</sup> Sample sizes reported ranged from 96, 124, 116, 122, 126, 125, 126; corresponding to the variables of knowledge, education, income, race, Hispanic ethnicity, marital status, and risk factors, respectively. <sup>b</sup> Sample sizes reported ranged from 25, 32, 29, 30, 32, 32, 32; corresponding to the variables of knowledge, education, income, race, Hispanic ethnicity, marital status, and risk factors, respectively.

<sup>&</sup>lt;sup>29</sup> The risk factors are: 1) You have hemophilia and have received clotting factor concentrates between 1977 and 1985; 2) You are a native of Central or East Africa who has entered the United States since 1977;

<sup>3)</sup> Since 1977 you are or have been the sex partner of a man who had sex with another man even one time;

<sup>4)</sup> You have taken illegal drugs by needle at any time since 1977; 5) You have had sex for money or drugs at any time since 1977; 6) Since 1977, you are or have been the sex partner of any person who would answer yes to any of the items previously listed (Gilmore Research Group, 2003, p. 19)

Chi Square Results for the Association between Knowledge and Uptake Rates

	Uptake			$X^2$	Р
Knowledge	Yes (%)	No (%)			
Yes (%)	78 (79%)	21 (21%)		0.014	0.751
No (%)	18 (82%)	4 (18%)			

	Uptake		$X^2$	Р
Education	Yes (%)	No (%)		
≤ HS (%)	44 (80%)	11 (20%)	0.014	0.907
≥ HS (%)	80 (79%)	21 (21%)		
Income				
≤ 35K (%)	48 (87%)	7 (13%)	2.929	0.087
≥ 35K (%)	68 (76%)	22 (24%)		
Race				
	119			
White (%)	(81%)	28 (19%)	1.34	0.247
Non-White				
(%)	3 (60%)	2 (40%)		
Hispanic				
Yes (%)	12 (80%)	3 (20%)	0.001	0.98
	114			
No (%)	(80%)	29 (20%)		
Marital				
Yes (%)	87 (78%)	25 (22%)	0.906	0.341
No (%)	38 (84%)	7 (16%)		
Risk				
Yes (%)	10 (83%)	2 (17%)	0.103	0.748
	116			
No (%)	(79%)	30 (21%)		

Chi Square Results for Associations between Control Variables and Uptake Rates

Multivariate Regression Results for the Association between Knowledge and Uptake

		df	df P-Value		95.0% C.I. for Odd Ratio (OR)	
					Lower	Upper
	Knowledge*	1	.602	.647	.126	3.319

\*Controlling for the variables of education, income, race, Hispanic ethnicity, marital status, and risk factors.

# Figure 1







#### REFERENCES

- Aday, L. (1996). Designing and conducting health surveys. San Francisco, CA: John Wiley & Sons, Inc.
- Ades, A., Sculpher, M., Gibb, D., Gupta, R., & Ratcliffe, J. (1999). Cost effectiveness analysis of antenatal HIV screening in United Kingdom. *British Medical Journal* (*BMJ*), 319, 1230-1234.
- Airhihenbuwa, C., & Obregon, R. (2000). A critical assessment of theories/models used in health communication for HIV/AIDS. *Journal of Health Communication*, 5, 5-15.
- American College of Obstetricians and Gynecologists (ACOG). (1999). Joint statement of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. *Pediatrics*, 104, 128.
- Anderson, B., Simhan, H., & Landers, D. (2004). Improving universal prenatal screening for Human Immunodeficiency Virus. *Infectious Diseases in Obstetrics and Gynecology*, 12, 115-120.
- AVERT. (2005). World HIV & AIDS statistics. Retrieved March 15, 2006, from http://www.avert.org/worldstats.htm
- Boyd, F., Simpson, W., Hart, G., Johnstone, F., & Goldberg, D. (1999). What do pregnant women think about the HIV test? A qualitative study. *AIDS Care, 11*, 21-29.
- British Broadcasting Company (BBC). (2004). *The global spread of HIV*. Retrieved December 16, 2004, from <u>http://news.bbc.co.uk</u>.

