A PLAUSIBLE CAUSAL MODEL OF TREATMENT OPTIMISM BELIEFS & ATTITUDES

ON HIV RISK BEHAVIOR AND UNDIAGNOSED INFECTION AMONG

YOUNG MSM, AND THE POTENTIAL OF RAPID

HIV SELF TESTING FOR PREVENTION

by

DUNCAN MACKELLAR

(Under the Direction of Su-I Hou)

ABSTRACT

Although considerable research has evaluated HIV/AIDS complacency and inadequate

HIV testing practices as important causes for the growing HIV epidemic among men who have

sex with men (MSM), many unanswered questions remain. Among these, three are particularly

important: (1) does HIV/AIDS complacency due to beliefs about highly active antiretroviral

therapy (HAART) cause or is caused by heightened HIV-acquisition behavior; (2) do differential

influences of HAART-efficacy beliefs explain, in part, racial HIV-infection disparities; and (3)

do main reasons for not testing for HIV, testing intentions, and potential use of an over-the-

counter rapid HIV test vary by important demographic and risk groups among MSM who have

never tested for HIV? To help address these questions, this dissertation evaluated data from two

cross-sectional surveys of MSM from eight U.S. cities recruited at MSM-identified venues

(1998-2000) and internet websites (2007).

Findings from these surveys suggest that among MSM: (1) HIV/AIDS complacency,

shaped in part by strong beliefs that HAART mitigates HIV/AIDS severity and HIV

susceptibility, both causes and is caused by heightened HIV-acquisition behavior; (2) racial HIV-

infection disparities are explained, in part, by racial/ethnic differences in the strength of these HAART-efficacy beliefs and their influence on HIV-infection risk; (3) most who have never tested for HIV (NTMSM) report not testing because of low perceived risk, structural barriers, and fear of testing positive, and although many report substantial risk behavior, few have strong testing intentions; and (4) main reasons for not testing vary by age, racial/ethnic, and risk subgroups, however, most NTMSM within these subgroups are accessible to prevention services and strongly intend to use an over-the-counter rapid HIV test should it become available.

Given the dramatic improvement in HAART to prolong quality life, compelling evidence that HAART reduces HIV transmission, and the growing HIV epidemic among MSM attributed, in part, to inadequate testing, translating these findings into contemporary prevention practices may be of considerable importance to reducing HIV incidence among MSM. This dissertation hopes to spur new research needed to replicate these findings and to inform the development of effective interventions to reduce HIV-acquisition risks, racial disparities, and undiagnosed HIV infection among MSM.

INDEX WORDS: HAART optimism, HIV risk behavior, Undiagnosed HIV infection, Over-the-counter rapid HIV tests, Structural equation modeling

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CHAPTER 1

INTRODUCTION

Public Health Significance

At the end of 2006, the Centers for Disease Control and Prevention (CDC) estimates that in the United States, 568,737 persons had died from HIV/AIDS since the beginning of the epidemic and a further 1.1 million persons were living with HIV/AIDS (CDC, 2008a; CDC, 2009a). In 2006 alone, 56,300 (95% confidence interval (CI), 48,200-64,500) persons were estimated to have been infected with HIV (Hall et al., 2008). Of those estimated to be living with HIV/AIDS at the end of 2006, 48.1% were men who have sex with men (MSM), 18.5% were injecting drug users (IDU), 27.6% were high-risk heterosexuals, and 65.4% were persons of color (CDC, 2008a). Persons of black (1,715.1 prevalent HIV infections per 100,000) and Hispanic (585.3 prevalent HIV infections per 100,000) race/ethnicity, had an estimated 7.6 and 2.6 times greater HIV prevalence respectively than persons of white race (224.3 prevalent HIV infections per 100,000) (CDC, 2008a).

Prior to the widespread availability and use of highly active antiretroviral therapy (HAART), HIV/AIDS was the 4th leading cause of premature mortality nationally in 1995, and among males, was the leading cause of premature mortality in 4 U.S. states (accounting for 13.9-22.7% of total years of potential life lost, YPLL) and in 51 U.S. cities (12.6-50.9% of YPLL); among females, HIV/AIDS was the leading cause of premature mortality in 11 U.S. cities (11.6-31.4% of YPLL) (Selik & Chu, 1997). Since the availability of HAART in 1996, excess HIV-associated mortality and YPLL have declined considerably with incremental improvements in the safety and efficacy of HAART (Bhaskaran et al., 2008; Antiretroviral Therapy Cohort

Collaboration, 2008). Although medical care for persons diagnosed with AIDS has been estimated to have saved at least 3 million years of life in the United States, considerable excess HIV-associated mortality and YPLL remains, attributed in large part, to late diagnosis and initiation of care (Walensky et al., 2006; Antiretroviral Therapy Cohort Collaboration, 2008). Had all persons with AIDS received timely care, one model estimates that at least 740,000 additional life years could have been saved (Walensky et al., 2006).

The magnitude of late HIV diagnosis, and prevalence and duration of persons with undiagnosed HIV infection are arguably the most important determinants of the course and severity of the HIV/AIDS epidemic in the United States. In 34 states with named HIV reporting, of 281,421 persons reported with HIV infection from 1996 through 2005, 38.3% and 45.0% were diagnosed with AIDS within 1 and 3 years, respectively, of their HIV diagnosis (CDC, 2009b). The consequence of delayed or infrequent testing is considerable. At the end of 2006, of the estimated 1.1 million persons living with HIV, an estimated 232,700 (21%) were undiagnosed and unaware of their infection (CDC, 2008a).

Since the average interval in time from HIV infection to AIDS is 10-11 years (Collaborative Group on AIDS Incubation and HIV Survival, 2000), many of the estimated 232,700 HIV-infected, unaware persons in 2006 had been infected for years and could neither take advantage of medical care known to prolong quality life nor take heightened steps to prevent transmission to others. A meta-analysis of 11 studies suggests that persons who become aware of their HIV infection substantially reduce their unprotected sexual risks with HIV-negative or unknown-status partners, and that risk reductions appears durable over time (Marks et al., 2005).

The impact of undiagnosed infection on the HIV/AIDS epidemic is thus thought to be substantial. Of the estimated 47,600 sexually-transmitted incident HIV infections in 2006 (Hall

et al., 2008), 25,704 (54%) to 33,320 (70%) are attributed to partners who were unaware of their HIV infection (Marks et al., 2006). Using the lower-bound estimate of 54% of incident infections attributed to infected-unaware partners, persons with undiagnosed infection have an estimated HIV transmission rate 3.5 times that of persons diagnosed and aware of their infection (Marks et al., 2006).

The considerable numeric toll of the HIV/AIDS epidemic in the United States can only be appreciated in the context of the appalling physical, psychological, social, and economic consequences HIV/AIDS. At the individual level, prior to HAART, HIV/AIDS resulted almost invariably in a visibly stigmatizing death from Kaposi's Sarcoma, pneumonia, systemic fungal infections, and a host of other opportunistic infections and cancers (Shilts, 1987; DeVita et al., 1988). The psychological and social ramifications were nearly as horrific as the disease.

Overt victimization of persons with HIV/AIDS including loss of important social networks, employment, housing, insurance, health care, educational opportunities, and emotional or physical abuse was common early in the epidemic and still occurs today (Shilts, 1987; Zierler et al., 2000; Rao et al., 2008). The double or triple stigmatization of being diagnosed with HIV/AIDS, belonging to a historically ostracized group overtly blamed as purveyors of a horrendous epidemic (e.g., MSM), and being a racial minority substantially raises vulnerability to stress, depression, and hopelessness; harmful coping strategies including substance use, unprotected sex, and promiscuity; and suicide (Cochran et al., 2003; Stall et al., 2003; Wolitski et al., 2008; Pre´au et al., 2008; Hatzenbuehler et al., 2008;). At the societal level, the economic burden of HIV/AIDS is considerable. For 2002 alone, the estimated lifetime direct medical and lost-productivity costs based on 40,000 estimated incident infections is $36.4 billion, or nearly $1

million per incident infection (Hutchinson et al., 2006a). In fiscal year 2010 alone, the presidential request for HIV/AIDS care, research, and prevention was $25.8 billion (Kaiser Family Foundation, 2009a).

The Epidemic Among MSM

Well into the third decade of epidemic in the United States, more cases of HIV/AIDS have been reported among MSM than among any other socio-demographic group (CDC, 2009a). By the end of 2006, 266,272 MSM had died from HIV/AIDS since the epidemic began, and an estimated 532,000 MSM were living with HIV/AIDS (CDC, 2008a). Increasing trends in reported diagnoses of syphilis and gonorrhea since the mid and late 1990s (Fox et al., 2001; Chen et al., 2002; Heffelfinger et al., 2007), coupled with increasing trends in sexual risk behaviors (Ekstrand et al., 1999; Katz et al., 2002; Chen et al., 2002) and reported HIV diagnoses (CDC, 2008b) raised concerns that the HIV epidemic might be resurging among MSM (Wolitski et al., 2001). Recently released HIV incidence estimates unfortunately affirmed these concerns.

Compared with IDU and high-risk heterosexuals in which estimated HIV incidence trends have declined or remained stable respectively, estimated HIV incidence among MSM has increased steadily from a nadir of approximately 20,000 annual infections in 1991-1993 to approximately 30,000 annual infections in 2003-2006 (Hall et al., 2008). In 2006, an estimated 53% of the 56,300 new HIV infections in the United States occurred among MSM, compared with 31% among heterosexuals and 12% among IDU (Hall et al., 2008). The surveillance findings also affirmed previous surveys that young black and Hispanic MSM are particularly at high risk for incident infection. MSM aged 13–29 years accounted for 38% of the total estimated

HIV incident infections among MSM in 2006, and 52%, 43%, and 25% of the estimated total incident infections among black, Hispanic, and white MSM, respectively (CDC, 2008c).

Early evidence that the HIV/AIDS epidemic might disproportionately affect younger generations of MSM emerged in the late 1980s from behavioral surveys in which younger men reported greater HIV exposure risks than older MSM (Hays et al., 1990; Ekstrand & Coates, 1990; Stall et al., 1992). These early concerns were confirmed by the first HIV seroprevalence survey of young MSM conducted in 1992 and 1993 (Lemp et al., 1994). In his seminal report, Lemp and colleagues (1994) observed that 9.4% of 425 young MSM 17-22 years of age sampled from public venues in San Francisco and Berkeley had already acquired HIV, and that young black MSM had much higher HIV seroprevalence than young white MSM (21.2% vs. 8.1%, Adjusted Odds Ratio (AOR), 2.5; 95% CI, 1.1-6.1) (Lemp et al., 1994).

These findings were confirmed in a subsequent 7-city survey that found 7.2% of 3492 15-22 year-old MSM sampled from public venues were HIV infected, and that HIV seroprevalence increased from 0% among 15 year-olds to 9.7% among 22 year-olds (Valleroy et al., 2000). Compared with young men entering the military during this period (~ 0.1% HIV+), HIV seroprevalence among young MSM was approximately 70-fold higher (cited in Valleroy et al., 2000). Finally, young black (14.1% HIV-positive) and Hispanic (6.9% HIV-positive) MSM had 6.3 and 2.3 times greater adjusted odds of HIV infection relative to young white MSM (3.3% HIV-positive) (Valleroy et al., 2000). Although population-based HIV-incidence rates are not estimated for MSM because of uncertainty about denominators at risk, both the racial-ethnic distribution of estimated incident infections among young MSM noted above (CDC, 2008c) and survey-based prevalence and incidence estimates among young MSM (Valleroy et al., 2000;

CDC, 2001) suggest that current HIV incidence rates among young black MSM are considerably higher than those of young white MSM in many metropolitan areas of the United States.

As in the broader population, the high HIV incidence among young MSM can be explained, in part, by infrequent or delayed HIV testing, the magnitude and distribution of undiagnosed HIV infection, and the sexual mixing patterns among young MSM. Although nearly all MSM report having ever tested for HIV (CDC, 2006a), considerably fewer younger MSM repeatedly test. In the same seven-city survey noted above, for example, of 3430 MSM aged 15-22 years, 74% reported previously testing 2 or fewer times (MacKellar et al., 2002). In a follow-up survey in six cities, 2797 MSM aged 23-29 years reported a median of only 3 prior tests (interquartile range 1-6) and 1281 (45.8%) had not tested in the past year (MacKellar et al., 2006a). The magnitude of infrequent or delayed testing may best be reflected in the proportion of MSM diagnosed with AIDS soon after their HIV diagnosis. In 34 states with named HIV reporting from 1996 through 2005, of 100,231 new HIV diagnoses among MSM, 40.9% and 47.8% were diagnosed with AIDS within 1 and 3 years of their HIV diagnosis, respectively (CDC, 2009b).

The consequence of infrequent HIV testing among young MSM on the prevalence unrecognized infection is considerable. Among 5,649 MSM 15-29 years of age sampled from public venues in 6 US cities, for example, 573 (10%) were found to be HIV infected; of those infected, 439 (77.7%) were unaware of their infection (MacKellar et al., 2005). The 439 HIV-infected, unaware MSM reported a median of only 2 prior HIV tests (interquartile range, 1-4); young black MSM in this survey had 6.8 times greater adjusted odds for unrecognized HIV infection than young white MSM (MacKellar et al., 2005).

In a follow-up study of 1767 MSM $\geq$18 yrs in five of these cities, of 450 (25%) MSM who tested HIV-positive, 67.5% of black, 47.5% of Hispanic, and 18.1% of white MSM reported being unaware of their infection (CDC, 2005a). The proportion of undiagnosed HIV infection decreased from a high of 78.9% among infected MSM 18-24 years of age to a low of 30.8% among infected MSM > 40 years of age (CDC, 2005a). Considering that infected-unaware persons have a conservatively estimated 3.5-fold higher HIV transmission rate than infected-aware persons (Marks et al., 2006), the substantially higher prevalence of undiagnosed HIV infection among young MSM, explains in part, the higher incidence of HIV infection among young MSM. In turn, the racial-ethnic distribution of unrecognized HIV infection noted above and assortative partnership practices help to explain, in part, the considerable racial-ethnic disparity in HIV incidence among MSM.

Assortative mating, the propensity of socio-demographic groups to have sexual partnerships within the same group, has been proposed as an important determinant for the concentration of sexually transmitted diseases, including HIV, within black communities (Laumann & Youm, 1999; Millett et al., 2006). Although additional research is needed, several reports suggest assortative partnership practices occur among young MSM. That is, a much larger percentage of young black MSM report having sex with predominately partners of black race than young white and Hispanic MSM (Bingham et al., 2003; Berry et al., 2007). After adjustment for the race of partners, Bingham and colleagues (2003) observed a 20% attenuation of the adjusted odds of HIV infection of young black MSM relative to young white MSM. In a follow-up report of 487 MSM participants in the 2008 behavioral surveillance survey in Los Angeles (% HIV-positive: black MSM, 31.9%; Hispanic MSM, 18.7%; white MSM, 14.7%), the adjusted odds for HIV infection between black and white MSM decreased 47% (AOR 10.4 vs.

AOR 5.5) after adjustment for anal sex with mostly black MSM partners and incarceration (Bingham & Sey, 2009). Attenuation of the adjusted odds for infection is expected under the hypothesis that inter-racial HIV-infection differences are determined, in part, by differences in assortative partnerships, with higher infection risks among black MSM sex partners (Bingham et al., 2003; Bingham & Sey, 2009).

The above findings demonstrate that nearly three decades of HIV/AIDS awareness and prevention programs have been unable to prevent new generations of MSM from acquiring what remains a severe and costly disease. Given the increasing incidence and racial disparities of HIV, this failure is all the more tragic for young black MSM. In response to the unrelenting epidemic of HIV among MSM and other at risk populations in the United States, the Department of Health and Human Services (DHHS) and CDC funded the Minority AIDS Initiative in 1999 (DHHS, 2005; Kaiser Family Foundation, 2006) and the Advancing HIV/AIDS Prevention (AHP) initiative in 2003 (CDC, 2003a). The objectives of these initiatives were to expand primary and secondary HIV prevention services to underserved minority communities and persons with undiagnosed HIV; to reduce the prevalence of undiagnosed HIV infection and incidence attributed to HIV-infected, unaware persons; and to increase early diagnoses and linkage to care (CDC, 2003a; DHHS, 2005). In FY 2004 alone, the governmental allocation for MAI and AHP was approximately $557 million (CDC, 2005b; Kaiser, 2006).

As part of AHP, CDC distributed over 1 million rapid HIV tests and initiated demonstration projects to expand the availability of testing in non-traditional, community-based settings; through provider-based partner-referral services; and through routine, opt-out testing in high-prevalence clinical settings (CDC, 2003a; CDC, 2006b; Heffelfinger et al., 2008). To further support AHP, CDC released revised testing recommendations for adolescents, adults, and

pregnant women in health-care settings (CDC, 2006c). These recommendations called for screening patients in all health-care settings and annual screening of persons at high risk for infection (CDC, 2006c). In 2007, CDC funded ($36 million) the expanded testing initiative (EIT) in 23 state and city health departments to screen 1.5 million patients for HIV in health-care and correctional settings in accordance with these guidelines (NASTAD, 2009). Finally, in 2009, DHHS and CDC supplemented MAI, AHP, and EIT with a new 5-year, Act Against AIDS campaign and a corresponding leadership initiative to further mobilize minority communities to reduce HIV incidence (CDC, 2009c). The first phase of this $45 million multi-faceted mass media and direct-to-consumer communication campaign is designed to increase awareness of risks, reduce risk behaviors, and to increase testing in the highest risk population in the United States: black MSM (CDC, 2009c).

While the impact of EIT and the Act Against AIDS Campaign will not be known for several years, given the above epidemiologic findings, AHP and MAI apparently failed to reduce the prevalence of undiagnosed HIV infection and associated incidence among MSM. Although the estimated proportion of undiagnosed HIV infection among all persons living with HIV/AIDS has decreased from approximately 25% in 2003 to 21% in 2006, 70% of this reduction was attributed to an increase in the estimated number of persons living with HIV/AIDS as a result of continuing declines in mortality, rather than a reduction in persons with undiagnosed infection (CDC, 2008a). Clearly, more research is needed to clarify current determinants of risk behavior and HIV acquisition among young MSM, as well as the potential acceptability of new HIV diagnostic technologies that might be used to help reduce the prevalence of undiagnosed infection. In the context of rising HIV incidence among MSM reaching an estimated 30,000 new

infections in 2006, this research is critical to help inform the development or applications of more effective primary and secondary HIV prevention efforts for young MSM.

<div align="center">Purpose</div>

To help address these research needs, this dissertation has two broad purposes that are addressed by three separate manuscripts. The purpose of the first two manuscripts is to explore one of the prevailing hypotheses for the increasing HIV epidemic among MSM: that is, because HAART has made HIV disease a less visibly severe and nearly manageable chronic condition, increased optimism about the efficacy of HAART has led to complacency, increased risk behaviors, and increased HIV transmission among MSM (Wolitski et al., 2001). To meet this purpose, the first manuscript will use data from a multi-city, venue-based sample of young MSM to evaluate a plausible, theoretically-based causal model that HAART-optimism beliefs influence reduced HIV/AIDS concern (i.e., complacency), and that reduced HIV/AIDS concern, in turn, causes increased HIV risk behavior. Using the same data, the second manuscript will evaluate the independent association between reduced HIV/AIDS concern (the key mediating variable of the causal model) and undiagnosed HIV infection, adjusting for socio-demographic characteristics, risk perception, and HIV risk behavior.

The importance of clarifying the relationships between HAART-optimism beliefs and attitudes on HIV infection risk among MSM is underscored by the theoretical basis of the ACT Against AIDS campaign (CDC, 2009c). This national campaign is predicated, in part, on the above hypothesis that HAART optimism underlies complacency and heightened transmission risks (CDC, 2009c; Kaiser Family Foundation, 2009b). The campaign intends to confront complacency by increasing awareness and concern about the incidence ("Every 9½ minutes,

someone in the U.S. is infected with HIV") and consequences of HIV (CDC, 2009c). While some evidence for the underlying theoretical basis of the campaign exists, additional information about the role of complacency as a hypothesized mediator of specific HAART-optimism beliefs on increased HIV-acquisition risk might help inform specific communication messages that are currently under development for MSM (CDC, 2009c).

The main purpose of the third manuscript of this dissertation is to assess among MSM who report having never tested for HIV strong intentions to use an over-the-counter rapid HIV test (OTCRT). Rapid HIV tests may soon be available in the United States for OTC purchase (FDA, 2005; FDA, 2006; OraSure Technologies Inc., 2009). Depending on pricing, availability, and use by public-health prevention programs, OTCRT offers the promise of increasing the uptake of testing by reducing or eliminating well-known testing barriers such as lack of anonymity, and disclosure of risk behaviors and lifestyle to health providers (Irwin et al., 1996; CDC, 2005a; CDC, 2006a). In the third manuscript, an exploratory analysis will be conducted to evaluate socio-demographic and behavioral correlates of strong intentions to use an OTCRT in a separate multi-city, internet-based sample of MSM who reported have never tested for HIV (NTMSM).

The importance in initiating formative research on the magnitude and correlates of potential OTCRT use among NTMSM is underscored by the profound prevalence of undiagnosed HIV infection among MSM and the likely approval of the test by the blood products advisory committee of the FDA (FDA, 2005; FDA, 2006). Findings from this formative research may thus help to inform future research on potential public-health applications of this promising new technology for men who might benefit the most from testing.

The third manuscript will also evaluate of NTMSM (1) attendance at MSM-identified venues and use of the internet to obtain HIV information, (2) the distribution of main reasons for not testing by demographic, risk, and internet-use characteristics, and (3) strong intentions to test in the upcoming year. Although considerable research has evaluated correlates of ever, repeat, and recent testing among MSM, no reports in the United States have focused on NTMSM (Heckman et al., 1995; Roffman et al., 1995; McFarland et al., 1995; Phillips et al., 1995; Povinelli et al., 1996; Campsmith et al., 1997; Kalichman et al., 1997; Leaity et al., 2000; Maguen et al., 2000; Spielberg et al., 2001; Kellerman et al., 2002; MacKellar et al., 2002; Fernandez et al., 2003; MacKellar et al., 2005; CDC, 2005a; CDC, 2006a; MacKellar et al., 2006a; Mimiaga et al., 2007; Sumartojo et al., 2008; Mimiaga et al., 2009). Thus, information on potential locations to deliver HIV testing or test-promotion services, appropriate content of interventions to address reasons for not testing, and information about NTMSM who don't intend to test and should receive priority interventions have not been reported and are unknown.

In summary, this dissertation seeks to clarify the plausible role of reduced HIV/AIDS concern (complacency) as an important mediator of specific HAART-optimism beliefs on sexual risk behavior and undiagnosed HIV infection, and characteristics of MSM who have never tested for HIV including their reasons for not testing, testing intentions, and potential use of a new diagnostic technology that might soon become available. The dissertation, thus, speaks to both disease-acquisition determinants, and primary and secondary prevention in arguably the most important population affected by HIV/AIDS.

CHAPTER 2

REVIEW OF THE LITERATURE: MANUSCRIPTS 1 & 2

<u>Causal Theoretical Basis of HAART Optimism on Risk Behavior</u>

Since 1995, the approval and use of protease inhibitors used in combination with other classes of anti-HIV drugs has improved the clinical management of persons with HIV disease by substantially reducing HIV viral load, immunologic deterioration, and progression to AIDS and death (Bhaskaran et al., 2008; Antiretroviral Therapy Cohort Collaboration, 2008). As a consequence, the highly stigmatizing AIDS opportunistic infections and cancers seen of nearly all HIV-infected MSM in the 1980s and early 1990s is now virtually unknown to younger generations of MSM. Because of the drastic reductions in HIV viral loads, HAART also likely reduces the per-contact transmission risk from HIV-infected persons to their partners (Quinn et al., 2000; Gray et al., 2001; Wawer et al., 2005). Now almost routinely used during pre- and intra-natal care for HIV-infected women, HAART has nearly eliminated perinatal HIV transmissions in the United States (CDC, 2007). After nearly two decades of research, the identification of an effective bio-medical intervention made possible a new public-health approach to fighting the HIV/AIDS epidemic through HIV testing, diagnosis, and treatment (Janssen et al., 2001).

Increased efficacy of HAART, however, was accompanied by increasing concerns that HAART optimism among persons at risk for HIV might reduce their perceived susceptibility to and severity of HIV/AIDS, and subsequently, lead to an increase in risk taking. Perceived susceptibility and severity of disease are fundamental constructs of many health-behavior theories, including two of the most widely known: health belief model (HBM) and protection

motivation theory (PMT) (Becker, 1974; Rosenstock, 1974; Rogers, 1975). Latest versions of HBM posit that health behavior is determined by six socio-cognitive constructs: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy (Armitage & Conner, 2000; Redding et al., 2000). Under HBM, the quantity and quality of enacted health-protective behaviors (e.g., consistently using condoms correctly with partners of unknown HIV status) is determined by the degree to which persons perceive themselves susceptible to the disease and that the disease is severe; their expectations that the benefits of protective behaviors outweigh the barriers or costs in enacting them; and their perceived ability to perform the behavior (Armitage & Conner, 2000; Redding et al., 2000). Environmental cues (e.g., being informed that a sex partner was diagnosed with HIV) are also thought to increase motivations to enact protective behaviors (Armitage & Conner, 2000; Redding et al., 2000).

In accordance with the latest version of PMT, two cognitive processes, threat and coping appraisals, influence the degree of protection motivation, which in turn determines the extent to which a health-protective behavior is enacted (Prentice-Dunn & Rogers, 1986). The threat appraisal process is determined, in part, by perceived vulnerability and severity of the disease, and the copying appraisal process is determined, in part, by perceived self efficacy in performing the behavior and the perceived efficacy that the behavior will avert the disease (response efficacy). The strength of protection motivation (and subsequently intentions and enacted behavior) is determined by both (1) the extent to which perceived disease vulnerability and severity outweigh extrinsic and intrinsic rewards for performing risk behaviors, and (2) the extent to which perceived response efficacy and self-efficacy outweigh the costs in performing the behavior (Prentice-Dunn & Rogers, 1986).

HBM and PMT have been extensively researched and found to predict significant variance in health behavior or health-behavior intentions (Armitage & Conner, 2000). The generally accepted theoretical basis and empirical evidence of the role of reduced perceptions of disease severity and personal susceptibility on attenuating health-protective behavior, thus, was the foundation for early concerns about HAART optimism. Many thought that the benefits of the new serostatus-approach to fighting the HIV/AIDS epidemic might be offset by increased risk taking and HIV incidence attributed to the very bio-medical intervention that enabled the approach (Janssen et al., 2001).

These concerns seemed justified in the mid-1990s, when just as the efficacy of HAART was emerging, several studies suggested that both HIV risk taking and the incidence of sexually transmitted diseases (STDs) among MSM were also increasing (Wolitski et al., 2001). Concerns were further underscored by direct-to-consumer advertising by pharmaceutical companies that increasingly marketed the benefits of HAART drugs. Images of healthy HIV-infected men living normal, active lives and often accompanied with incomplete or misleading information about drug safety and efficacy became widespread and recognizable by most MSM (Altman, 1996; Lyco et al., 1996; Klausner et al., 2002; Kallen et al., 2007). Thus, "treatment optimism" was suspected as the principal reason for the increased incidence in sexual risk taking and STDs among MSM. Early research in the late 1990s supported this hypothesis.

<div align="center">Cross-sectional Studies</div>

The first manuscript on HAART optimism and increased sexual risk behavior was published as a letter to the editor of the New England Journal of Medicine by Dilley and

colleagues (1997). Of 54 HIV-negative and high-risk MSM recruited into an intervention counseling study conducted in San Francisco, Dilley and colleagues (1997) administered a brief questionnaire that included 4 Likert-type items on perceptions of HAART optimism and sexual behavior. Measured on a 4-point response scale, participants could respond to each item from "strongly agree" to "strongly disagree; " (sample items: "Because of the new treatments for HIV-positive people, I am more willing to take a chance of getting infected when I have sex."). Many MSM (26%) agreed that because of the new treatments, they were "less concerned about becoming HIV-positive" and 15% reported having "already taken a chance of getting infected" because of the new treatments (Dilley et al., 1997). The four items were assumed to be face valid, presumably because the measurements included both cause and effect (e.g., "Because of new treatments for HIV-positive people, I have already taken a chance of getting infected when I had sex.").

Subsequent cross-sectional studies by Remien and colleagues (1998), Kelly and colleagues (1998), Van de Ven and colleagues (1999), Elford and colleagues (2000), Demmer (2002), Koblin and colleagues (2003), Halkitis and colleagues (2004), and Sullivan and colleagues (2007), affirmed the findings by Dilley and colleagues (1997) suggesting that although a minority of MSM held HAART-optimism beliefs/attitudes, either HIV-positive or HIV-negative/unknown MSM who endorsed at least one belief/attitude were more likely to report HIV-transmission behaviors. Only one cross-sectional study of MSM by Bakeman and colleagues (2007), which also found that a minority of MSM endorsed optimistic beliefs/attitudes, failed to observe a statistically significant association between at least one optimism belief/attitude and HIV risk behavior.

Sullivan and colleagues (2007), for example, asked MSM recruited from gay bars in 11 U.S. cities in 2000-2001 whether they agreed (strongly or mildly) with a single-item, HAART-optimism measure that included both cause and effect (item: "You are less careful about being safe with sex or drugs than you were 5 years ago because there are better treatments for HIV now."). Of 1,477 MSM respondents, 228 (15%) agreed with the statement; black MSM were more likely to agree with the statement than white MSM (22% vs. 13%; AOR 1.8; 95% CI, 1.2-2.7). Those who endorsed the statement were also more likely to report unprotected receptive anal intercourse (URAI) with partners believed to be HIV-negative (OR, 1.6; 95% CI, 1.1-2.3) and to report unprotected insertive anal intercourse (UIAI) with partners of unknown status or who were HIV-positive (OR, 2.6; 95%CI, 1.4-4.8) (Sullivan et al., 2007).

With the exception of Van de Ven and colleagues (1999) in which true/false items were used, all above cross-sectional studies used 4- or 5-point Likert-type items to measure HAART optimism. Findings were typically reported as proportions of MSM who agreed with one or more separate HAART-optimism items (Kelly et al., 1998; Remien et al., 1998; Elford et al., 2000; Demmer, 2002; Sullivan et al., 2007), and one or more items were used as separate categorical predictors of unprotected anal intercourse (UAI) in univariate or multivariate logistic regression models (Van de Ven et al., 1999; Elford et al., 2000; Sullivan et al., 2007). None of the above cross-sectional studies combined items to measure specific HAART-optimism dimensions (constructs), and none reported methods used to assess the reliability or validity (excluding predictive validity) of measures used. The remaining summary of cross-sectional studies addresses those studies that used more advanced measurement and analytic techniques to assess HAART-optimism constructs.

In a study of 298 HIV-negative gay and bisexual men attending a gay-pride festival in Atlanta in 1997, Kalichman and colleagues (1998) used principal-component analysis (PCA) to combine responses to 4-point, Likert-type items (1, strongly disagree; 4, strongly agree) measuring three HAART-optimism constructs labeled: "treatment optimism" (5 items), "preventive-treatment beliefs" (3 items), and "AIDS complacency" (3 items). The three-factor PCA solution explained 52% of the observed variance of the items; however, examples of the items were not provided (Kalichman et al., 1998). Mean composite scores on preventive-treatment beliefs, but not on treatment optimism and AIDS complacency, were higher among MSM who reported URAI than MSM who did not report URAI (mean, 0.31; standard deviation (SD), 1.2 vs. mean, -0.6; SD, 0.9; p-value, 0.05). Notably, mean composite scores on preventive-treatment beliefs were very low, suggesting that only a minority of MSM endorsed those beliefs. Among those who practiced URAI, compared with HIV-infected MSM not on HAART, MSM on HAART and MSM with undetectable viral loads had significantly lower mean scores on perceived risk of URAI to transmit HIV (Kalichman et al., 1998).

In subsequent reports, Kalichman and colleagues (2006, 2007a, 2007b), provided additional information about the 3 preventive-treatment-belief items (items: "HIV positive persons who take HIV drug cocktails are less likely to infect their sex partners during unsafe sex", "It is safe to have anal sex without a condom with an HIV positive man who has an undetectable viral load", "New AIDS treatments make it easier to relax about unsafe sex."). PCA factor loadings of the three items ranged from 0.72 to 0.79 (Kalichman et al., 2007a). In a study of 158 HIV-positive men (mostly MSM) and women in Atlanta who were taking HAART, the composite score on preventive-treatment beliefs was significantly associated with frequency of

unprotected intercourse with HIV-negative or unknown-status partners (β, 0.21; standard error (SE), 0.02; p-value, 0.02) (Kalichman et al., 2006).

Kalichman and colleagues also assessed preventive-treatment beliefs and risk behaviors in repeated cross-sectional surveys of MSM attending gay pride festivals in Atlanta in 2005 and 2006. Compared with MSM surveyed in 1997 (noted above), statistically significant increases in the proportion of MSM who reported UAI and in mean composite scores of preventive-treatment beliefs were observed in 2005 and 2006 (Kalichman et al., 2007a; Kalichman et al., 2007b). Adjusting for survey year, among both HIV-negative/unknown status and HIV-positive MSM, those who engaged in URAI were significantly more likely to endorse preventive-treatment beliefs and to report significantly lower risk ratings for URAI with partners who have an undetectable viral load (Kalichman et al., 2007a; Kalichman et al., 2007b).

Although not labeled as such, the HAART-optimism dimension that preventive-treatment beliefs seemed to measure was reduced transmissibility of HIV because of HAART (Kalichman et al., 2007a; Kalichman et al., 2007b). Although clearly related, the items did not specifically assess perceptions of reduced personal susceptibility to HIV or reduced AIDS severity because of HAART, constructs presumed to drive increased risk taking among MSM according to HBM and PMT. Although factor loadings of the 3 preventive-treatment-belief items were high, internal consistency (e.g., Cronbach's coefficient alpha) or other reliability assessments were not reported (Kalichman et al., 1998, 2006, 2007a, 2007b).

Measurement development advanced in 2000 and 2001 with the publication of evidence supporting the reliability and validity of items used to measure HAART-optimism (Vanable et al., 2000; Van de Ven et al., 2000) composed of two dimensions (Huebner & Gerend, 2001). On a cross-sectional sample of 554 MSM recruited during a street fair in Chicago in 1997, Vanable

and colleagues (2000) used 8, 4-point Likert-type items ("strongly disagree" to "strongly agree") to measure reduced HIV concern because of HAART (sample items: "The new AIDS treatments make me less anxious about having unsafe sex." "I am less concerned about having anal sex without a condom now that combination treatments are available." "By taking the new drug combinations, an HIV+ man decreases the chances that he will infect his partners with HIV."). The authors did not subject the items to exploratory or confirmatory factor analysis; however, the items were moderately correlated (corrected item-total correlations: 0.33-0.46) and demonstrated acceptable internal consistency in two separate samples of MSM (n=554, alpha, 0.71; n=346, alpha, 0.78) (Vanable et al., 2000).

Supporting previous research, although a minority of MSM (6%-21%) endorsed the 8 reduced-concern items, the composite score was found to significantly predict both unprotected anal sex (AOR, 2.54; 95% CI, 1.44-4.50) and number of sexual partners (β, 0.17; p-value, < 0.001) (Vanable et al., 2000). In a follow-up cross-sectional analysis of 547 MSM in the Multicenter AIDS Cohort Study in 1999, the reduced HIV-concern scale developed by Vanable and colleagues (2000) demonstrated good internal consistency (alpha, 0.85), and categorized composite scores were statistically significantly associated with URAI among HIV-negative MSM (AOR, upper quartile vs. lower quartile, 3.31; 95% CI, 1.27-8.62), and UIAI among HIV-positive MSM (AOR, upper quartile vs. lower quartile, 6.05; 95% CI, 2.24-16.33) (Ostrow et al., 2002).

Van de Ven and colleagues (2000), tested a 32-item, 4-point Likert-type scale to measure HAART optimism-scepticism on a cross-sectional sample of 532 MSM in Sydney, Australia, in 1999. After factor analysis, the scale was reduced to 12 items and assessed for internal consistency and predictive validity. The reduced HAART optimism-scepticism scale (sample

items: "I'm less worried about HIV infection than I used to be." "New HIV treatments will take the worry out of sex." "Because of the new treatments fewer people are becoming infected with HIV." "Until there is a complete cure for HIV/AIDS, prevention is still the best practice.") was internally consistent (alpha, 0.79), had item-total correlations ranging from 0.28 to 0.57, and was positively skewed (mean, 19.8; SD, 4.7), suggesting that most MSM were skeptical about HAART (Van de Ven et al., 2000). Like previous research, however, mean composite scores were statistically significantly higher among MSM who reported any UAI with casual partners versus those who did not in two separate samples of MSM in Australia (Van de Ven et al., 2000).

Van de Ven and colleagues' (2000) scale was used in two subsequent cross-sectional studies. In the first study of 5,882 HIV-negative and positive MSM surveyed in 2000 in London, Paris, Sydney/Melbourne, and Vancouver, 4 items from the scale were used to measure HAART-optimism (sample items: "New HIV treatments will take the worry out of sex." "HIV/AIDS is a less serious threat than it used to be because of the new treatments.") (International Collaboration on HIV Optimism, 2003). Factor analysis was not performed; however, the 4-item scale demonstrated acceptable internal consistency (city-specific alphas: 0.6-0.8; combined, 0.7) (International Collaboration on HIV Optimism, 2003). Mean composite scores were low in each city (city-specific means: 5.1-6.8), suggesting that most MSM were not optimistic about HAART, and excluding Vancouver, MSM from other cities who reported UAI with casual partners had statistically significantly higher mean composite scores than MSM who did not report UAI (International Collaboration on HIV Optimism, 2003).

In the second study, Van de Ven and colleagues' (2000) full 12-item optimism-scepticism scale was used in a survey of 338 HIV-positive MSM in New South Wales and Victoria, Australia, in 2003 (Rawstorne et al., 2007). Factor analytic and internal-consistency outcomes of

the 12-item scale used on this sample of MSM were not reported (Rawstorne et al., 2007).

Again, mean composite scores were low, suggesting that most MSM were skeptical about

HAART; however, MSM who sometimes engaged in UAI with casual partners had higher mean

composite scores compared with MSM who never engaged in UAI with casual partners,

(sometimes UAI: mean, 1.90; SD, 0.40; never UAI: mean, 1.64; SD, 0.45; p<0.01) (Rawstorne et

al., 2007).

Notably, in their HAART reduced-concern and optimism-scepticism scales, both Vanable

and colleagues (2000) and Van de Ven and colleagues (2000) interspersed items about HAART

attitudes (e.g., "I am less concerned about having anal sex without a condom now that

combination treatments are available.") with HAART *beliefs* (e.g., "Because of the new

treatments fewer people are becoming infected with HIV."). Also, although each scale seemed to

primarily measure reduced transmissibility of HIV because of HAART, the scales were

composed of items that could be interpreted as measuring other dimensions including AIDS

severity (e.g., "I'm less worried about HIV infection than I used to be." "The new AIDS

treatments make me less anxious about having unsafe sex.") (Van de Ven et al., 2000; Vanable et

al., 2000).

In 2001, Huebner and Gerend addressed these limitations using a new 10-item Likert-type

5-point scale ("strongly disagree" to "strongly agree") composed of items designed to measure

three hypothesized HAART belief constructs labeled health improvement (e.g., "Because of the

new antiviral drugs, people with HIV/AIDS are living longer."), transmission prevention (e.g.,

"Sex with someone who has HIV/AIDS and is on the new antiviral drugs is safer than with

someone who has HIV/AIDS and is not on the drugs."), and treatment complications (e.g., "The

antiviral drugs have many serious side effects."). The items were administered to a cross-

sectional sample of 575 MSM in Phoenix, Arizona, in 1998 and analyzed using a split-sample, confirmatory factor analysis (CFA) design (Huebner & Gerend, 2001). With the exception of one item that failed to load on health improvement on the first split sample, all other items had significant loadings on specified factors. A re-specified model that excluded the one item was used on the second split sample. This model demonstrated adequate fit (χ^2, n=283, 24 degrees of freedom (df), 26.33, p>0.05; Comparative Fit Index (CFI), 0.997; Root Mean Square Error of Approximation (RMSEA), 0.02) and was consistent with the original model in that all items had significant standardized loadings on specified factors (Huebner & Gerend, 2001).

Using the entire sample of 575 MSM, items retained for the health improvement (2 items; r, 0.77), transmission prevention (3 items; alpha, 0.69), and treatment complication (3 items; alpha, 0.80) demonstrated acceptable internal consistency (Huebner & Gerend, 2001). Mean composite scores on health improvement were generally high among untested (3.96; SD, 0.75), HIV-negative (4.12; SD, 0.64), and HIV-positive (4.47; SD, 0.70) MSM, as were scores on treatment complications (mean, 3.65; SD, 0.59; mean, 3.73; SD, 0.63; mean, 4.03; SD, 0.75, respectively) (possible response range: 0-5). Thus, most MSM generally agreed with realistic statements concerning health improvements and complications associated with HAART (Huebner & Gerend, 2001). However, mean composite scores on transmission prevention were lower among untested (2.22; SD, 0.85), HIV-negative (2.09; SD, 0.82), and HIV-positive (1.93; SD, 0.84) MSM (possible response range: 0-5). Thus, most MSM did not endorse beliefs of reduced HIV transmissibility because of HAART (Huebner & Gerend, 2001). The composite score for transmission-prevention beliefs (but not health-improvement and treatment-complications beliefs) were positively associated with URAI with casual partners among all

MSM (AOR, 1.3; 95% CI, 1.1-1.7) and among HIV-positive MSM (AOR, 2.3; 95% CI, 1.2-4.1) (Huebner & Gerend, 2001).

All investigations reviewed heretofore were cross-sectional studies, and were thus unable to demonstrate that HAART optimistic beliefs or attitudes preceded risk behaviors. Demonstration of beliefs or attitudes that precede behaviors is requisite (but insufficient) evidence that the behavior is influenced or caused by those beliefs or attitudes. Findings from three of four studies that evaluated trends in beliefs/attitudes and risk behaviors suggest that an alternative theoretical framework might also explain the relationship between HAART optimism and risk behavior.