Buchner, A., Faul, F., & Erdfelder, E. (2006). Types of analyses. Retrieved March 21, 2006 from <u>http://www.psycho.uni-</u>

duesseldorf.de/aap/projects/gpower/reference/reference\_manual\_03.html

- Carusi, D., Learman, L., & Posner, S. (1998). HIV test refusal in pregnancy: A challenge to voluntary testing. *Obstetrics & Gynecology*, 91, 540-545.
- Centers for Disease Control and Prevention (CDC). (2004). *Routine perinatal testing the Opt-Out approach question and answers*. Retrieved October 1, 2004 from: <u>http://www.cdc.gov/hiv/projects/perinatal/materials/C\_1.htm</u>
- CDC. (2004). *HIV/AIDS among women*. Retrieved December 2, 2004 from: http://www.cdc.gov/hiv/pubs/facts/women.htm
- Connor, E., Sperling, R., Gelber, R., Kiselev, P., Scott, G., O'Sullivan, M., et al. (1994).
  Reduction of maternal-infant transmission of Human Immunodeficiency Virus
  Type 1 with Zidovudine treatment. *The New England Journal of Medicine* (*NEJM*), 331, 1173-1180.
- Counseling Standard AIDS Counseling, Washington Administrative Code 246-100-208 (Am. 2005).
- Culnane, M., Fowler, M., Lee, S., McSherry, G., Brady, M., O'Donnell, et al. (1999).
   Lack of long-term effects of in utero exposure to Zidovudine among uninfected children born to HIV-infected women. *Journal of the American Medical Association (JAMA)*, 281, 151-157.

- Dorr, N., Krueckeberg, S., Strathman, A., & Wood, M. (1999). Psychosocial correlates of voluntary HIV antibody testing in college students. *AIDS Education and Prevention*, 11, 14-27.
- Fernandez, M., Wilson, T., Ethier, K., Walter, E., Gay, C., & Moore, J. (2000). Acceptance of HIV testing during prenatal care. *Public Health Report*, 115, 460-468.

Garrett, L. (1994). The Coming Plague. New York, NY: Penguin Books.

- Gilmore Research Group. (2003). 2003 Knowledge, Attitudes, and Beliefs Survey of AIDS awareness. *Washington State Department of Health, C03058*, 1-26.
- Hodge, J., Gostin, L., Gebbie, K., & Erickson, D. (2006). Transforming public health
  law: The Turning Point Model State Public Health Act. *Journal of Law, Medicine*& *Ethics, 34*, 77-84.
- Hoyle, R., Harris, M., & Judd, C. (2002). *Research methods in social relations*. Belmont,CA: Wadsworth Thomson Learning.
- Immergluck, L., Cull, W., Schwartz, A., & Elstein, A. (2000). Cost-effectiveness of universal compared with voluntary screening for Human Immunodeficiency Virus among pregnant women in Chicago. *Pediatrics*, 105, e54-e70. Retrieved March 20, 2004 from:

http://www.aidslaw.ca/Maincontent/issues/testing/07mandate1.html

Jayaraman, G., Preiksaitis, J., & Larke, B. (2003). Mandatory reporting of HIV infection and Opt-Out prenatal screening for HIV infection: Effect on testing rates. *Canadian Medical Association (CMAJ)*, 168, 679-682.

- Kaiser Family Foundation (KFF). (2004). *HIV testing for mothers and newborns, 2002*. Retrieved June 30, 2005 from: <u>http://www.statehealthfacts.kff.org</u>
- Kline, M., & O'Connor, K. (2003). Disparity between Pediatricians' knowledge and practices regarding perinatal Human Immunodeficiency Virus counseling and testing. *Pediatrics*, *112*, e367-e370. Retrieved March 20, 2004 from: <u>http://pediatrics.aappublications.org/cgi/reprint/112/5/e367</u>
- Kuzma, J., and Bohnenblust, S. (2001). *Basic statistics for the health sciences*. Fourth edition. Mountain View, CA: Mayfield Publishing Company.
- Lazzarini, Z., (2002). Legal issues concerning public health efforts to reduce perinatal HIV transmission. *Yale Journal of Health Policy, Law and Ethics, 1*, 1-32.
- Lewis, R., O'Brien, J., Ray, D., & Sibai, B. (1995). The impact of initiating a Human Immunodeficiency Virus screening program in an urban obstetric population. *American Journal of Obstetrics and Gynecology*, 173, 1329-1333.
- Mauskopf, J., Paul, J., Wichman, D., White, A., & Tilson, H. (1996). Economic impact of treatment of HIV-positive pregnant women and their newborns with Zidovudine. *JAMA*, 276, 132-138.
- Mofenson, L., Lambert, J., Stiehm, R., Bethel, J., Meyer, W., Whitehouse, J., et al.(1999). Risk factors for perinatal transmission of Human Immunodeficiency VirusType 1 in women treated with Zidovudine. *NEJM*, *341*, 385-393.