<u>Serial Cross-sectional and Longitudinal Studies:</u>

<u>An Alternative Theoretical Framework</u>

In a study of four annual cross-sectional surveys of 2938 MSM conducted in London from 1998 to 2001, Elford and colleagues (2002) used both single-item measures and 8 items selected from Van de Ven and colleagues' (2000) optimism-scepticism scale to evaluate statistically significant annual increases in the proportion of MSM who reported UAI with non-concordant, casual partners. Of the 8 items, 4 were used to measure a construct labeled reduced severity (e.g., "I am less worried about HIV than I used to be.", "HIV/AIDS is a less serious threat than it used to be because of the new treatments."); and 4 were used to measure a construct labeled reduced susceptibility (e.g., "A person with undetectable viral load cannot pass on the virus.", "People with undetectable viral loads do not need to worry so much about infecting others with HIV."). Factor analytic and internal-consistency outcomes were not reported for either of the 4-item scales (Elford et al., 2002). For all years combined, 25% of MSM endorsed

reduced severity and 20% endorsed reduced susceptibility; however, no increase in endorsement was observed for either construct across survey periods (Elford et al., 2002). In each survey and all years combined, HIV-negative and HIV-positive MSM who endorsed these constructs were statistically significantly more likely to report non-concordant UAI with casual partners (Elford et al., 2002).

However, in multivariate logistic regression analyses that included year of survey and both optimism constructs, year of survey remained statistically significantly associated with UAI, and significant interactions were not observed between the two HAART-optimism constructs and year of survey in predicting UAI. That is, the yearly increase in UAI in the cross-sectional surveys was observed among both groups of MSM who endorsed and did not endorse HAART-optimism constructs (Elford et al., 2002). If the observed annual increase in UAI was attributed to HAART optimism, the increases should have been restricted to MSM who endorsed at least one of the constructs (Elford et al., 2002).

Elford and colleagues (2002) concluded that an alternate explanation might account for the observed cross-sectional association between HAART-optimism and risk behavior. That is, MSM who engage in HIV transmission behaviors may modify their beliefs or attitudes to reduce the cognitive dissonance that results from knowingly placing themselves or others at risk for HIV (Festinger, 1957). In contrast to HBM and PMT, cognitive dissonance theory (CDT) posits that persons experience negative emotional states (e.g., stress, shame, guilt, embarrassment, etc.) after recognizing their stated ideas or enacted behaviors contradict internalized attitudes or beliefs (i.e., cognitions are dissonant) (Festinger, 1957). Depending on the perceived severity of consequences of the contradictory idea or behavior, cognitive dissonance can be a powerful motivation to modify internalized attitudes or beliefs to avoid severe emotional states (Festinger,

1957). Thus, according to CDT, attitudes and beliefs can be a consequent of behavior,

particularly when the behavior results in harm to oneself or others; in this context, attitudes and

beliefs are modified to justify the behavior (Festinger, 1957; Aronson, 1969). Considerable

experimental evidence supports CDT (Festinger, 1957; Aronson, 1969; Aronson, 1980), and

dissonance-based interventions have been used to reduce a range of risk behaviors including

eating disorders, and tobacco, drug, and non-condom use (Aronson, 1991; Stone et al., 1994;

Stice et al., 2008).

The alternative hypothesis that HAART optimism is caused by, rather than causes risk

behavior is supported by findings from two additional studies. In a study of two cross-sectional

surveys in 1999 and 2002, of 3,183 MSM attending gay bars in Glasgow and Edinburgh,

Scotland, two single-item measures of reduced severity ("I am less worried about HIV infection

now that treatments have improved.") and susceptibility ("I believe that new drug therapies make

people with HIV less infectious.") were used to evaluate the observed statistically significant

increase in reported UAI with casual partners between the two survey periods (Williamson &

Hart, 2004). MSM who agreed with each item were categorized as endorsing the respective

construct. Although few MSM endorsed either construct, endorsement increased during the two

survey periods (reduced severity: 1999, 13.9%; 2002, 23.2%; $p<0.001$; reduced susceptibility:

1999, 7.6%; 2002, 12.5%; $p<0.001$). Although reduced severity and susceptibility were

significantly associated with UAI in both survey years, in multivariate analyses, survey year

remained significantly associated with UAI and interactions between the constructs and survey

year were not observed. Thus, like Elford and colleagues (2002), Williamson and Hart (2004)

found that increases in reported UAI occurred in both MSM who endorsed and did not endorse

the two HAART-optimism dimensions, and that increases in UAI between survey years could not therefore be attributed to HAART optimism.

In a separate longitudinal cohort study of 837 HIV-negative MSM in Phoenix, Arizona, Albuquerque, New Mexico, and Austin, Texas, Huebner and colleagues (2004) evaluated determinants of UAI with non-primary partners using two items to measure HAART-optimism ("With all the new AIDS drugs, I'm not that concerned about getting HIV", and "I'm not that concerned about catching HIV since there will probably be a cure by the time I get sick."). Measured on a 6-point scale (disagree strongly to agree strongly), responses to the two items were moderately correlated (r, 0.43) and were combined into a composite score (Huebner et al., 2004). Most MSM were not HAART optimistic and HAART optimism did not increase during the two survey periods (1998/1999: mean score, 1.48; SD, 0.84; 2000/2001: mean score, 1.47; SD, 0.75). The authors used two analytical approaches to assess the causal pathway between HAART-optimism and risk behavior.

First, in cross-sectional analysis, ordinary least squares regression was used to regress UAI (yes/no) and perceived susceptibility (also measured on the same 6-point scale) on HAART-optimism. A significant interaction was observed between UAI and perceived susceptibility such that only among those men who perceived themselves as susceptible ($\geq+1$ standard deviation on susceptibility scale) did MSM who had UAI report a significantly higher mean HAART-optimism score than men who had not had UAI (Huebner et al., 2004). Among those MSM with lower perceived susceptibility, no differences in mean HAART-optimism scores were observed between MSM who engaged and did not engage in UAI (Huebner et al., 2004).

Huebner and colleagues (2004) postulated that if HAART-optimism preceded (i.e., caused) UAI, the association with UAI should have been observed independent of perceived

susceptibility. Under cognitive dissonance theory, however, only among MSM who perceived themselves as susceptible would the association between UAI and HAART optimism be expected. That is, based on their risk behavior, optimism would be modified (i.e., endorsed) to cope with the cognitive dissonance of placing oneself at increased personal risk for HIV infection when those risks are recognized as increasing susceptibility to HIV (Festinger, 1957; Aronson, 1969).

In the second analytical approach, Huebner and colleagues (2004) conducted two separate comparisons of MSM interviewed in 1998/1999 (wave 1) with the same men interviewed in 2001/2002 (wave 2). Using logistic regression, Huebner and colleagues (2004) regressed HAART-optimism and UAI measured in wave 1 on UAI measured in wave 2. Controlling for UAI in wave 1, HAART-optimism *did not* significantly predict UAI in wave 2 (AOR, 0.95; $p > 0.05$); UAI in wave 1 did significantly predict UAI in wave 2 (AOR, 2.42; $p < 0.01$). Using ordinary least squares regression, Huebner and colleagues (2004) also regressed UAI and HAART-optimism measured in wave 1 on HAART-optimism measured in wave 2. Controlling for HAART-optimism in wave 1, UAI significantly *predicted* optimism in wave 2 (β, 0.11; $p < 0.05$); wave 1 HAART-optimism also significantly predicted wave 2 HAART-optimism (β, 0.41; $p < 0.001$). Thus, in their longitudinal study, Huebner and colleagues (2004) were unable to support the causal pathway from HAART-optimism to risk behavior, but found evidence from two analytic approaches for the causal pathway from risk behavior to HAART optimism.

In contrast to the above findings by Elford and colleagues (2002), Williamson and Hart (2004), and Huebner and colleagues (2004), in a longitudinal cohort study of 217 HIV negative MSM conducted in Amsterdam from September 1999 through May 2002, Stolte and colleagues (2004a) found evidence supporting the causal pathway from one HAART-optimism belief to

URAI with casual partners. In their study, three HAART-optimism belief constructs were evaluated using 17 items on a 7-point response scale (1 strongly disagree to 7 strongly agree). Principal component analysis was used to measure the following 3 constructs: (1) reduced threat (5 items; example: "I think HIV/AIDS is a less serious threat than it used to be because of the new HIVAIDS treatments."); (2) reduced need for safe sex (3 items; example: "I think that condom use during sex is less necessary now that new HIV/AIDS treatments are available."); and (3) HAART as a cure for HIV/AIDS (2 items; example: "I think that someone who is HIV positive and uses new HIV/AIDS treatments can be cured."). Adequate internal consistency among the 3 sets of items were observed at each of 5 measurement waves that occurred every 6 months (range of alphas for 5 measurement waves: reduced threat, 0.73-0.87; reduced need for safer sex, 0.78-0.84; HAART as cure, 0.70-0.75) (Stolte et al., 2004a). The median scores of the three HAART-optimism constructs were low (range of the three median scores, 1.0-2.0), indicating that the majority of MSM strongly disagreed with the statements (Stolte et al., 2004a).

To evaluate causality, Stolte and colleagues (2004a) assessed whether a change from no behavioral risk (i.e., consistent condom use) to risk (i.e., URAI or UIAI) measured in two consecutive waves was associated with higher optimistic beliefs measured in the preceding wave. During the 5 waves of observations, a total of 146 HIV-negative MSM contributed 178 change-to-risk outcomes for URAI or UIAI with casual partners (Stolte et al., 2004a). Controlling for age and UIAI with casual partners, reduced threat (but not reduced need for safe sex and HAART as a cure for HIV/AIDS) was associated with a change to URAI with casual partners (AOR, 1.60; 95% CI,1.16-2.22; p<0.01) (Stolte et al., 2004a). None of the three constructs were associated with a change to UIAI with casual partners in either univariate or multivariate analyses (Stolte et al., 2004a). In a follow-up report restricted to HIV-infected MSM, more favorable perceptions of

viral load level (but none of the three optimistic constructs) was significantly associated with a change to UAI with steady partners (AOR=5.58; 95%CI, 1.94-16.05, p<0.01) (Stolte et al., 2004b).

Finally, in the only study found of its kind, van der Snoek and colleagues (2005) assessed the influence of HAART optimism on disease acquisition and found evidence supporting the causal pathway from HAART optimism to STD/HIV infection. In their study, van der Snoek and colleagues (2005) assessed the incidence of syphilis, gonorrhea, chlamydia, herpes, hepatitis B, and HIV among 151 STD/HIV-negative MSM during 5 biannual study visits from January 2000 to April 2003 in Rotterdam, The Netherlands. HAART-optimism was evaluated on the first and only of the 5 biannual visits using 17 Likert-type items measured on a 5-point response scale (1 strongly disagree to 5 strongly agree). Principal component analysis was used to identify 3 HAART optimism constructs (apparently identical to those of Stolte et al., 2004a): (1) reduced threat (5 items; example: "I think HIV/AIDS is a less serious threat than it used to be because of the new HIVAIDS treatments."); (2) reduced need for safe sex (3 items; example: "I think that condom use during sex is less necessary now that new HIV/AIDS treatments are available."); and (3), HAART as a cure for HIV/AIDS (2 items; example: "I think that someone who is HIV positive and uses new HIV/AIDS treatments can be cured."). Adequate internal consistency among the 3 sets of items were observed (range of alphas: 0.73-0.93) (van der Snoek, 2005). The median (SD) scores of the three HAART-optimism constructs were 2.17 (0.16) for reduced threat, 1.13 (0.05) for reduced need for safe sex, and 1.70 (0.13) for HAART as a cure for HIV/AIDS (possible range:1-5), suggesting that the majority of MSM strongly disagreed with the statements (van der Snoek, 2005).

At the end of the 5th biannual visit, van der Snoek and colleagues (2005) used logistic regression to identify socio-demographic, psychological, and behavioral predictors for any incident STD (excluding HIV). A total of 69 incident STD infections were observed. Controlling for age, reduced threat (but not reduced need for safe sex and HAART as a cure for HIV/AIDS) was associated with incident STD infection (AOR, 1.71; 95% CI, 1.17–2.50; $p<0.01$) (van der Snoek, 2005). Because 7 HIV seroconversions were observed, only univariate analyses were used to evaluate associations between HAART optimism and HIV infection. Reduced need for safe sex (but not reduced threat and HAART as a cure for HIV) was associated with incident HIV infection (OR, 3.22; 95%CI, 1.27–8.16; $p<0.05$). The authors did not report conducting an analysis evaluating HAART optimism as a predictor of incident risk behavior (van der Snoek, 2005).

Summary of Literature Review

In summary, nearly all published cross-sectional and longitudinal studies that evaluated HAART optimism among MSM suggest that a minority of MSM are HAART optimistic; however, MSM who are HAART optimistic (on one or more dimensions) are more likely to report higher HIV acquisition or transmission risk behaviors. Reported statistically significant associations between one or more HAART-optimism dimensions and risk behavior generally had low to moderate magnitudes, suggesting that at the individual level, other determinants of risk may be equally or more important. The low to moderate magnitudes of association is consistent with HBM, PMT, and other health-behavior theories that posit a range of important determinants of health behavior. At the population level, the combination of low prevalence of HAART-optimism and the low to moderate association between HAART-optimism and risk behavior

suggests that incident risk behavior in MSM communities attributable to HAART-optimism may be quite low, as suggested by Elford (2004).

Nearly all studies, however, were conducted relatively soon after the widespread availability of HAART, and thus the current prevalence of HAART optimism, magnitude of association between HAART optimism and risk behavior, and population-attributable risks among MSM in the U.S. are unknown. One of two U.S. studies of MSM conducted in one southeastern city suggests that the prevalence of HAART optimism increased from 1997 to 2006, and one U.S. study suggests that MSM of black or Hispanic race/ethnicity, or who had less than a high-school education, were more likely to endorse the statement about being less careful about sex because of HAART. While this finding is intriguing, the magnitude of excess HIV incidence among black MSM relative to white MSM that may be attributable to HAART optimism is unknown.

Of four serial cross-sectional or longitudinal studies that were able to evaluate the plausible causal direction of observed associations with risk behavior, three suggest that one or more dimensions of HAART-optimism is a consequent of risk behavior, and one study suggests that the HAART-optimism dimension, reduced perceived threat (i.e., complacency), is a determinant of risk behavior among HIV-negative MSM. A related dimension of reduced transmissibility, perceived low viral load, was also found to predict subsequent risk behavior among HIV-positive MSM. The one study identified that evaluated STD/HIV as the outcome of interest (rather than risk behavior) suggests that stronger endorsement of reduced threat and reduced need for safe sex because of HAART increased STD (reduced threat) and HIV (reduced need for safe sex) risk, though the concordant association with risk behavior was not established. Thus, the empirical literature suggests that both causal pathways are plausible, each supported by

strong theoretical foundations of the health belief model and protection motivation theory or cognitive dissonance theory. Whether both causal pathways might account for observed associations at the individual level is unknown.

As supported by HBM, PMT, and CDT, perceived reduced transmissibility (a construct similar to reduced personal susceptibility) and reduced threat were HAART-optimism dimensions that were consistently statistically significantly associated with risk behavior. Of these, reduced transmissibility was explicitly measured under constructs labeled preventive-treatment beliefs (Kalichman et al., 1998, 2006, 2007a, 2007b), transmission-prevention beliefs (Huebner & Gerend, 2001), and optimism 2 (Elford, et al., 2002; Williamson & Hart, 2004). Van de Ven and colleagues (2000) optimism-scepticism and Vanable and colleagues (2000) reduced-HIV-concern scales were also predominately composed of items that measured reduced transmissibility. Composite scores of this HAART-optimism dimension were consistently statistically significantly associated with risk behavior among both HIV-negative and positive MSM in multiple surveys in the United States, Europe, and Australia.

Contrary to theoretical expectations under HBM, PMT, and CDT, the HAART-optimism dimension, reduced AIDS severity, was not explicitly shown as a determinant or consequent of risk behavior. However, as discussed below, the lack of evidence might be attributed to measurement limitations. The HAART-optimism dimension, "reduce threat," had significant measurement limitations and might have served as a proxy measure for reduced AIDS severity.

<u>Research Limitations & Gaps in Understanding</u>

Research conducted on HAART optimism among MSM, although considerable, is subject to significant measurement and analytical limitations that prevent a more complete understanding

of the dimensionality of HAART optimism and relationships with risk behavior. Considerable measurement limitations were observed in nearly every study, including those that used "face-valid" cause and effect items, and studies that relied upon single or multiple items to measure HAART-optimism constructs.

Cause and effect items are especially subject to interpretation and analytic limitations. Two typical cause and effect items, for example, were: (1) "Because of the new treatments for HIV-positive people, I am more willing to take a chance of getting infected when I have sex." (Dilley et al., 1997), and (2) "You are less careful about being safe with sex or drugs than you were 5 years ago because there are better treatments for HIV now." (Sullivan et al., 2007). In these and other examples, both the cause and effect are unclear. For example, is the cause of taking a chance or being less careful attributed to reduced HIV transmissibility, AIDS severity, or some other attribute of HAART? Understanding the explicit cause is important for prevention. With respect to the effect on risk behavior, how does "willing to take a chance" and "less careful about being safe" relate to actual HIV acquisition or transmission risks? Moreover, when these and other similarly worded measures are used to quantify the association with behavioral risks, biased estimates of unknown direction may occur because the compound measure is prone to misclassify persons who meet one, but not both cause and effect conditions. Quantifying an unbiased association is critical for evaluating the relevance of presumed determinants (or consequents) of behavior.

Similarly, many items used either alone or in combination to measure purported HAART-optimism dimensions lacked adequate clarity. For example, typical items used to measure the construct "reduced severity" or "reduced threat" were: "HIV/AIDS is a less serious threat than it used to be because of the new treatments" (Elford et al., 2002), "I am less worried about HIV

infection now that treatments have improved" (Williamson & Hart, 2004), "I think HIV/AIDS is a less serious threat than it used to be because of the new HIVAIDS treatments" (Stolte et al., 2004a). For those who agree with these items, is the respondent less worried because treatments reduce the severity of AIDS (as implied in the construct label), because treatments reduce the transmissibility of HIV, because significant others who are HIV-infected have fewer debilitating symptoms and are living better lives, or because of other reasons? The construct labeled "reduced severity" or "reduced threat" are open to interpretation given the lack of specificity about the target and contexts of "worried" or "less serious." Although reduced severity or threat (complacency) most likely serves as an important mediating variable in the above studies, not knowing the belief and attitudinal variables that "reduced severity" mediates limits the usefulness of the measure for both theory development and HIV/AIDS prevention.

Analytical limitations also were prevalent in the HAART-optimism literature. These limitations included using multi-item scales in whole or part without assessing evidence of validity through exploratory or confirmatory factor analyses, structural equation modeling, or other techniques. As a consequence, many of the scales (some of which were used repeatedly in whole or part), had arguably poorly defined constructs. For example, several studies used composite scores of items that assessed both beliefs and attitudes (Vanable et al., 2000; Van de Ven et al., 2000; Ostrow et al., 2002; Rawstorne et al., 2007), or that assessed seemingly distinct HAART-optimism dimensions (Vanable et al., 2000; Van de Ven et al., 2000; Ostrow et al., 2002; Elford et al., 2002; International Collaboration on HIV Optimism, 2003; Huebner et al., 2004; Rawstorne et al., 2007). Again, while statistically significant associations were observed between composite scores and risk behavior, the measurement approach precluded meaningful interpretation about the specific belief and attitudinal dimensions of HAART-optimism and their

association with risk behavior. A clear understanding of the underlying beliefs that drive the link between HAART-optimism and risk behavior is critical for the development of prevention messages or risk-reduction programs that have the best chance to work.

Finally, three fundamental gaps in understanding were noted in the literature review. First, no published studies have evaluated a plausible nomological network (causal model) that maps out the interrelationships between HAART beliefs and attitudes, and the potential casual pathways between HAART-associated beliefs, attitudes, and risk behaviors. That is, nearly all published studies evaluated the relationship between single- or multi-items measures, of purportedly different HAART-optimism dimensions, separately with risk behavior, instead of within an over-arching theoretical framework. The analytical methods, thus, prevented assessment of the strength of inter-relationships between belief and attitudinal dimensions, and the mediation of the effect of HAART-optimism beliefs on risk behavior.

Second, only one of the published HAART-optimism studies assessed HIV infection risk as the outcome of interest. Sexual behavior commonly accepted as increasing HIV infection risk (e.g., UAI) is sometimes an inadequate proxy for infection risk (Peterman et al., 2000) and in explaining exceptionally large HIV-infection disparities between black and white MSM (Millett et al., 2006; Millett et al., 2007). If HAART optimism is an important determinant (or consequent) of relevant HIV-risk behaviors, HAART-optimism should also be a determinant (or consequent) of HIV infection. Although the objective of a new $45 million HIV/AIDS prevention campaign is to reduce HIV incidence by reducing HIV/AIDS complacency attributed, in part, to HAART optimism, the linkage between HAART-optimism and HIV acquisition risk has not been established in the literature.

Finally, no published studies have evaluated plausible causal HAART-optimism models to predict both risk behavior and HIV infection among MSM of different race/ethnicity. Previously studies, with the exception of Sullivan and colleagues (2007), were composed of predominately white MSM and either did not evaluate or report HAART-optimism and risk behavior relationships by race/ethnicity. It is unknown whether the association between HAART optimism and risk behavior that is well established in the literature, occurs across racial/ethnic groups of MSM.

Evaluating plausible causal models of HAART-related beliefs, attitudes, risk behavior, and HIV infection is important for advancing health-behavior theory and in providing initial models which might be used prospectively to examine which HAART-optimism constructs, if any, become more influential on risk behaviors and HIV-infection risk as HAART improves. Furthermore, understanding which beliefs and attitudes are most relevant (i.e., have greatest effect), on risk behavior and HIV-infection risk is important for developing effective prevention messages or activities. Assessing these relationships for different racial/ethnic groups of MSM, particularly black MSM, is critical based on considerable and apparently growing racial disparities in HIV incidence among MSM.

<div align="center">Research Aims</div>

To help address these limitations and gaps in understanding, the first two manuscripts of this dissertation further investigates the dimensionality of HAART optimism and relationships with HIV-related risk behavior and HIV infection. Both manuscripts will use the same data of young, MSM enrolled in the second phase of the Centers for Disease Control and Prevention's multi-city, cross-sectional, Young Men's Survey (YMS) (MacKellar et al., 1996). In the first

manuscript, structural equation modeling will be used to evaluate a plausible, theoretically-based causal HAART-optimism model. Stratified analyses will be used to assess the directionality of two key paths of the model.

In the second manuscript, a logistic regression model will be used to evaluate the independent association of reduced HIV/AIDS concern, the central mediating variable of the causal model, and undiagnosed HIV infection. The directionality and racial/ethnic homogeneity of observed associations will be assessed via tests for interactions. Thus, both manuscripts seek to clarify the plausible role of reduced HIV/AIDS concern (complacency) as an important mediator of specific HAART-optimism beliefs on sexual risk behavior and undiagnosed HIV infection among MSM.

Manuscript 1: Plausible Causal Model

Structural equation modeling (SEM) will be used to evaluate a proposed nomological network that posits the casual relationships between HAART-related beliefs, attitudes (i.e. concerns) about HIV/AIDS, and HIV risk behaviors (Figure 2.1). The model posits that external factors such as age, race/ethnicity, education, and lifetime experiences (e.g., knowing someone who is taking HAART) shape the development of personal salient beliefs about the efficacy of HAART to mitigate HIV/AIDS severity and susceptibility to HIV. These two belief constructs, in turn, are posited to shape the complacency attitude reduced HIV susceptibility concern. Reduced susceptibility concern, belief that HAART mitigates HIV/AIDS severity, and lifetime HIV risk behavior are posited to shape the more generalized attitude reduced HIV/AIDS concern. Finally, lifetime risk behaviors and reduced HIV/AIDS concern are posited to influence decisions to engage in new (i.e., recent) risk behaviors. External factors posited to shape the development

of HAART-optimism beliefs are not analyzed and are thus not represented in the model (Figure 2.1).

The HAART-optimism beliefs and attitudes are represented as four latent constructs in the proposed causal model (Figure 2.1). Both lifetime and recent risk behaviors are measured as indices of observed variables. In accordance with convention, latent constructs are distinguished from observed variables by the use of ovals. Correlations between exogenous variables and disturbance terms representing the unique influences of unmeasured factors are omitted in Figure 2.1 for purposes of clarity.

Manuscript 1: Hypotheses

The effects of the two HAART-optimism beliefs are proposed to influence increased risk behavior entirely through the attitude reduced HIV/AIDS concern. This HAART-associated HIV/AIDS complacency construct, thus, is central to the proposed causal model. The effect of the belief that HAART mitigates HIV susceptibility on this attitude is also hypothesized to be mediated entirely through its corresponding attitude, reduced susceptibility concern. The effect of the belief that HAART mitigates HIV/AIDS severity is hypothesized to be only partially mediated through reduced susceptibility concern because of incomplete correspondence between the two constructs (Figure 2.1). Finally, the model hypothesizes that reduced HIV/AIDS concern is at least partially a consequent of lifetime risk behavior as well as at least a partial determinant of new (i.e., recent) risk behavior. Thus, analyses of the first manuscript will test the following four sets of hypotheses:

Hypothesis 1: Stronger endorsement of beliefs that HAART mitigates HIV/AIDS severity and susceptibility to HIV are associated with stronger endorsement of reduced susceptibility concern.

Hypothesis 2: Greater lifetime behavioral risks and stronger endorsements of HAART mitigates HIV/AIDS belief and reduced susceptibility concern are associated with stronger endorsement of reduced HIV/AIDS concern.

Hypothesis 3: Greater lifetime behavioral risks and stronger endorsement of reduced HIV/AIDS concern are associated with greater recent behavioral risks.

Hypothesis 4: Compared with the belief that HAART mitigates HIV/AIDS severity, the belief that HAART mitigates HIV susceptibility will explain more variation in reduced HIV/AIDS concern and recent risk behavior.

Manuscript 1: Theoretical Justification

The proposed structure and causal relationships of the nomological network are based on principles derived from theories of planned behavior and reasoned action, health-belief, protection motivation, and cognitive dissonance (Fishbein & Ajzen, 1975; Ajzen & Fishbein, 1980; Becker, 1974; Rosenstock, 1974; Rogers, 1975; Festinger, 1957; Aronson, 1969). In accordance with the theory of planned behavior and reasoned action (Fishbein & Ajzen, 1975; Ajzen & Fishbein, 1980), the model proposes that background demographics, social factors, and experiences, shape the development of beliefs, which in turn shape attitudes that drive both intentions and behavior (Figure 2.1). The theory of planned behavior and its predecessor, the theory of reasoned action, have been extensively evaluated. Findings from over 200 studies support the causal pathway from background experiences to beliefs, beliefs to attitudes, attitudes

to intentions, and intentions to behavior (Godin & Kok, 1996; Hausenblas et al., 1997; Armitage and Conner, 2000; Armitage and Conner, 2001). Background experiences and intentions were not measured in YMS, and are thus omitted from the causal model (Figure 2.1).

In accordance with HMB, PMT, and CDT summarized above, the central mediating variable, reduced HIV/AIDS concern, is hypothesized as both a determinant (path A) and consequent (path B) of risk behavior (Figure 2.1). Empirical evidence for this dual role is provided by serial cross-sectional and longitudinal studies by Elford and colleagues (2002), Williamson and Hart (2004), Heubner and colleagues (2004), and Stolte and colleagues (2004a). As a determinant of risk behavior, reduced HIV/AIDS concern due to HAART is supported by HBM and PMT, as described above. As a consequent of lifetime risk behavior, reduced HIV/AIDS concern is hypothesized to serve as a coping mechanism to reduce the cognitive dissonance that results from knowingly engaging in life-threatening behavior (Festinger, 1957; Aronson, 1969). In the causal model, risk behaviors reported over the subject's lifetime are used to increase the probability that behaviors that composed the index preceded either formulation or modification of the reduced HIV/AIDS concern construct.

Notably, HBM and PMT acknowledge that prior behavior (lifetime risk behavior) might also separately influence new decisions to engage in risk through habitation or extrinsic or intrinsic pleasures or rewards (Rogers, 1975; Prentice-Dunn & Rogers, 1986). In the proposed causal model, recent risk behaviors (measured in the 6-months preceding interview) are used to increase the probability that reported behaviors occurred after the most recent formulation or modification of the reduced HIV/AIDS concern due to HAART construct.
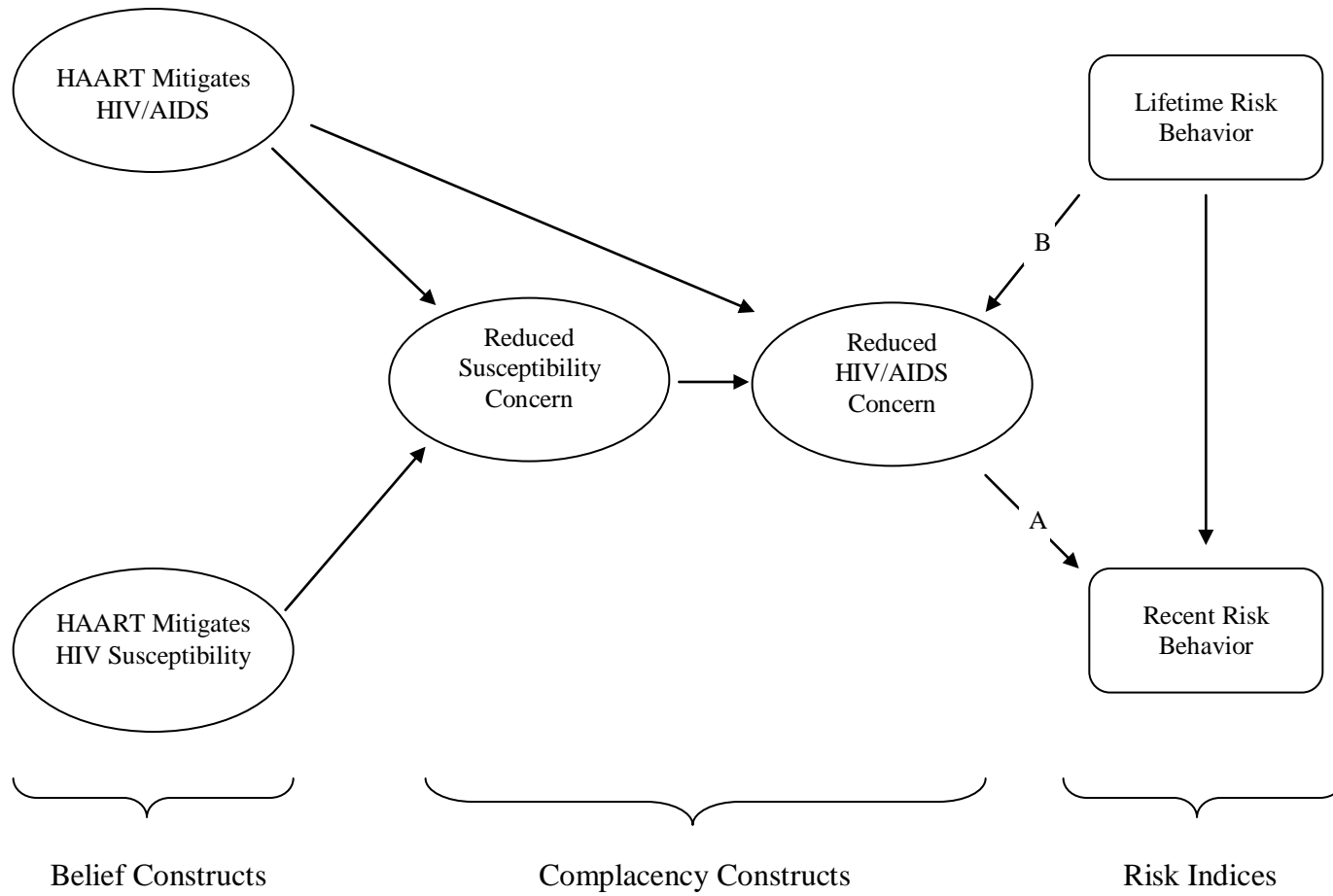
Figure 2.1 Plausible causal model of HAART-optimism beliefs, HIV/AIDS complacency, and HIV risk behavior.

Manuscript 1: Assessment of Mediation and Directionality of Effects

To assess mediation (indirect effects) of HAART-optimism beliefs, the proposed causal model will be compared against alternative models that include direct effects that were constrained to zero in the proposed model (Figure 2.1). For example, one alternative model will include direct effects of the two beliefs on recent risk behavior. Strong evidence for complete mediation is observed when (1) the magnitudes of these direct effects are small and statistically non-significant, (2) the magnitudes of indirect effects are at least moderate and statistically significant, (3) the fit of alternative models with direct effects from posited mediated variables is not significantly improved over the fit of the original model with only indirect effects, and (4) the amount of variance explained in the dependent variable (i.e., recent risk behavior) is not meaningfully different between the original and alternative models (Baron & Kenny, 1986; Bryan et al., 2007).

To assess evidence on directionality of effects, the original proposed model (Figure 2.1) will be evaluated separately for MSM who perceived themselves at very low and at some risk for HIV infection. If CDT alone explains the association, the proposed model should fail (i.e., have poor fit and statistically non-significant path coefficients) when evaluated among MSM who perceive themselves at very low risk for HIV. Model failure is expected in this stratum because the only presumed motivation underlying the causal relationships (i.e., cognitive dissonance) should be nearly eliminated among MSM who perceive themselves at very low risk for HIV. Alternatively, if HBM/PMT alone explains the association, excluding path B (Figure 2.1), all other path coefficients should be statistically significant and the model should fit adequately for both risk-perception strata of MSM. Finally, if both CDT and HBM/PMT explain the

association, the proposed model should fit adequately for both strata; however, path B should be statistically significant only among MSM who perceive at least some risk for HIV.

Manuscript 1: Hypotheses of Mediations and Directionality of Effects

Hypothesis 5: All direct path coefficients in alternative models that were constrained to zero in the original model will be small and statistically non-significant.

Hypothesis 6: Alternative models will not fit significantly better than the original model.

Hypothesis 7: The proposed model will demonstrate adequate fit among both MSM who perceive themselves at very low risk for HIV and among MSM who perceive themselves at some risk for HIV.

Hypothesis 8: In accordance with CDT, path B (Figure 2.1) will be statistically significant only among MSM who perceive themselves at some risk for HIV.

Manuscript 2: Purpose

Observing that reduced concern for HIV/AIDS due to HAART significantly mediates the influence of HAART-optimism belief constructs on increased HIV risk behavior (manuscript 1), while important, does not address the important question of whether reduced HIV/AIDS concern increases HIV infection risk. Evaluating the independent association between reduced HIV/AIDS concern and HIV infection is necessary because (1) simplistic risk behavior measures (e.g., UAI) are often poor surrogates of HIV infection risk (see empirical justification below), and (2), because the outcome of interest in public health is preventing the acquisition of HIV, not necessarily unprotected sex or other risk behaviors. In spite of the poor predictive validity of measured risk behaviors, the linkage from heightened risk behavior (due to HAART optimism) to

heightened HIV acquisition risk is central to and assumed by the HAART-optimism literature, as well as CDC's new ACT Against AIDS campaign (CDC, 2009c). Concordance on observed relationships between HAART-optimism beliefs and reduced HIV/AIDS concern due to HAART with both risk behavior (manuscript 1) and undiagnosed HIV infection (manuscript 2) will provide greater support for the prevailing theory and current multi-million dollar prevention campaign. The second manuscript, thus, will evaluate the association of reduced HIV/AIDS concern due to HAART, the central mediating variable of the above causal HAART-optimism model, with undiagnosed HIV infection. This analysis was not undertaken in the first manuscript as SEM is not the optimal procedure for use with dichotomized outcome variables (Kline, 2005).

<u>Manuscript 2: Causal Model</u>

If reduced HIV/AIDS concern due to HAART is an important determinant (or consequent) of the specific behaviors that result in HIV infection, reduced HIV/AIDS concern due to HAART should be associated with HIV infection when analyzed in the absence of those mediating behaviors. Moreover, because all the specific behaviors that result in acquiring HIV infection is difficult, if not impossible, to measure, reduced HIV/AIDS concern should be associated with HIV infection even when adjusting for behaviors commonly accepted to transmit HIV (e.g., UAI). Thus, although risk behavior is assumed to completely mediate the influence of reduced HIV/AIDS concern on HIV infection risk, because of inadequate measurement, measured behaviors may serve as only a partial mediator (if at all), as represented in Figure 2.2.
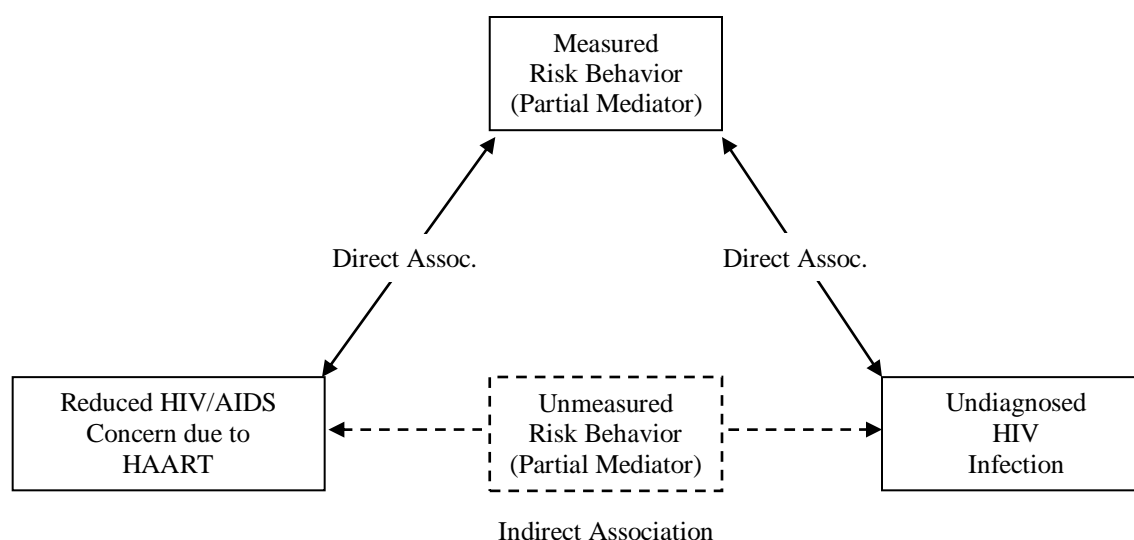
Figure 2.2. Directed acyclic graph of reduced HIV/AIDS concern, risk behavior, and undiagnosed HIV infection.

In the above directed acyclic graph, double-headed arrows indicate that reduced HIV/AIDS concern due to HAART may be either a determinant or consequent of undiagnosed HIV infection, mediated entirely through measured or unmeasured risk behavior. Undiagnosed HIV infection is represented as the outcome, rather than incident HIV infection (which would be optimal), because YMS was a cross-sectional survey and incident from prevalent HIV infection could not be distinguished. Undiagnosed HIV infection is distinguished from diagnosed because the analysis is restricted to MSM who reported never previously testing HIV positive. The analysis, thus, addresses acquisition risk rather than transmission risk. Arrows represent assumed causal pathways; solid lines represent direct associations; the dashed line represents an association that is assumed to be indirect because of unmeasured behavioral mediation.

The strength of the assumed indirect association between reduced HIV/AIDS concern due to HAART and undiagnosed HIV infection depends on the predictive validity (with respect to HIV acquisition risk) and reliability of measured risk behavior. If *all* the behaviors which are

influenced by reduced HIV/AIDS concern and which result in HIV infection are reliably measured, then an association between reduced HIV/AIDS concern due to HAART and undiagnosed HIV infection should not be observed when analyzed in the presence of those behaviors (assuming that reduced HIV/AIDS concern does not serve as a surrogate for other, unmeasured, determinants or consequents). That is, only statistically significant associations should be observed along paths indicated by solid lines (Figure 2.2).

Under the hypothesis that reduced HIV/AIDS concern due to HAART ultimately influences or is influenced by undiagnosed HIV infection, the strength of the observed association between reduced HIV/AIDS concern and undiagnosed HIV infection will increase as measurement of the mediating behavioral variables become less valid and reliable (with respect to predicting acquisition risk). That is, the associations observed along the paths indicated by the solid lines should attenuate, while the association observed along the path indicated by the dashed line should strengthen (Figure 2.2). When measured behaviors fail to represent all the specific behaviors that are influenced by reduced HIV/AIDS concern and that result in HIV infection, attenuation of the association between reduced HIV/AIDS concern and HIV infection should not be observed, when adjusted for these risk behaviors. That is, the magnitude of the assumed indirect association (dashed line) should be maximized (Figure 2.2). While Figure 2.2 is restricted to one psychological state (for simplicity), the association with undiagnosed HIV infection and other socio-demographic characteristics (e.g., race- and age-specific assortative partnerships) and psychological states (e.g., perceived risk for infection, perceived self-efficacy and social support to use condoms, depression, etc.) are also all assumed to be mediated by measured and unmeasured risk behaviors.

Under the assumption of unmeasured behavioral mediation, two principal sets of analyses will be conducted for the second manuscript. First, logistic regression will be used to evaluate the independent association between reduced HIV/AIDS concern and undiagnosed HIV infection, after adjusting for important confounders (e.g., age and race) and other determinants of infection (e.g., measured risk behavior). In parallel with first manuscript, the plausible direction of the association between reduced HIV/AIDS concern due to HAART and undiagnosed infection will be evaluated through assessment of interaction on perceived risk for infection. Because of exceptional racial HIV-infection disparities, the homogeneity of associations across racial/ethnic groups will also be assessed. The principal groups of variables and interaction terms included in the logistic regression model, thus, are represented in Figure 2.3.

The logistic regression model assumes that measured risk behaviors and *some* socio-demographic variables (e.g., decreased risk for HIV infection among white MSM via CCR5-delta 32 genotype) are directly associated with undiagnosed HIV infection without mediation (Dean et al., 1996). Other socio-demographic characteristics, reduced HIV/AIDS concern due to HAART, and perceived risk for being HIV infected are hypothesized to be only indirectly associated with undiagnosed HIV infection through unmeasured, behavioral mediation. To assess the homogeneity of associations between reduced HIV/AIDS concern and undiagnosed HIV infection across levels of perceived risk (two levels: very low vs. some) and race-ethnicity, two-way interaction terms are included in the model (represented as the last two bottom-most boxes in Figure 2.3). As before, solid lines represent direct associations and dashed lines represent assumed indirect associations via unmeasured mediation (Figure 2.3). Double-headed arrows indicate that causal pathways can be in either direction (i.e., psychological states can be either a

determinant or consequent of undiagnosed HIV infection, via unmeasured behavioral mediation) (Figure 2.3).