Morbidity and Mortality Weekly Report (MMWR). (2003, April 18). Advancing HIV prevention: New strategies for a changing epidemic – United States, 2003. Retrieved December 4, 2004 from:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5215a1.htm

MMWR. (2002, November 15). HIV testing among pregnant women – United States and Canada, 1998 - 2001. Retrieved December 4, 2004 from: <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5145a1.htm</u>

 MMWR. (2002, April, 26). Prevalence of selected maternal behaviors and experiences, Pregnancy Risk Assessment Monitoring System (PRAMS), 1999. Retrieved December 4, 2004 from:

http://www/cdc.gov/mmwr/preview/mmwrhtml/ss5102al.htm

MMWR. (2001, November 9). Revised recommendations for HIV screening of pregnant women. Retrieved December 4, 2004 from:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

- National Institute of Health [NIH]. (2005). Recommendations for use of antiretroviral drugs in pregnant HIV-1 infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Retrieved Februray 24, 2005 from: <u>http://AIDSinfo.nih.gov</u>
- Postma, M., Beck, E., Hankins, C., Mandalia, S., Jager, J., De Jong-Van Den Berg, L., et al. (2000). Cost effectiveness of expanded antenatal HIV testing in London. *AIDS*, 14, 2383-2389.

- Postma, M., Beck, E., Mandalia, S., Sherr, L., Walters, S., Houweling, H., et al. (1999). Universal HIV screening of pregnant women in England: Cost effectiveness analysis. *BMJ*, 318, 1656-1660.
- Rime, T. (2004). Washington State HIV/AIDS Knowledge, Attitudes and Beliefs Survey (KAB) 2003. Washington State Department of Health.
- Rime, T., Courogen, M., and Peppert, J. (2001). Washington State HIV/AIDS Knowledge Attitudes and Beliefs Survey: 1995-2000. Washington State Department of Health: Office of HIV/AIDS Prevention and Education.
- Ruiz, J., Molitor, F., Prussing, E., Peck, L., & Grasso, P. (2002). Prenatal HIV counseling and testing in California: Women's experiences and providers' practices. *AIDS Education and Prevention*, 14, 190-195.
- Sanders, G., Bayoumi, A., Sundaram, V., Bilir, S., Neukermans, C., Rydzak, C., et al. (2005). Cost-effectiveness of screening for HIV in the era of Highly Active Antiretroviral Therapy. *NEJM*, 352, 570-585.
- Sharland, M., Gibb, D., & Tudor-Williams, G. (2002). Advances in the prevention and treatment of paediatric HIV infection in the United Kingdom. *Archives of Disease in Childhood*, 87, 178-180.
- Shearer, W., Quinn, T., LaRussa, P., Lew, J., Mofenson, L., & Almy, S. (1997). Viral load and disease progression in infants infected with Human Immunodeficiency Virus Type 1. *NEJM*, *336*, 1337-1342.
- Shi, L. (1997). Health services research methods. Boston, MA: Delmar Publishers.

- Simpson W., Johnstone, F., Goldberg, D., Gormley, S., & Hart, G. (1999). Antenatal HIV Testing: Assessment of a routine voluntary approach. *BMJ*, *318*, 1660-1661.
- Stringer, E., Stringer, J., Cliver, S., Goldenberg, R., & Goepfert, A. (2001). Evaluation of a new testing policy for HIV to improve screening rates. *Obstetrics & Gynecology*, 98, 1104-1108.
- The Body. (2004). *HIV medications*. Retrieved November 3, 2004, from http://www.thebody.com/treat/antivir.html
- Troccoli, K., Pollard, H., McMahon, M., Foust, E., Erickson, K., & Schulkin, J. (2002). Human Immunodeficiency Virus counseling and testing practices among North Carolina providers. *The American College of Obstetricians and Gynecologists,* 100, 420-427.
- The Joint United Nations Programme on HIV/AIDS / World Health Organization [UNAIDS / WHO]. (2004). *Global summary of the AIDS epidemic*. Retrieved November 11, 2004, from

http://www.unaids.org/bangkok2004/GAR2004\_html

U.S. Department of Health and Human Services: Health Resources and Services Administration (HRSA). (2004). *Ryan White CARE Act*. Retrieved December 12, 2005, from <u>http://hab.hrsa.gov/history.htm</u>

Watts, H. (2002). Management of HIV infection in pregnancy. NEJM, 346, 1879-1891.

Wolf L.E., Lo B., & Gostin L.O. (2004). Legal barriers to implementing recommendations for universal, routine prenatal HIV testing. *The Journal of Law, Medicine & Ethics, 32*, 137-147.