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┌─────────────────┐
│    Measured     │
│  Risk Behaviors │
└─────────────────┘

┌─────────────────┐
│ Socio-demographic│
│ Characteristics │
└─────────────────┘

┌─────────────────┐
│ Perceived Risk for│
│ Being HIV-infected│
└─────────────────┘

┌─────────────────┐        ┌──────────────┐        ┌──────────────┐
│ Reduced HIV/AIDS│        │  Unmeasured  │        │  Undiagnosed │
│ Concern due to  │        │ Risk Behavior│        │     HIV      │
│     HAART       │        │  Mediation   │        │   Infection  │
└─────────────────┘        └──────────────┘        └──────────────┘

┌─────────────────┐
│ Reduced HIV/AIDS│
│    Concern      │
│       X         │
│ Perceived Risk for│
│ Being HIV-infected│
└─────────────────┘

┌─────────────────┐
│ Reduced HIV/AIDS│
│    Concern      │
│       X         │
│  Race/Ethnicity │
└─────────────────┘
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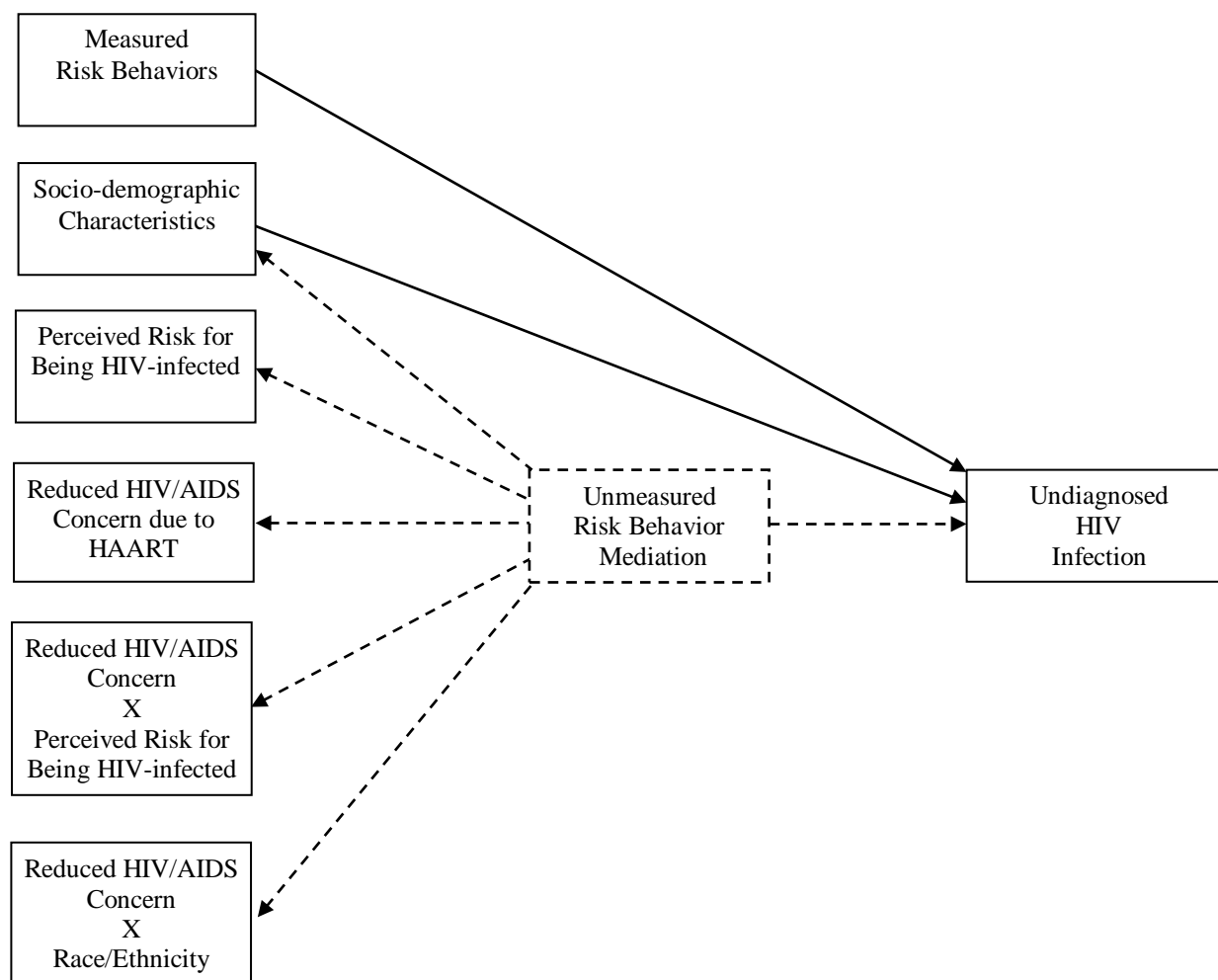
Figure 2.3. Logistic regression model of undiagnosed HIV infection.

Although determining the direction of observed associations is not possible with the cross-sectional survey data of YMS, the strategy proposed by Huebner & Gerend (2001) will again be used to assess evidence of the causal pathway. If CDT alone explains the association, the interaction term that includes perceived risk should be statistically significant and the

association between reduced HIV/AIDS concern and undiagnosed HIV infection should be restricted to MSM who perceive themselves at some risk for HIV. The association should not be observed among MSM who perceive themselves at very low risk for HIV because the only driver underlying the association (cognitive dissonance) should be very weak in this group. Alternatively, if HBM/PMT operates at least in part, the interaction term should be statistically non-significant and the association between reduced HIV/AIDS concern and undiagnosed HIV infection should be observed in both risk-perception groups (Figure 2.3).

The second set of analyses of the second manuscript will be performed only if reduced HIV/AIDS concern remains independently, statistically significantly associated with undiagnosed HIV infection. These analyses will assess (1) mediation of the two belief constructs (HAART mitigates HIV/AIDS severity and HIV susceptibility) by reduced HIV/AIDS concern, (2) the relative strengths of association between the two belief constructs and undiagnosed infection, and (3) the homogeneity of these associations across levels of race/ethnicity and perceived risk for infection. Assessment of homogeneity of associations is important to assess plausible race-specific effects of beliefs on infection risks (given known racial HIV/AIDS disparities among MSM), and to assess the consistency of evidence on the plausible direction of observed cross-sectional associations of the three HAART constructs and HIV infection.

To assess mediation, the two belief constructs, HAART mitigates HIV/AIDS severity and HIV susceptibility, will be included in the logistic regression model (Figure 2.4). If the theory is correct that attitudes mediate the influence of beliefs on behavior (and ultimately on infection risk), and all three HAART-optimism constructs are measured perfectly, the two belief constructs and undiagnosed HIV infection should not be associated when analyzed in the presence of reduced HIV/AIDS concern (Figure 2.4). However, because psychological constructs are not

measured perfectly, only partial mediation may occur, and one or both of the HAART belief

constructs may be significantly associated with undiagnosed HIV infection when analyzed in the

presence of reduced HIV/AIDS concern due to HAART.
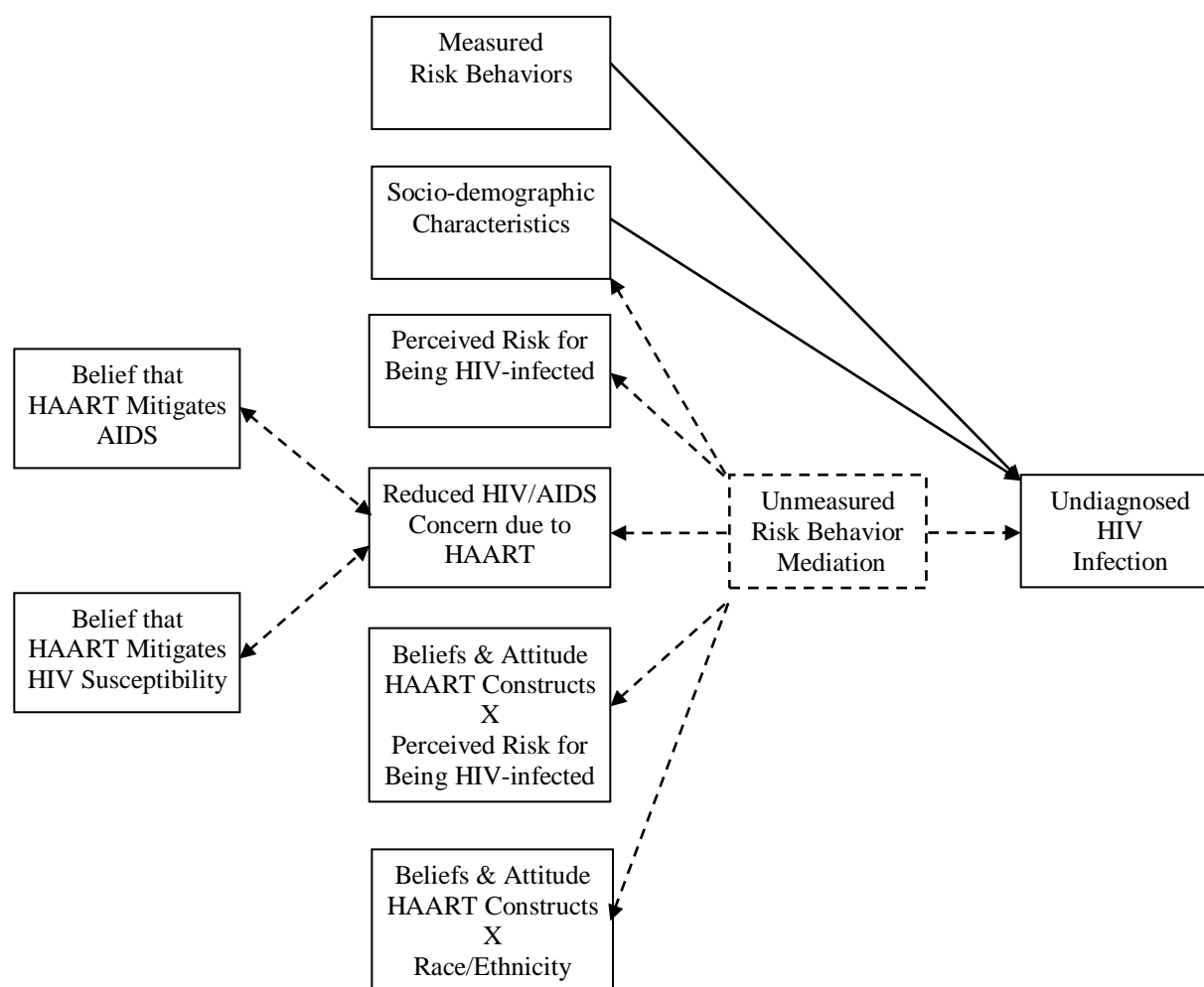
Figure 2.4. Logistic regression model assuming complete mediation of HAART-optimism beliefs by reduced HIV/AIDS concern due to HAART.

When analyzed in the absence of reduced HIV/AIDS concern due to HAART, the

association between the two belief constructs and undiagnosed HIV infection, after adjustment

for confounding and other presumed determinants, can be evaluated (Figure 2.5). Evidence for

mediation is observed when the following two conditions are met: (1) a statistically significant association between undiagnosed HIV infection and one or both of the belief constructs is observed when analyzed in the absence of reduced HIV/AIDS concern due to HAART, and (2) either attenuation or elimination of the above statistically significant association(s) is observed when analyzed in the presence of reduced HIV/AIDS concern due to HAART.
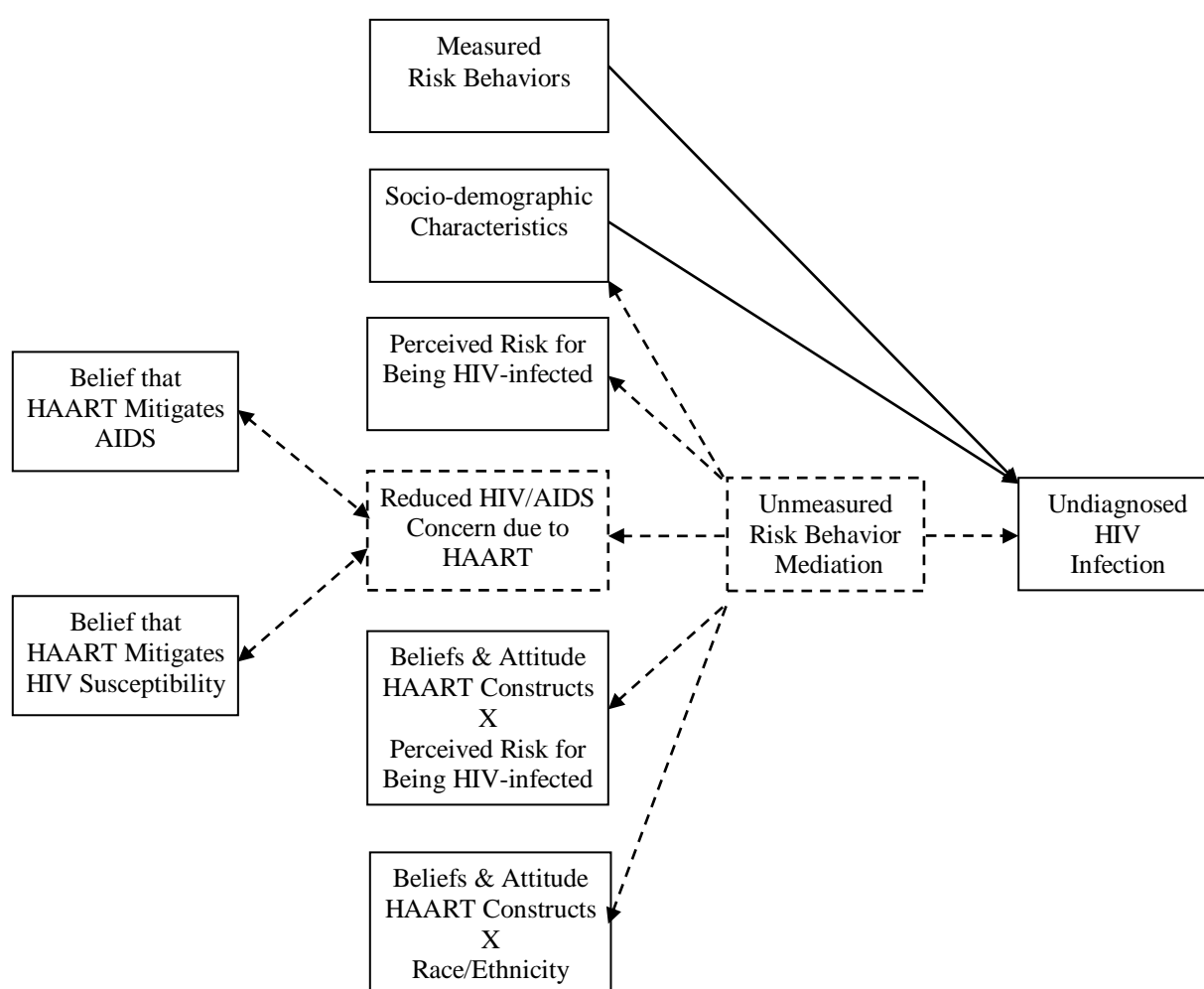
Figure 2.5. Logistic regression model including HAART-optimism belief constructs, excluding reduced HIV/AIDS concern due to HAART.

Manuscript 2: Hypotheses

In summary, the second manuscript of the dissertation intends to assess the strength, plausible direction, and racial-ethnic homogeneity of the association between reduced HIV/AIDS concern due to HAART and undiagnosed HIV infection, and the relative strengths, plausible direction, and racial-ethnic homogeneity of two belief constructs that theoretically drive that association (should it exist). The following specific hypotheses will be tested:

Hypothesis 9:   After adjustment for socio-demographic variables (e.g., race, age, testing history, etc.), risk behaviors, and perceived risk, reduced HIV/AIDS concern due to HAART will be statistically significantly associated with undiagnosed HIV infection.

Hypothesis 10:   The magnitude of association between reduced HIV/AIDS concern and undiagnosed HIV infection will not be significantly different across levels of race and perceived risk (i.e., tests for interactions will be statistically non-significant).

Hypothesis 11:   The magnitude of association between the belief that HAART mitigates HIV susceptibility and undiagnosed HIV infection will be larger than the association between the belief that HAART mitigates HIV/AIDS severity and undiagnosed HIV infection.

Hypothesis 12:   The magnitude of associations between undiagnosed HIV infection and beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility will not be statistically significantly different across levels of race/ethnicity and perceived risk for infection.

Hypothesis 13:　Beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility will be associated with undiagnosed infection when evaluated in the absence of reduced HIV/AIDS concern and will not be associated with undiagnosed infection when evaluated in the presence of reduced HIV/AIDS concern.

Manuscript 2: Unmeasured Behavioral Mediation

In this dissertation, the extensive scientific evidence that HIV is predominately transmitted during sexual and injection drug behavior via semen, vaginal secretions, and blood, and is not or only very rarely transmitted by other behaviors, is accepted and is not reviewed herein. Thus, the only meaningful causal mechanism linking psychological determinants (or consequents) and undiagnosed HIV infection is mediation by sexual or injection-drug risk behavior. However, because HIV transmission is conditional on these behaviors with HIV-infected partners, and because these same behaviors occur with non-infected partners, distinguishing behaviors that do and do not lead to transmission, at the individual level, is difficult.

Moreover, sexual behaviors change depending on partners and contexts. MSM and other persons at risk for HIV/STD infection, for example, tend to engage in safer sexual practices with persons perceived to be at higher risk for HIV/STDs, and tend to engage in riskier sexual practices with persons perceived at lower risk for HIV/STDs (Peterman et al., 2000). Specifically, the prevalence of self-reported UAI among MSM is considerably higher when partnerships involve steady partners or partners who disclose or are perceived to be HIV-negative (Dawson et al., 1994; Kippax et al., 1997; Hoff et al., 1997; Davidovich et al., 2000; Crawford et al., 2001; Prestage et al., 2005). Thus, simple behavioral measures can fail to predict STD/HIV

infection risk because with some partners and in some contexts, the behaviors lead to infection, and in others, the behavior never leads to infection (i.e., partners selected are all HIV-negative) (Peterman et al., 2000). One study of young MSM, for example, suggests that perceived lifetime risk for infection, rather than risk behavior, is a better predictor of undiagnosed HIV infection (MacKellar et al., 2007a).

The most striking example of the limitation of current behavioral measures is the inability to distinguish young black MSM at highest risk for HIV infection who typically report, on commonly used measures, risks similar to those of white MSM (Millett et al., 2006; Millett et al., 2007). Clearly, simple behavioral measures fail to capture all the complexities of behaviors that result in HIV transmission such as choosing sexual partners who are at high risk for undiagnosed infection (Bingham et al., 2003; Bingham & Sey, 2009). Thus, in data obtained from YMS and other surveys in which only simple behavioral measures were used (and not partner-selection and other behaviors of import), the magnitude of unmeasured behavioral mediation is assumed to be large.

CHAPTER 3

REVIEW OF THE LITERATURE: MANUSCRIPT 3

<u>CLIA-waived Rapid HIV Testing</u>

To reduce the prevalence of undiagnosed HIV infection among MSM and other populations at risk, CDC's Advancing HIV Prevention initiative established demonstration projects in non-clinical settings to learn how to manage and use new rapid HIV tests that became available in the United States in 2003 (CDC, 2003a; Heffelfinger et al., 2008). These safe and simple-to-use tests were waived of federal and state regulatory oversight under the federal Clinical Laboratory Improvement Amendments (CLIA), permitting their use outside the laboratory by persons without formal laboratory training (Greenwald et al., 2006). Subsequent post-marketing surveillance and studies on 174,127 rapid tests conducted in 432 settings affirmed that when stored, managed, and used outside of the laboratory, CLIA-waived rapid HIV tests continued to meet the manufacturer's FDA-approved performance claims (Wesolowski et al., 2006; Delaney et al., 2006). Thus, as part of AHP and the Expanded Testing Initiative, CLIA-waived rapid HIV testing became CDC's primary tool to expand testing services in non-traditional, community settings as well as some outpatient clinical settings, emergency care departments, and correctional facilities (CDC, 2003a; Heffelfinger et al., 2008; NASTAD, 2009).

Besides expanding access to HIV, CLIA-waived rapid tests offered the promise of increasing the demand for testing over conventional, laboratory-based tests. Used on oral fluid or finger-stick whole blood and providing results in less than 30 minutes, CLIA-waived rapid HIV tests are strongly preferred over conventional, laboratory-based assays by MSM and other persons at risk for HIV (CDC, 2003a; Spielberg et al., 2003; Spielberg et al., 2005a; San

Antonio-Gaddy et al., 2006). Also, because as many as two-thirds of persons who test at publicly funded clinics never return for their conventional test results, it was thought and subsequently confirmed that the use of rapid tests would increase the number of persons who actually learn their results, including those who test HIV positive (CDC, 2003a; Sullivan et al., 2004; San Antonio-Gaddy et al., 2006; Hutchinson et al., 2006b). Given these testing preferences and advantages over laboratory assays, the use of CLIA-waived rapid HIV tests in the United States has grown dramatically. In 2008, state and local health departments expected to use 2 million CLIA-waived rapid HIV tests, representing approximately 52% of all HIV tests conducted in their programs (NASTAD, 2008).

CLIA-waived rapid HIV testing, however, has not eliminated several well-recognized barriers of having to go to a provider for testing such as inconvenience, costs in time and money, lack of anonymity, and fear of discovery and stigmatization (Irwin et al., 1996; Spielberg et al., 2003). As reviewed earlier, the promise of CLIA-waived rapid tests to reduce the prevalence of undiagnosed HIV infection and associated incidence has not yet materialized, particularly for young black MSM. However, a rapid HIV test that could be purchased over the counter or obtained discretely from public-health programs, and that could be stored and used when needed, could ultimately reduce these remaining provider-associated testing barriers, and thus increase the uptake of testing.

Although an over-the-counter, HIV home-sample-collection (HSC) test has been available in the United States since 1996, these tests are distinguished from over-the-counter rapid HIV tests (OTCRT) in that only the specimen (blood spot on filter paper) is collected and mailed to a central lab for testing (Branson, 1998; Home Access Health Corporation, 2009). As part of the testing procedure, clients must first register with the company via phone to obtain an

anonymous code associated with the purchased kit and to complete pretest counseling either through an automated questionnaire or with a counselor (Home Access Health Corporation, 2009). After submitting their specimen, clients use the code to receive their test results by phone either via automated response for results that are negative (counselor is available upon request) or from a counselor for results that are positive. HIV HSC testing costs $44 for results in 7 days and $59.95 for results in 48hrs (Home Access Health Corporation, 2009). When approved in 1996, many hoped that the availability of HIV HSC tests would increase testing in the United States. However, the estimated proportion of all tests conducted in the United States that are HSC tests is thought to be very small (<1%) (Branson, 1998), and two multi-city, cross-sectional surveys suggest that home HSC tests are rarely used by MSM (Colfax et al., 2002; Greensides et al., 2003).

OTC Rapid HIV Testing

In 2005, OraSure Technologies Inc., the manufacturer of the CLIA-waived rapid HIV test OraQuick® *Advance*, sought guidance from the Food and Drug Administration (FDA) on application requirements for re-labeling OraQuick® *Advance* for over-the-counter sale (FDA, 2005; OraSure Technologies Inc., 2009). In response to that inquiry, the FDA sought input from the Blood Products Advisory Committee (BPAC) on criteria needed to approve ≥1 CLIA-waived rapid tests for home use (FDA, 2005). At the November 3, 2005 BPAC hearing, FDA invited testimonies from the manufacturer, CDC, the research community, and the public on OraSure's inquiry on home use. Based on the results of that hearing, the FDA released guidance in March 2006 on required clinical trials and performance-approval thresholds (FDA, 2006).

OraSure Technologies Inc. and Trinity Biotech (manufacturer of the CLIA-waived rapid test: Uni-Gold[TM]), subsequently announced their intentions to seek OTC labeling of their products (OraSure Technologies Inc., 2009; Trinity Biotech, 2008). In April 2007, OraSure announced that Constella Group would develop and administer the 7-day, 24-hr telephone and web-based information-access and counseling systems necessary for an OTCRT in the United States (OraSure Technologies Inc., 2007). Clinical trials that demonstrate that untrained persons can correctly perform and interpret rapid-test results based on instructional materials alone have recently been completed, and OraSure, announced its intentions to submit a pre-market approval application (PMA) to the FDA for OTC labeling of OraQuick® *Advance* before the end of 2009 (OraSure Technologies Inc., 2009).

While FDA approval isn't certain, the large investment by OraSure, to fund Constella and submit the PMA suggests that the company is confident that they can meet BPAC device performance and safety benchmarks and obtain FDA approval. Much of the public testimony at the Nov. 2005 hearing advocated for approval, touting the considerable individual and public-health benefits of approving a rapid HIV test that can be used at home among at-risk persons who might not test elsewhere (FDA, 2005; FDA, 2006). With an estimated prevalence of undiagnosed HIV infection of 14% (37% among those who are black) of MSM sampled in 5 U.S. metropolitan areas and increasing annual HIV incidence nationwide since 1991-1993, MSM have arguably the most to benefit from an FDA-approved, OTCRT (CDC, 2005a; Hall et al., 2008).

Potential Public Health Applications of OTCRT

When an OTCRT becomes available, considerable research will be needed to determine the magnitude and scope of public-health applications, if any, for this promising new technology. These public-health applications might include the promotion of rapid HIV self testing or targeted distribution of tests to populations at highest risk of undiagnosed infection. For example, public-health programs could make OTCRT available at specific venues where undiagnosed infection is likely (e.g., black MSM venues) or where considerable HIV transmission is thought to occur (e.g., bathhouses) (Raymond et al., 2008; Bingham et al., 2008).

Public-health programs might also promote OTCRT use among partners as a means to avoid HIV infection. Since the early 1990s, many MSM have attempted to avoid infection by selecting partners or engaging in unprotected sex with only those partners who disclose being HIV-negative (Dawson et al., 1994; Kippax et al., 1997; Crawford et al., 2001). Unfortunately, many MSM who perceive themselves at low risk and disclose being HIV negative are actually HIV-infected, and as a consequence, considerable HIV transmission is thought to occur through HIV-negative serosorting (Golden et al., 2004, 2008; Koblin et al., 2006, MacKellar et al., 2006b). If new partners tested themselves before engaging in sexual relations, HIV transmission risks associated with HIV-negative serosorting could be nearly eliminated (Varghese et al., 2002). The plausible convenience, safety, and accuracy of an OTCRT could finally make HIV negative serosorting an effective primary-prevention practice for many MSM and other persons at risk for HIV.

HIV Testing Preferences of MSM

Although an OTCRT is not currently available, some information on its potential use among MSM is available. In a qualitative, formative-research study conducted in Seattle, WA, for example, Spielberg and colleagues (2001) investigated beliefs on barriers and facilitators of HIV testing of 27 mostly white MSM.   Perceived lack of confidentiality and having to wait for results for one to two weeks were the most frequently cited HIV-testing-attribute barriers (Spielberg, 2001). The most frequently cited testing-attribute facilitators included clinics that made anonymous, walk-in, and free testing available. Hypothetical test modalities favored by MSM included oral-fluid testing with fast results (a technology that was not available at that time) and rapid HIV testing that could occur in the home (Spielberg, 2001).

In a follow-up quantitative, cross-sectional study conducted in two MSM bathhouses in Seattle, WA in 1998, Spielberg and colleagues (2003) assessed beliefs about barriers and facilitators to HIV testing at individual, policy, and test-attribute levels. Beliefs were compared between MSM who never tested or delayed testing versus MSM who had never delayed testing. Of 436 mostly white MSM surveyed, proportionally more MSM who had never tested (n=56) or who had delayed testing (n=129) versus MSM who never delayed testing (n=251) stated that they did not want to go to a clinic for HIV testing (36% and 27% vs. 8%); felt that waiting for HIV test results made them anxious (52% and 60% vs. 16%), and did not want to talk with a counselor (30% and 21%, vs. 8%). Rapid HIV testing at home was the most preferred hypothetical testing modality reported by participants who had never previously tested (Home (H), 30%; serum-based test at Clinic (C), 12.5%), and was equally preferred among delayed (H, 22%; C, 19%) and never-delayed testers (H, 17%; C, 17%) (Spielberg et al., 2003).

Three additional reports confirmed the findings by Spielberg and colleagues that many MSM would prefer to test at home with a rapid HIV test if it was available. First, in a cross-sectional survey conducted at 4 publicly funded HIV testing clinics and mobile units in San Francisco in 1999, Skolnik and colleagues (2001) asked participants to rate their preferences of testing for HIV at a publicly funded clinic, a doctors office, or at home with either an HSC or rapid HIV self test. Of 149 mostly white MSM participants, 71% preferred testing at a public clinic, 23% preferred to test at home with a rapid HIV self test; 6% preferred to test at a doctor's office, and none preferred to use an HIV HSC test (Skolnik et al., 2001). Among MSM who preferred rapid HIV testing at home (responding as if it was available), 92% preferred it because of the instant results and the convenience with testing at home (Skolnik et al., 2001). Since the study was restricted to MSM sampled from publicly funded test sites, the reported preference for testing in public clinics was probably upwardly biased, as noted by the authors (Skolnik et al., 2001).

In the second report based on data obtained from the same study, Phillips and colleagues (2002) conducted a conjoint analysis and found that stated preferences depended on the perceived accuracy and price of the test. The testing scenario involving an instant, highly accurate home HIV test had the greatest preference among MSM provided the test was available at $10 (Phillips et al. 2002). HIV HSC tests and testing in the doctor's office at prices of $50 each were the two scenarios of lowest preference (Phillips et al., 2002).

Finally, testing preferences and the influence of pricing on reported willingness to use an OTCRT was reported by Spielberg in her testimony at the FDA BPAC hearing on rapid HIV self tests (Spielberg, 2005b). Among 240 HIV-infected persons (mostly MSM) enrolled in a cross-sectional survey in Seattle, WA, proportionally more participants preferred using a rapid HIV

test at home (H) over testing at a clinic (C) on the following test attributes: location (H, 61%; C, 37%), privacy (H, 73%; C, 6%), convenience (H, 76%; C, 10%), comfort (H, 70%; C, 10%), and safety (H, 48%; C, 21%). Clinic-based testing was preferred over home testing on only one attribute: perceived test accuracy (H, 22%; C, 43%) (Spielberg, 2005b). Similarly high proportions of participants reported being willing to pay for either an oral fluid (OF) or finger-stick whole blood (WB) OTCRT at relatively low prices: $5: 89% OF, 87% WB; $10: 87% OF, 85% WB; $15: 69% OF, 70% WB. Fewer MSM, however, reported being willing to pay for an OTCRT at higher prices: $20: 43% OF, 37% WB; 30$: 19% OF; 13% WB (Spielberg, 2005b).

In the only study of its kind, Phillips and Chen (2003) used the Behavioral Risk Factor Surveillance System in California in 1999 to assess the magnitude and correlates of self-reported willingness to use an OTCRT. Of 871 respondents aged 18 to 44 years, 55% reported they would be willing to use an OTCRT. Independent correlates of willingness to use an OTCRT included never versus ever testing for HIV (AOR, 1.72; 95%CI, 1.20-2.45), planning to test in the next year versus not planning (AOR, 1.17; 95%CI, 1.00-1.36), preferring to test at home versus elsewhere (AOR, 9.7; 95%CI, 4.84-19.42), and preferring rapid HIV tests (AOR, 1.53; 95%CI, 1.09-2.16) (Phillips & Chen, 2003). The percentage of participants willing to use an OTCRT, however, dropped considerably with price; only 24% reported that they were definitely or probably willing to use the test if it was priced at $50 (Phillips & Chen, 2003). The study did not stratify results by sexual orientation, and thus the population-based estimate on the magnitude and correlates of willingness to use an OTCRT among MSM in California (as elsewhere) is unknown.

Summary of Literature & Potential Benefits of Early Research

An OTCRT is not currently available and its future availability depends upon BPAC recommendations and an FDA ruling that may occur in 2010. Notably, the FDA has never approved an over-the-counter application for a diagnostic test of an infectious disease (FDA, 2008). However, the increasing incidence of HIV among MSM after more than two decades of prevention, unacceptably large and growing racial disparities in HIV morbidity and mortality, and the high prevalence of undiagnosed HIV infection suggests that FDA approval is likely if the manufacturers can provide adequate evidence for the accuracy and lack of harm associated with OTCRT use.

Research based on self-reported preferences suggests that the HIV-test attributes preferred by most MSM are testing anonymously with a highly accurate, low-cost test that provides nearly instant results. In three studies, testing at home was the most preferred strategy; however, this preference was conditional on low price. Although the predictive validity of stated preferences for an OTCRT cannot be known (since the test is unavailable), considerable research and public-health-program data suggest that CLIA-waived rapid testing is clearly the preferred testing modality by MSM and other persons at risk for HIV. Thus, although unknown, the literature suggests the potential for considerable uptake of OTCRT among MSM, especially if the tests are subsidized or distributed by public-health programs.

The public-health benefit of rapid HIV self tests, however, depends largely on whether MSM with undiagnosed HIV infection, particularly those who are black, will use the test. Compared with HIV-negative MSM, HIV-infected, unaware MSM are more likely to report never testing for HIV or only remotely testing for HIV (i.e., more than 1 or 2 years ago) (CDC, 2005a; MacKellar et al., 2005). When asked why they had not tested for HIV in the past year,

HIV-infected, unaware MSM were more likely than HIV-negative MSM to report not testing because they feared either learning their result, that others would learn of their results, or that they would lose family relationships, their job, or insurance (CDC, 2005a; MacKellar et al., 2005). Thus, understanding the variation in intentions to use OTCRT among never-tested MSM, particularly those who are black, and who report not testing because of the above reasons would provide timely information on whether the availability of OTCRT might help reduce undiagnosed infections among those MSM.

Research AIMS & Analytical Approach

To help meet these early information needs, the primary aim of the third manuscript of the dissertation is to conduct an exploratory analysis of the magnitude and correlates of strong intentions to use OTCRT among MSM who report having never tested for HIV. Analyses will use data obtained from CDC's Web-based HIV Behavioral Surveillance (WHBS) Survey. Conducted in 2007, WHBS was a survey of risk and preventative behaviors of MSM who resided in six U.S. cities and who used the internet. Contingency table analyses will be conducted to identify demographic and behavioral correlates of strong intention to use an OTCRT if it became available among those MSM who reported never testing for HIV (NTMSM).

Since WHBS was not designed to evaluate a theoretical model and because no prior studies have been published on correlates of intentions to use an OTCRT among NTMSM, analyses of the third manuscript will be exploratory in nature rather than restricted to test a set of predetermined a priori hypotheses. In the absence of prior research and a priori knowledge, an

exploratory analytical approach is important to avoid missing potentially important variation in reported intentions to use an OTCRT.

Secondary research aims of the third manuscript are to evaluate of NTMSM (1) attendance at MSM-identified venues and use of the internet for HIV information, (2) the distribution of main reasons for not testing by demographic, risk, and internet-use characteristics, and (3) strong intentions to test in the upcoming year. Although considerable research has evaluated correlates of ever, repeat, and recent testing among MSM, no reports in the United States have focused on NTMSM (Heckman et al., 1995; Roffman et al., 1995; McFarland et al., 1995; Phillips et al., 1995; Povinelli et al., 1996; Campsmith et al., 1997; Kalichman et al., 1997; Leaity et al., 2000; Maguen et al., 2000; Spielberg et al., 2001; Kellerman et al., 2002; MacKellar et al., 2002; Fernandez et al., 2003; MacKellar et al., 2005; CDC, 2005a; CDC, 2006a; MacKellar et al., 2006a; Mimiaga et al., 2007; Sumartojo et al., 2008; Mimiaga et al., 2009). Thus, information on potential locations to deliver HIV testing or test-promotion services, appropriate content of interventions to address reasons for not testing, and information about NTMSM who don't intend to test and who should receive priority interventions have not been reported and are unknown.

CHAPTER 4

A PLAUSIBLE CAUSAL MODEL OF HAART-EFFICACY BELIEFS, HIV/AIDS

COMPLACENCY, AND HIV-ACQUISITION RISK AMONG YOUNG

MEN WHO HAVE SEX WITH MEN[1]

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Abstract

Despite considerable research, the causal relationship between HIV/AIDS complacency, measured as treatment-related reduced HIV/AIDS concern, and risk behavior remains unclear. Understanding the directionality and underpinnings of this relationship is critical for programs that are designed to reduce HIV/AIDS complacency as a means to decrease HIV incidence among men who have sex with men (MSM). This report uses structural equation modeling to evaluate a theory-based, HIV/AIDS complacency model on 1593 MSM who participated in a venue-based, cross-sectional survey in six U.S. cities, 1998-2000. Demonstrating adequate fit and stability across geographic samples, the model suggests that reduced HIV/AIDS concern acts as both a consequent and determinant of risk behavior. As a determinant, reduced HIV/AIDS concern increases HIV-acquisition behavior by mediating the effects of two underlying treatment beliefs. New research is needed to assess model effects on current HIV acquisition risks, and thus help inform programs designed to reduce HIV/AIDS complacency among MSM.

Introduction

Notwithstanding considerable public-health efforts, the annual HIV incidence among men who have sex with men (MSM) has increased steadily since the early 1990s (Hall et al., 2008). Young black and Hispanic MSM are particularly affected (Valleroy et al., 2000; CDC, 2005a). MSM aged 13-29 years accounted for 38% of the estimated 30,000 new infections among MSM in 2006, and 52% and 43% of the estimated new infections among black and Hispanic MSM, respectively (CDC, 2008c).

To help reduce HIV incidence among MSM and other high-risk persons, the Centers for Disease Control and Prevention (CDC) announced in 2009 a new national Act Against AIDS campaign (CDC, 2009c). The prevention strategy of this $45 million campaign is based on the hypothesis that many high-risk persons believe that HIV/AIDS is no longer a serious health threat because of highly active antiretroviral therapy (HAART), and that those who are less concerned (i.e., more complacent) about the disease are more likely to acquire HIV by engaging in greater risks (CDC, 2009c; Kaiser Family Foundation, 2009b). In apparent support of this hypothesis, 16 cross-sectional studies found that although a minority of HIV-negative or unknown-status MSM endorsed HAART-related optimistic beliefs and/or reduced HIV/AIDS concern, MSM who endorsed at least one optimistic belief or attitude were more likely to engage in risk behavior (Dilley et al. 1997; Remien et al., 1998; Kalichman et al., 1998, 2007a, 2007b; Kelly et al., 1998; Van de Ven et al., 1999, 2000; Elford et al., 2000; Vanable et al., 2000; Huebner & Gerend, 2001; Ostrow et al., 2002; International Collaboration on HIV optimism, 2003; Koblin et al., 2003; Halkitis et al., 2004; Sullivan et al., 2007).

Because of their cross-sectional designs, however, these studies could not evaluate the directionality of observed associations: whether HAART-optimistic beliefs or attitudes were a

determinant or consequent of risk behavior. Two contrasting theories that attempt to explain

these associations have emerged from longitudinal studies that found evidence for both

directions.

First, motivational health-behavior theories such as the health belief model (HBM) and

protection motivation theory (PMT) hypothesize that persons are less motivated to enact

behaviors to prevent disease if they perceive less susceptibility to that disease or that the disease

is not severe (Becker, 1974; Prentice-Dunn & Rogers, 1986). Thus, under HBM/PMT, risk

behavior is determined, in part, by the motivational underpinnings of perceived susceptibility and

severity. In support of HBM/PMT, two longitudinal studies conducted in the Netherlands found

that MSM who endorsed reduced HIV/AIDS concerns because of HAART were more likely to

subsequently engage in sexual risks and to acquire a sexually transmitted disease (STD)

including HIV (Stolte et al., 2004a; van der Snoek et al., 2005).

In serial cross sectional studies conducted in England and Scotland, however, annual

increases in the prevalence of risk behavior occurred among both MSM who were and *were not*

less concerned about HIV/AIDS because of HAART (Elford et al., 2002; Elford et al., 2003;

Williamson & Hart, 2004). Moreover, in a longitudinal study of MSM in the U.S., reduced

HIV/AIDS concern due to HAART did not predict subsequent risk behavior; however, risk

behavior predicted subsequently measured reduced HIV/AIDS concern (Huebner et al., 2004).

Based on their findings, Elford and colleagues (2002, 2003), Williamson and Hart (2004), and

Huebner and colleagues (2004) proposed that cognitive dissonance theory might better explain

observed cross-sectional associations.

In contrast to HBM/PMT, cognitive dissonance theory (CDT) posits that persons

experience negative emotional states (e.g., stress) upon recognizing that their stated ideas or

enacted behaviors contradict internalized beliefs or attitudes (i.e., cognitions are dissonant) (Festinger, 1957; Aronson, 1969). Under CDT, beliefs or attitudes are modified to diminish the stress associated with the behavior that produced the cognitive dissonance (Festinger, 1957; Aronson, 1969). The motivation to modify beliefs or attitudes (e.g., concern about HIV/AIDS) can be very powerful if the behavior that produces the cognitive dissonance is perceived as particularly harmful to oneself or others (Festinger, 1957; Aronson, 1969).

Inconsistent findings from the above longitudinal studies, thus, suggest complexity in the causal relationship between the HAART-related attitude, reduced HIV/AIDS concern, and risk behavior. Moreover, the literature yields inconsistent findings on two plausible underlying beliefs of HBM/PMT import. Of 13 studies that measured the belief that HAART reduces susceptibility to HIV, for example, seven found significant associations between this belief and risk behavior (Kalichman et al., 1998, 2007a, 2007b; Van de Ven et al., 1999; Vanable et al., 2000; Huebner & Gerend, 2001; Halkitis et al., 2004) and six did not (Elford et al., 2000, 2002, 2003; Ostrow et al., 2002; Koblin et al., 2003; Williamson & Hart, 2004). Of six studies that measured the belief that HAART reduces HIV/AIDS severity, *none* found that this belief was significantly associated with risk behavior, contrary to theoretical expectations under HBM/PMT (Kalichman et al., 1998, 2007b; Van de Ven et al., 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a).

Public Health Significance & Prior Research Limitation

Understanding the complexity of the causal relationship between HAART-related reduced HIV/AIDS concern and risk behavior, and of the relative importance of underlying beliefs is critical for prevention programs that target HIV/AIDS complacency as a means to

reduce HIV incidence among MSM. Two principal limitations of past research have prevented a more complete understanding of this relationship.

First, previous studies evaluated HAART-related beliefs or attitudes as independent predictors of risk without regard to a theoretical framework that maps out direct and indirect (i.e., mediated) effects on risk behavior. Through structural equation modeling (SEM), a HAART-efficacy belief and HIV/AIDS complacency model can be evaluated that might help explain inconsistent findings on both the directionality of direct effects between reduced HIV/AIDS concern and risk behavior, and the relative importance of the indirect effects of underlying beliefs.

Second, none of the prior HAART-optimism studies in the United States evaluated HIV infection as the outcome of interest. Simple behavioral measures do not typically include partner risks for infection, and thus can be poor surrogates of STD risk (Peterman et al., 2000) and in differentiating MSM known to have considerably different HIV infection risks (Bingham et al., 2003; Harawa et al., 2004; Millett et al., 2006; Millett et al., 2007; Berry et al., 2007; Bingham et al., 2009). Thus, it is important to evaluate whether HIV/AIDS complacency, the target of a new national social marketing campaign, is associated with both increased risk behavior and HIV infection.

To help meet these needs, this report uses data from the second phase of CDC's Young Men's Survey (YMS) to evaluate a plausible HAART-efficacy belief and HIV/AIDS complacency model among young MSM, and whether HIV/AIDS complacency, as the hypothesized mediating construct in the model, presumably operates under HBM/PMT to increase both risk behavior and HIV-acquisition risk. In this paper, "efficacy" is used rather than "optimism" to better reflect our measures on perceived effects of HAART, which are now

generally recognized as true (Quinn et al., 2000; Montaner et al., 2006; Antiretroviral Therapy

Cohort Collaboration, 2008; Attia et al., 2009; Sullivan et al., 2009b; Donnell et al., 2010).

Methods

YMS methods have been described previously (MacKellar et al., 1996). In summary, the

second phase of YMS was conducted from 1998 through 2000 of men who attended MSM-

identified venues in Baltimore, Maryland; Dallas, Texas; Los Angeles, California; Miami,

Florida; New York, New York; and Seattle, Washington. Formative research was conducted to

construct monthly sampling frames of the days, times, and venues attended by young MSM.

From these sampling frames, 12 or more venues and their associated day/time periods were

selected randomly and scheduled as recruitment events each month. During recruitment events,

men were approached consecutively to assess their eligibility. Men aged 23 to 29 years who

resided in a locally defined area and who had never previously participated in the second phase

of YMS were eligible and encouraged to participate. Participants had blood drawn for HIV

testing, and were interviewed using a standard questionnaire, provided counseling and referral

for care, and reimbursed $50 for their time. Specimens were tested at local laboratories with

FDA-approved assays. The YMS protocol was approved by institutional review boards at CDC,

and at state and local institutions that conducted the survey.

Plausible Causal Model

Drawing upon several behavioral theories, our model posits that stronger beliefs about the

efficacy of HAART to mitigate HIV/AIDS severity and susceptibility to HIV reduces concerns

(i.e., increases complacency) about personal susceptibility to HIV and about HIV/AIDS overall

(Figure 4.1). Reduced concern about HIV/AIDS because of HAART, in turn, is posited to increase risk behavior (path A) and subsequently HIV infection risk (HIV infection risk is evaluated separately and is not included the model).

The effects of the two belief constructs on reduced HIV/AIDS concern are hypothesized to either be completely mediated (mitigate susceptibility belief) or partially mediated (mitigate HIV/AIDS belief) by reduced susceptibility concern (Figure 4.1). Finally, the model posits that risk behaviors measured since onset of sexual activity (i.e., sexual lifetime) act to reduce concerns about HIV/AIDS (path B) and affect new (i.e., recent) risk behavior. In the model, HAART-efficacy beliefs and reduced susceptibility and HIV/AIDS concern are measured as latent constructs, lifetime and recent risk behaviors are indices of observed variables, and all paths are hypothesized to have positive signs (Figure 4.1).

Theoretical Justification

The posited causal relationships of the model are based on principles derived from theories of planned behavior (TPB), health-belief model, protection motivation, and cognitive dissonance (Fishbein & Ajzen, 1975; Ajzen & Fishbein, 1980; Becker, 1974; Rosenstock, 1974; Rogers, 1975; Festinger, 1957; Aronson, 1969). In accordance with TPB, the model posits that beliefs are underlying determinants of behavior, and that the effects of beliefs on behavior are mediated, in part, by attitudes (Ajzen & Fishbein, 1980). Mitigate susceptibility belief, for example, is posited to be completely mediated by its corresponding attitude in accordance with TPB (Figure 4.1). Considerable observational and experimental research supports the hypothesis that attitudes can mediate the effects of beliefs on behavior (Godin & Kok, 1996; Hausenblas et al., 1997; Armitage and Conner, 2000; Armitage and Conner, 2001).

In accordance with HBM/PMT and CDT, the key complacency construct, reduced HIV/AIDS concern, is hypothesized as both a determinant (path A) and consequent (path B) of risk behavior (Figure 4.1). Empirical evidence for this dual role is provided by serial cross-sectional and longitudinal studies by Elford and colleagues (2002, 2003), Williamson and Hart (2004), Heubner and colleagues (2004), Stolte and colleagues (2004a), and van der Snoek and colleagues (2005) discussed above. Because our study was cross-sectional, we used lifetime and recent (prior six months) behaviors as a reasonable means to discern plausible effects on and from reduced HIV/AIDS concern. Finally, lifetime risk behavior is posited to serve as a surrogate for unmeasured extrinsic or intrinsic pleasures or rewards that are posited under HBM/PMT to influence decisions to engage in new risk behavior (Figure 4.1) (Becker, 1974; Rosenstock, 1974; Prentice-Dunn & Rogers, 1986).

Measures—Latent Constructs

One standard questionnaire was used in all cities to measure socio-demographic characteristics, sexual and drug-use behaviors, HAART-efficacy belief and complacency constructs, and perceived risk for infection. The four latent constructs were measured with 14 manifest variables (items) based, in part, from previous research on HAART optimism (Table 4.1) (Kalichman et al., 1998; Vanable et al., 2000; Ostrow et al., 2002).

The 14 items were included in a separate section of the questionnaire on knowledge and beliefs about HAART, which was defined as the "new combination-drug treatments for HIV and AIDS that include protease inhibitors." Responses were measured on a 5-point scale ranging from (1) strongly disagree to (5) strongly agree. The 14 items were only administered to

participants who reported being aware of HAART and either having never tested for HIV or having last tested HIV negative.

To evaluate the association between reduced HIV/AIDS concern and HIV infection, scores on items 11, 12, 13, and 14 (Table 4.1) were summed into a composite score and dichotomized into two endorsement levels labeled weak and moderate/strong. Weak endorsement included composite scores between 4 and 8 (i.e., representing average disagreement with the items). Moderate/strong endorsement included all other responses and was combined because very few MSM strongly agreed with the items.

Risk Behavior Indices

Indices used to measure lifetime and recent risk behaviors were based on factors associated with prevalent and incident HIV infection among MSM (Table 4.1) (Valleroy et al., 2000; Koblin et al., 2006). The lifetime risk behavior index was composed of the following 4 variables weighted in accordance with reported adjusted odds ratios for prevalent HIV infection: number of lifetime male sex partners, ever having anal sex with another male, ever being diagnosed with an STD, and ever having used needles or "works" to inject non-prescription drugs (Valleroy et al., 2000). The recent risk behavior index was composed of the following 5 variables measured in the prior six months weighted in accordance with reported adjusted hazard ratios for incident HIV infection: number of male sex partners; amphetamine use; heavy alcohol use; use of alcohol or drugs before sex; and unprotected anal intercourse (UAI) with HIV-infected/unknown-status male partners (Koblin et al., 2006). Additional information on the rationale, weighting mechanism, and validity of these indices is provided in Appendix 1.

Perceived Risk for Infection

Perceived risk for infection was measured with the following item: "Using this card, choose a number that best describes how likely it is that you are HIV-positive today." The card included 6 possible responses (1, very unlikely; 2, unlikely; 3, somewhat likely; 4, likely; 5, very likely; 6, HIV-positive). Responses were categorized into two levels (1, labeled "very low perceived risk" vs. 2-6, labeled "some perceived risk") required for stratified SEM analyses (see *Hybrid Model—Assessment of Directionality of Effects*).

Analyses—Data Screening

Analyses were first performed to evaluate (1) recruitment outcomes, socio-demographic characteristics, risk behaviors, and item distributions overall and by YMS city; (2) the normality of items and indices used for SEM; and (3) correlations between the 16 items and indices. Severe univariate non-normality was defined as $> |3|$ for skew or $> |8|$ for kurtosis (Kline, 2005). Multivariate non-normality was defined as having a relative multivariate kurtosis value $>|2|$. The magnitude of proportions of explained variance was interpreted in accordance with Cohen's recommendations: <9%, small; 9-25%, moderate; >25%, large (Cohen, 1992; Armitage and Conner, 2000). For all analyses, *P* values <0.05 and SEM t-test values >1.96 were considered statistically significant. All univariate data screening, internal consistency, SEM, and contingency table analyses were conducted using FREQ, CORR, and CALIS procedures in SAS version 9.1 (SAS Institute Inc., Cary, NC).

Parameter Estimation & Model Fit Criteria

To estimate SEM parameters, maximum likelihood (ML) estimation was used on covariance matrices. For all models, fit was evaluated using the model χ^2 fit statistic, root mean square error of approximation (RMSEA), root mean square residual (RMR), and non-normed (NNFI), incremental (IFI or Bollen's Delta2), and comparative (CFI) fit indices (Hu & Bentler, 1998; Kline, 2005).

Because of the large sample size of this study and the highly constrained measurement and structural models, the model χ^2 fit statistic was expected to be statistically significant, indicating that the model does not fit the data perfectly (i.e., relative to the just-identified model in which all possible paths are modeled) (Kline, 2005). Thus, although the model χ^2 fit statistic is reported for reference purposes, model fit is based on the remaining indices in accordance with the following interpretative criteria: RMSEA <0.05, close approximate fit, 0.05-0.08, reasonable approximate fit, >0.08, poor fit; RMR <0.05, good fit, 0.05-0.09, adequate fit, >0.09, poor fit; NNFI, IFI, CFI: <0.90, inadequate fit; 0.90-0.95, adequate fit, >0.95, good fit (Kline, 2005).

Measurement Model

The original measurement model included the 4 latent constructs and their respective items (Table 4.1). To reduce capitalization on chance, separate confirmatory factor analyses (CFA) were performed to evaluate the measurement model in the entire sample and across all 20 combinations of sub-samples restricted to 3 YMS cities (Breckler, 1990; MacCallum et al., 1992). To derive the final measurement model, changes to the original model were considered only when parameter estimates suggesting the change were consistent across all 20 sub-samples. Sub-samples from 3 YMS cities were chosen to provide approximately 20 cases for each

estimated parameter in accordance with SEM sample-size recommendations (Kline, 2005).

Finally, the reliability of measured constructs was assessed with Cronbach's alpha on items

retained for the final measurement model.

Hybrid Model—Assessment of Fit, Stability, and Mediation

The original hybrid model included the final measurement model and the original

structural model (Figure 4.1). To assess the stability of fit and parameter estimates, SEM was

used to evaluate the original hybrid model for the entire sample and for all 20 combinations of

sub-samples. To assess mediation of HAART-efficacy beliefs, the original hybrid model was

compared against an alternative model that included 4 direct effects that were constrained to zero

in the original hybrid model. Improvement of fit between original and alternative hybrid models

was evaluated using the χ^2 difference test for nested models (Kline, 2005).

Hybrid Model—Assessment of Directionality of Effects

To assess evidence on directionality of effects, the original hybrid model was evaluated

separately for MSM who perceived themselves at very low and at some risk for HIV infection.

If CDT alone explains hypothesized associations, the hybrid model should fail (i.e., have poor fit

and statistically non-significant path coefficients) when evaluated among MSM who perceive

themselves at very low risk for HIV. Model failure is expected because the only presumed

motivation underlying the causal relationships (i.e., cognitive dissonance) should be nearly

eliminated among MSM who perceive themselves at very low risk for HIV. Alternatively, if

HBM/PMT alone explains hypothesized associations, excluding path B (Figure 4.1), all other

path coefficients should be statistically significant and the model should fit adequately for both

risk-perception strata of MSM. Finally, if both CDT and HBM/PMT operate, the hybrid model should fit adequately for both strata; however, path B should be statistically significant only among MSM who perceive at least some risk for HIV.

HIV/AIDS Complacency & HIV Infection

Finally, to evaluate whether the key complacency construct of the hybrid model, reduced HIV/AIDS concern, is associated with HIV infection, two stratified contingency table analyses were performed. Stratification variables included (1) perceived risk for infection, and (2) interval in time since last HIV-negative test result (never tested/$\geq$1 year vs. <1 year). Stratified analyses were performed to assess the consistency of patterns of associations between reduced HIV/AIDS concern and both recent risk behavior and recent HIV infection.

Results

Derivation of Analytic Sample

At 181 venues in the 6 cities, staff enrolled 3,137 (57.6%) men of 5,443 who were identified as eligible. Of the 3,137 participants, the following were removed from analyses: 53 (1.7%) duplicates; 13 (0.4%) who gave contradictory responses or who were impaired by alcohol or drugs; 11 (0.4%) who reported never having sex; 121 (3.9%) who reported never having sex with men; 199 (6.3%) who reported previously testing HIV-positive (n=104), indeterminate (n=5), or who either didn't know their last result (n=89) or who refused to report their last result (n=1); and 1055 (33.6%) who reported either being unaware of HAART (n=1047) or who had missing information on awareness of HAART (n=8).

Of the remaining 1,685 MSM, 92 (5.5%) either reported not knowing, had missing responses, or refused to respond to one or more of the 14 items (n=90), or reported not knowing or refused to respond to the measure on perceived risk for being HIV infected (n=2). The 92 MSM were not significantly different from the 1593 MSM with complete responses by age group and race/ethnicity, or on median scores on lifetime and recent risk behavior (data not shown). Analyses were restricted to the 1593 MSM who reported being aware of HAART, and had either never tested for HIV or had last tested HIV negative, and on whom analyzable responses were obtained for each of the 14 items and perceived risk for HIV infection.

Participant Characteristics

Of the 1593 MSM, slightly over half were 26-29 years of age and of non-Hispanic white race, and most reported having some college education, being full or part-time employed, and previously testing for HIV (Table 4.2). Many MSM reported considerable lifetime and recent risk behaviors, and 120 (7.6%) tested positive for HIV at the time of their YMS interview (Table 4.2). Mean item scores suggest that a minority of MSM endorsed HAART-efficacy belief and complacency constructs across the six cities (Table 4.1).

Normality Assessment & ML Estimation

The relative multivariate kurtosis statistic (1.32) and univariate skew and kurtosis statistics for all items and risk-behavior indices did not meet criteria for severe non-normality for the entire sample (Table 4.1) and for all 20 sub-samples (data not shown). Maximum likelihood estimation of all original, alternative, and final models using the entire sample and all sub-

samples successfully converged without any estimation irregularities such as negative error variances or R^2 values >1.

Original and Final Measurement Models

With the exception of item 10, CFA performed on the entire sample and all 20 sub-samples confirmed the original measurement model (data not shown). The amount of variance of item10 explained by reduced susceptibility concern was 1.6% overall, and ranged from 0.5% to 3.3% for the 20 sub-samples. Because of these concordant findings, the final measurement model excluded item 10; no other changes were made.

The final measurement model demonstrated adequate fit, all unstandardized factor loadings (interpreted as regression coefficients) were statistically significant, and HAART-efficacy belief and complacency constructs explained moderate to large proportions of observed variance of respective items (Figure 4.2). Cronbach's coefficient alpha was 0.703 for the belief that HAART mitigates HIV/AIDS (items 1-4), 0.798 for the belief that HAART mitigates HIV susceptibility (items 5-7), and 0.803 for reduced HIV/AIDS concern (items 11-14). The correlation between items 8 and 9 (reduced susceptibility concern) was 0.469.

Original Hybrid Model—Assessment of Fit & Stability

The original hybrid model demonstrated adequate fit; all unstandardized path coefficients (interpreted as multiple regression coefficients) had positive signs and were statistically significant; and the model explained moderate to large proportions of variance in recent risk behavior and HIV/AIDS complacency constructs (Figure 4.3).

For all 20 sub-samples, the original hybrid model demonstrated adequate fit (data not shown); all estimated path coefficients had a positive sign; nearly all path coefficients were similar in magnitude; and similar proportions of variance in HIV/AIDS complacency constructs and recent risk behavior were explained (Data Table, Figure 4.3). Unstandardized coefficients for 4 paths, including the effect of reduced HIV/AIDS concern on recent risk behavior, were statistically significant in all 20 sub-samples. For 3 paths, 2 of the 20 sub-samples produced statistically non-significant path coefficients; no city combination produced >1 statistically non-significant path coefficient (Data Table, Figure 4.3).

Assessment of Mediation

Direct effects of HAART-efficacy beliefs and reduced susceptibility concern on recent risk behavior (paths D E F) were statistically non-significant in an alternative model that included these paths (Data Table, Figure 4.4). The direct effect of mitigate susceptibility belief on reduced HIV/AIDS concern (path C) was statistically significant in the two alternative models that included this path (Data Table, Figure 4.4).

Although the fit of the original model + C was statistically significantly better than the fit of the original model, a meaningful improvement in the proportion of variance explained in recent risk behavior was not observed (original, 15.0% vs. original + C, 15.1%) (Data Table, Figure 4.4). Because (1) paths D, E, and F were statistically non-significant, (2) the original hybrid model predicted essentially the same amount of variance in recent risk behavior as original + C, and (3) because the fit of the original hybrid model was adequate, the original model was retained on grounds of increased parsimony.

Assessment of Directionality of Effects

Among MSM who perceived themselves at very low risk for HIV infection, the original hybrid model demonstrated adequate fit; the effect of reduced HIV/AIDS concern on recent risk behavior (path A) was statistically significant; the effect of lifetime risk behavior on reduced HIV/AIDS concern (path B) was nearly zero and statistically non-significant; and removing the effect of reduced HIV/AIDS concern on recent risk behavior (path A) resulted in a model that had statistically significantly poorer fit and a 9.5% (1/10.5) loss in explained variance of recent risk behavior (Data Table, Figure 4.4).

Among MSM who perceived themselves at some risk for infection, the original hybrid model demonstrated adequate fit; the effect of reduced HIV/AIDS concern on recent risk behavior (path A) was statistically significant; the effect of lifetime risk behavior on reduced HIV/AIDS concern (path B), although small, was statistically significant; and removing the effect of reduced HIV/AIDS concern on recent risk behavior (path A), resulted in a model that had statistically significantly poorer fit and a 17.1% (2.4/14.0) loss in explained variance of recent risk behavior (Data Table, Figure 4.4).

Final Hybrid Models

Based on the stratified analysis, the hypothesized directions of paths A and B were retained and the original hybrid model was considered final with the exception that path B is relevant only among MSM who perceive at least some risk for HIV. Among MSM who perceived themselves at very low risk for HIV, the model explained smaller proportions of variance of reduced susceptibility concern and recent risk behavior (Figures 4.5 and 4.6).

Relative Effects of HAART-efficacy Beliefs

Among MSM with very low risk perception, the HAART-efficacy beliefs had similar effects on reduced HIV/AIDS concern (total standardized effect of mitigate-susceptibility belief on reduced concern: $0.533*0.603 = 0.321$; total standardized effect of mitigate-HIV/AIDS belief on reduced concern: $(0.166*0.603) + 0.200 = 0.300$; total standardized effect ratio: $0.321 / 0.300 = 1.07$) (Figure 4.5).

Among MSM with some risk perception, the effect of mitigate-susceptibility belief on reduced concern was approximately 69% greater than that of mitigate-HIV/AIDS belief (total standardized effect of mitigate-susceptibility belief on reduced concern: $0.677*0.622 = 0.421$; total standardized effect of mitigate-HIV/AIDS belief on reduced concern: $(0.126*0.662) + 0.166 = 0.249$; total standardized effect ratio: $0.421/0.249 = 1.69$) (Figure 4.6).

Reduced HIV/AIDS Concern & HIV Infection

Moderate/strong endorsement of reduced HIV/AIDS concern because of HAART was statistically significantly associated with HIV infection in the entire sample, and in sub-samples stratified by perceived risk for infection and interval in time since last HIV-negative test result (Table 4.3). Notably, moderate/strong endorsement of reduced HIV/AIDS concern was associated with HIV infection presumably acquired in the past year (Table 4.3).

Discussion

In a venue-based, cross-sectional study conducted in six U.S. cities 2-4 years after HAART became available, we evaluated a theory-based, HAART-efficacy belief, HIV/AIDS complacency, and risk behavior model among young MSM who reported having never HIV

tested or having last tested HIV negative. Our model demonstrated adequate fit and stability over multiple geographic samples with different socio-demographic and risk-behavior distributions. Among both MSM who perceived themselves at very low and at some risk for HIV, our model (1) demonstrated that HIV/AIDS complacency, measured as reduced HIV/AIDS concern because of HAART, mediated the effects of beliefs that HAART reduces HIV/AIDS severity and personal HIV susceptibility; and (2) predicted statistically significant variance in risk behavior known to be associated with incident HIV infection among MSM.

Although the amount of variance of recent risk behavior explained by HAART-efficacy belief and complacency constructs was small in our sample of MSM, reduced HIV/AIDS concern had a moderately strong (OR=2.51) association with HIV infection. Notably, the magnitude of this association was similar among MSM who perceived themselves at very low and at some risk for HIV, and among MSM who had remotely and recently tested HIV negative.

We found, thus, consistent associations between HAART-related reduced HIV/AIDS concern and both recent risk behavior and presumably recent HIV infection. In concordance with the Health Belief Model and Protection Motivation Theory, our findings support the plausibility that HIV/AIDS complacency, shaped in part by beliefs that HAART reduces susceptibility to and severity of HIV/AIDS, increases HIV acquisition risk among young MSM.

HIV/AIDS Complacency, Risk Behavior, & HIV-acquisition Risk

Our findings are consistent with 11 of 13 studies that evaluated the association between similar HAART-related reduced HIV/AIDS concern constructs and risk behavior among MSM who had not previously tested HIV positive (Van de Ven, 1999; Vanable et al., 2000; Elford et al., 2000, 2002, 2003; Ostrow et al., 2002; Koblin et al, 2003; Williamson & Hart, 2004; Stolte et

al., 2004a; Huebner et al., 2004; Kalichman et al., 2007b). The two studies that did not find an association between these variables were either conducted in the year following the availability of HAART (Kalichman et al., 1998) or included only MSM ≤25 years of age, many of whom had not yet heard of HAART (Bakeman et al., 2007). Our findings are also consistent with the only study of its kind that found reduced HIV/AIDS concern was associated with incident STD/HIV infection among MSM in the Netherlands (van der Snoek et al., 2005).

Because HIV acquisition risk is dependent on having partners who are HIV infected, excluding partner-risk variables from behavioral measures reduces the validity of these measures in predicting HIV infection (Bingham et al., 2003; Harawa et al., 2004; Berry et al., 2007; Bingham et al., 2009). Thus, because of imperfect measurement, it is not surprising that our reduced HIV/AIDS concern measure had a moderately strong association with HIV infection even though it predicted a small proportion of variance in our recent risk index, which excluded partner risks. Future research on HAART-related HIV/AIDS complacency should consider incorporating partner-risk variables in indices used as behavioral outcomes.

Dual Role of HIV/AIDS Complacency

Our findings also suggest that among MSM who perceive themselves at some HIV risk, HAART-related HIV/AIDS complacency may act as both a consequent and determinant of risk behavior. This finding is not unexpected given considerable empirical support for contrasting HBM/PMT and CDT theories, and may thus help to explain the inconsistent findings on the presumed causal pathway between reduced HIV/AIDS concern and risk behavior (Elford et al., 2002, 2003; Williamson & Hart, and Hart, 2004; Huebner et al., 2004; Stolte et al., 2004a; van der Snoek et al., 2005).

We are not aware of any theoretical rationale that would preclude both HBM/PMT and CDT pathways from operating within individuals over time. While our findings suggest that a reciprocal relationship may exist between HIV/AIDS complacency and heightened risk behavior among MSM, we chose not to include reciprocal pathways in our model because (1) we had no basis on which to assume the reciprocal relationship has reached equilibrium, a necessary assumption with cross-sectional data (Kaplan et al., 2001; Kline, 2005), and (2) based on factors known to be associated with prevalent and incident HIV infection, we were able to construct two behavioral indices reflecting different time periods from which reasonable unidirectional paths could be evaluated.

Reduced HIV Susceptibility

Our findings suggest that the relative influence of HAART-efficacy beliefs on HIV/AIDS complacency depends on perceived risk for HIV. Among MSM who perceived themselves at very low risk for infection, the effect of reduced-susceptibility belief attenuated, and both beliefs had similar effects on reduced HIV/AIDS concern and, thus, on recent risk behavior. This attenuation is reasonable among MSM who perceive themselves at very low risk for HIV.

Our finding on the significant indirect effect of HAART-related reduced-susceptibility belief on risk behavior is supported by seven of 13 studies that found significant direct effects between similar reduced-susceptibility constructs and risk behavior (Kalichman et al., 1998, 2007a, 2007b; Van de Ven et al., 1999; Vanable et al., 2000; Huebner & Gerend, 2001; Halkitis et al., 2004). None of these studies assessed mediation via reduced HIV/AIDS concern, and thus it is unknown whether these observed direct effects would attenuate under mediation analyses.

Our model may also help to explain some of the inconsistent findings. Of the six remaining studies, four reported statistically significant univariate associations between risk behavior and similar reduced-susceptibility constructs, but statistically non-significant associations after adjustment for reduced HIV/AIDS concern (Ostrow et al., 2002; Elford et al., 2002, 2003; Williamson & Hart, 2004). Given our findings, it is reasonable to expect that the association between reduced-susceptibility belief (exposure) and risk behavior (outcome) will attenuate when evaluated in the presence of its mediator (reduced HIV/AIDS concern) (Szklo & Nieto, 2007, Bryan et al., 2007).

Reduced HIV/AIDS Severity

Our findings stand in contrast to all six studies that did not observe an association between the belief that HAART reduces HIV/AIDS severity and risk behavior (Kalichman et al., 1998, 2007b; Van de Ven et al., 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a). Two reasons might account for these contrasting findings. First, we found that the effect of reduced HIV/AIDS severity belief on recent risk behavior was strongly mediated by reduced HIV/AIDS concern. None of the six studies evaluated whether reduced HIV/AIDS severity belief was associated with reduced HIV/AIDS concern, and thus could not address its plausible indirect effect on risk behavior. The absence of a statistically significant direct effect between an exposure (reduced HIV/AIDS severity belief) and outcome (risk behavior), does not rule out important mediated effects from that exposure on that outcome (Bryan et al., 2007).

Second, our measurement items required subjects to appraise their personal likelihood of a quality life taking HAART, assuming they had acquired HIV. In contrast, all six studies assessed how subjects perceived HAART in curing or reducing the severity of HIV/AIDS in

other persons or without explicit regard to self (Kalichman et al., 1998, 2007b; Van de Ven et al., 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a). Thus, it is possible that our personalized items were able to measure a belief construct more salient to reduced personal concerns about HIV/AIDS and risk behavior.

Implications for Research and Prevention

Considering that our study was conducted of young MSM shortly after the availability of HAART, we were not surprised that many were unaware of HAART, and of those who were aware, only a minority endorsed HAART-efficacy belief and complacency constructs. These findings are consistent with the literature on HAART optimism, the large body of which was also conducted shortly after HAART became available. Thus, the population-attributable risk of HAART-related HIV/AIDS complacency on the incidence of risk behavior and HIV infection among young MSM was probably very low at the time of our study, as pointed out by Elford and colleagues (2004) of MSM in the Netherlands.

However, given that the efficacy of HAART has improved substantially since the time of our study (Bhaskaran et al., 2008; Antiretroviral Therapy Cohort Collaboration, 2008) and that estimated annual HIV incidence among MSM has continued to increase (Hall et al., 2008), our findings underscore the importance in evaluating the current prevalence of HAART-efficacy beliefs and HIV/AIDS complacency among MSM, and their effects on current HIV acquisition risks. It is plausible that beliefs and attitudes about the efficacy of HAART have increased since the time of our study, as suggested in two reports by Kalichman and colleagues (2007a, 2007b).

Our findings also suggest three recommendations for intervention research and prevention programs that target HAART-related HIV/AIDS complacency among MSM. First, new research

is needed to evaluate the appropriate content, delivery, and efficacy of messages designed to counter HAART-efficacy beliefs that are now recognized as true. At a minimum, these messages should underscore the fact that transmission from HIV-infected persons on HAART occurs (Attia et al., 2009; Sullivan et al., 2009b; Donnell et al., 2010), and that HIV/AIDS remains a severely disabling, costly, and fatal disease (Hutchinson et al., 2006a).

Second, among young MSM who perceive themselves at some risk for HIV, messages that counter beliefs that HAART reduces HIV susceptibility may be more effective at reducing HIV/AIDS complacency and risk behavior than messages that counter beliefs that HIV is no longer a serious health threat. Among young MSM who perceive themselves at very low risk, however, the effects of these messages may be equally effective at reducing HIV/AIDS complacency.

Third, our findings suggest that prevention programs that target HIV/AIDS complacency consider strategies that address both HBM/PMT and CDT causal pathways. HBM/PMT-based interventions designed to heighten uncertainty of risk and perceived vulnerability might reduce HIV/AIDS complacency and risk behavior among some MSM; however, these messages may also threaten self-image and induce defensiveness (Witte & Allen, 2000; Sherman et al., 2000). CDT-based interventions designed to preserve self-image and interventions that incorporate affective outcomes such as anticipated regret have been effective in reducing risk behaviors and should also be considered (Richard et al., 1996; Sherman et al., 2000; Sandberg & Conner, 2008).

Limitations

The findings in this report are subject to several important limitations. First, since our survey was restricted to 23-29 year-old men who attended MSM-identified venues in six cities,

our findings may not generalize to MSM who are younger or older, who reside in other cities, and who do not attend MSM-identified venues. Second, because YMS was cross-sectional, the directionality of causal pathways could not be directly assessed and can only be inferred from reasonable evidence. Thus, we describe our final models and posited causal pathways as "plausible." Third, our risk-behavior indices are not presumed to be 100% reliable and valid as assumed by SEM, and thus our path coefficients are subject to bias of unknown direction and magnitude. Fourth, only two items were retained to measure reduced HIV susceptibility concern. Thus, adequate measurement of this construct is questionable and additional items should be developed and validated for this construct. Finally, YMS was not designed to evaluate any one particular behavioral theory and did not assess other potentially important determinants of risk. Additional research is needed to evaluate whether our model might explain meaningful variance in risk behavior and HIV-acquisition risk when evaluated in the presence of other theoretically important determinants of risk.

Conclusion

Despite these limitations, our consistent findings in multiple geographic samples in accord with considerable theoretical and empirical expectations, suggest that only a few years after the widespread availability of HAART, young MSM who held stronger HAART-related efficacy beliefs and complacency constructs were more likely to engage in risk behavior and acquire HIV. Whether HAART-related HIV/AIDS complacency and risk behavior have a reciprocal relationship remains to be clarified. We hope that our plausible model might spur new research to clarify this relationship and discern effects on current HIV acquisition risks among MSM, and thus help to inform prevention programs designed to reduce those risks.

Table 4.1. Distribution of scores on construct items and risk-behavior indices of 1,593 23-29 year-old MSM who were aware of HAART and who had never HIV tested or last tested HIV-negative, six U.S. cities, 1998-2000.[a]

Construct Items & Indices	Mean (SD)	Range of Means[b]	Skew	Kurtosis
HAART Mitigates HIV/AIDS Belief				
1. If I became infected with HIV today, I probably wouldn't get AIDS given the combination drug treatments that are available.	2.36 (1.16)	2.17-2.58	0.46	-0.76
2. If I got infected with HIV today I could live a long and healthy life by taking the combination drug treatments that are available.	3.22 (1.12)	3.07-3.33	-0.47	-0.64
3. HIV is now a manageable disease much like diabetes.	2.36 (1.26)	2.14-2.58	0.56	-0.85
4. If I became HIV infected today, the combination drug treatments would prevent me from getting AIDS for many years.	2.81 (1.20)	2.71-2.92	-0.04	-1.13
HAART Mitigates HIV Susceptibility Belief				
5. I would be less likely to get infected by an HIV positive partner with undetectable virus than a HIV positive partner with detectable virus.	1.92 (1.17)	1.86-1.97	1.01	-0.22
6. If I were having anal sex with an HIV-positive man and his condom broke, it would be less risky for me if he had no detectable virus.	1.88 (1.15)	1.74-2.05	1.07	-0.08
7. If my partner had a low viral load it would be less risky for me to have receptive anal sex with him than if he had a high viral load.	1.74 (1.07)	1.64-1.85	1.32	0.58
Reduced Susceptibility Concern				
8. If I had an HIV positive sex partner who was taking the new combination drug treatments for HIV, I would be less worried about getting infected by him	1.66 (1.04)	1.57-1.73	1.59	1.63
9. If I had an HIV positive sex partner who had a low viral load, I would be less worried about getting infected by him.	1.46 (0.87)	1.38-1.57	2.13	4.16
10. If my partner had a high viral load I would worry about having sex with him (reverse coded).	1.85 (1.29)	1.71-2.12	1.39	0.65
Reduced HIV/AIDS Concern				
11. Because of the combination drugs available for HIV, I am less concerned about becoming infected.	1.54 (0.93)	1.38-1.75	1.81	2.58
12. Because of the combination drugs available for HIV, I'm not as concerned about slipping and having unsafe sex.	1.44 (0.82)	1.32-1.63	2.14	4.34
13. With the good news about combination drugs for HIV, I worry less about having sex with partners that might be HIV-positive.	1.57 (0.93)	1.42-1.72	1.65	1.92
14. I'm not as concerned about HIV infection now that there are combination drugs available for HIV.	1.55 (0.97)	1.38-1.77	1.84	2.54
Risk Behavior Indices				
Lifetime	7.88 (1.94)	7.56-8.23	-1.05	2.58
Recent	3.17 (2.00)	2.88-3.38	0.99	0.21

[a]Possible value range: items, 1-strongly disagree, 5-strongly agree; indices: lifetime risk, 1-12; recent risk, 1-10.
[b]Of the six cities: Baltimore, MD; Dallas, TX; Los Angeles, CA; Miami, FL; New York, NY; and Seattle, WA.

Table 4.2. Recruitment, demographic, and risk characteristics of 1,593 23-29 year-old MSM who were aware of HAART and who had never HIV tested or last tested HIV-negative, six U.S. cities, 1998-2000.

Characteristic	Baltimore	Dallas	Los Angeles	Miami	New York	Seattle	All
Recruitment							
Venues #	19	26	40	32	38	26	181
Participation rate %[a]	58	60	55	58	59	54	58
Enrolled & analyzed #	279	248	248	236	233	349	1593
Age %[b]							
23-25	49.8	45.6	41.5	44.9	48.5	41.0	45.0
26-29	50.2	54.4	58.5	55.1	51.5	59.0	55.0
Race/Ethnicity %[b]							
Asian	3.9	1.6	10.5	2.1	10.3	8.6	6.3
Black	20.1	13.3	10.1	5.5	27.9	2.9	12.7
Hispanic	5.0	19.8	15.3	47.9	25.3	5.4	18.3
White	67.0	63.7	60.5	40.3	31.3	79.9	59.1
Mixed/Other	3.9	1.6	3.6	4.2	5.2	3.2	3.6
Education %[b]							
Some college or tech. school	84.2	82.7	84.7	86.0	88.0	88.2	85.7
Employment %[b]							
Part or full time	89.6	96.0	79.4	84.3	83.3	88.8	87.1
Last HIV-test result %[b]							
Never previously tested	9.3	7.7	8.1	6.8	9.9	9.7	8.7
Negative	90.7	92.3	91.9	93.2	90.1	90.3	91.3
Negative, <1 yr ago	57.0	59.3	59.7	59.7	54.1	62.8	59.0
Lifetime risks %[b,c]							
≥20 male sex partners	45.9	59.7	64.5	62.7	53.7	54.2	56.4
Engaged in anal sex	94.3	97.6	95.2	98.7	96.1	94.6	95.9
Diagnosed with an STD	23.7	29.0	27.8	28.4	30.0	27.5	27.6
Injected drugs	6.1	6.5	9.7	12.7	6.0	5.4	7.5
Recent risks %[b,d]							
≥10 male sex partners	12.2	16.1	21.0	19.9	18.0	15.8	17.0
UAI with HIV+/unk status male	20.1	29.0	28.2	17.0	28.8	20.9	23.7
Daily alcohol use	7.5	4.8	3.2	3.4	6.4	4.6	5.0
Methamphetamine use	6.8	12.9	19.8	22.9	6.9	18.6	14.8
Under influence of drugs/alcohol during sex	67.4	67.3	62.9	71.6	63.5	71.9	67.7
Perceived risk for having HIV %[b,e]							
Very unlikely	44.8	35.9	38.7	41.1	39.1	50.7	42.4
HIV-infected %[b,f]	10.0	13.1	4.5	6.8	12.2	1.7	7.6

[a]Of men identified as eligible.
[b]Of records analyzed.
[c]Since sexual debut.
[d]In the prior six months.
[e]Measure: "How likely is it that you are HIV-positive today?"
[f]Tested at the time of interview.
Note: UAI=unprotected anal intercourse; STD=sexually transmitted disease; unk status=unknown HIV status.

Table 4.3. Association between HIV infection and moderate/strong endorsement of reduced HIV/AIDS concern because of HAART of 1,575 23-29 year-old MSM, overall and stratified by perceived risk for HIV infection and interval since last negative HIV test result, six U.S. cities, 1998-2000.[a]

Strength of Endorsement	Total	HIV-positive n (%)	OR (95% CI)	AOR[b] (95% CI)
Total	1575	120 (7.6)	---	---
Reduced HIV/AIDS concern				
Weak	1302	81 (6.2)	---	---
Moderate/strong	273	39 (14.3)	2.51 (1.67-3.77)	---
Very low perceived HIV risk (n=668)				
Reduced HIV/AIDS concern				
Weak	579	16 (2.8)	Reference	---
Moderate/strong	89	8 (9.0)	3.48 (1.44-8.38)	---
Some perceived HIV risk (n=907)				
Reduced HIV/AIDS concern				
Weak	723	65 (9.0)	Reference	---
Moderate/strong	184	31 (16.8)	2.05 (1.29-3.26)	2.27 (1.50-3.41)
Never tested/tested HIV-neg $\geq$1 yr ago (n=644)				
Reduced HIV/AIDS concern				
Weak	533	44 (8.3)	Reference	---
Moderate/strong	111	21 (18.9)	2.59 (1.47-4.57)	---
Tested HIV-neg <1 yr ago (n=931)				
Reduced HIV/AIDS concern				
Weak	769	37 (4.8)	Reference	---
Moderate/strong	162	18 (11.1)	2.47 (1.37-4.47)	2.54 (1.68-3.82)

[a]HIV tests were not conducted on 18 participants.

[b]Mantel-Haenszel odds ratio adjusted for stratification variable; all Breslow-Day χ^2 tests for homogeneity of odds ratios were statistically non-significant.

Note: OR=odds ratio; CI=confidence interval; weak endorsement of reduced HIV/AIDS concern was defined as a composite score of 4-8, and moderate/strong was defined as a composite score $\geq$9, on items 11-14 (Table 4.1); very low perceived HIV risk was defined as responding "very unlikely," and some perceived risk was defined as responding "unlikely," "somewhat likely," "likely," "very likely," or "HIV-positive" when asked "how likely is it that you are HIV-positive today?"

Figure 4.1. Plausible causal model of HAART-efficacy beliefs, HIV/AIDS complacency, and HIV risk behavior.

HAART
Mitigates
HIV/AIDS

Lifetime Risk
Behavior

Reduced
Susceptibility
Concern

B

Reduced
HIV/AIDS
Concern

HAART
Mitigates HIV
Susceptibility

A

Recent Risk
Behavior

Belief Constructs

Complacency Constructs

Risk Indices
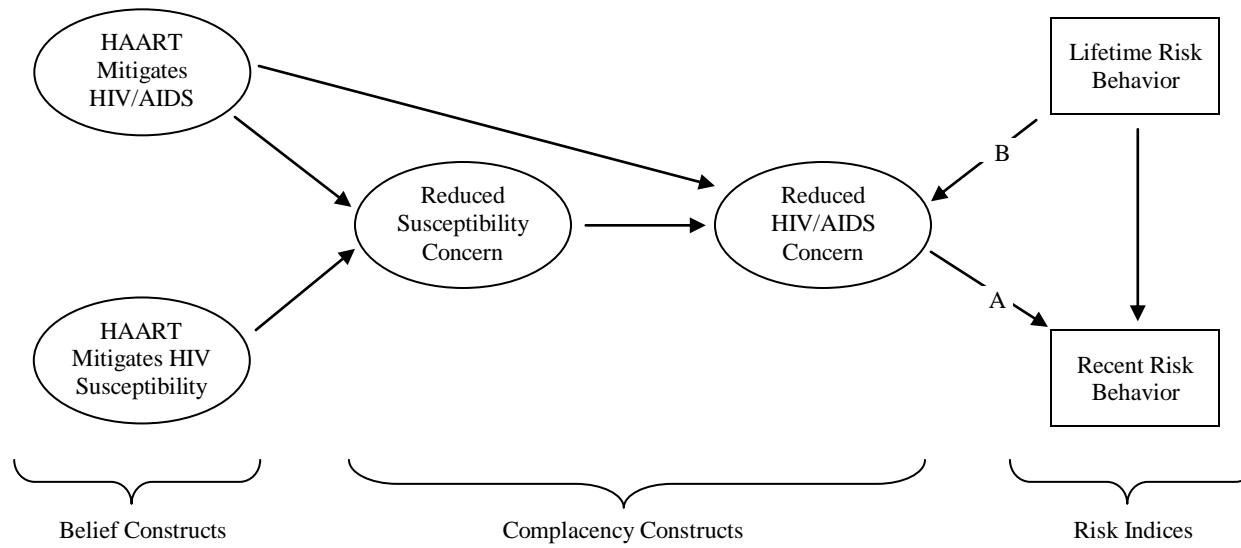
Figure 4.2. Final measurement model; latent constructs in circles, measured variables in rectangles, 1-headed arrows from constructs are standardized factor loadings, 2-headed arrows between constructs are correlations, error (E) parameters are unexplained variance.[a]

Model Fit
χ^2=290.2; n=1593; df=59; p<0.001
RMR, 0.043; RMSEA, 0.050 (0.044-0.055)
NNFI, 0.951; IFI, 0.963; CFI, 0.963
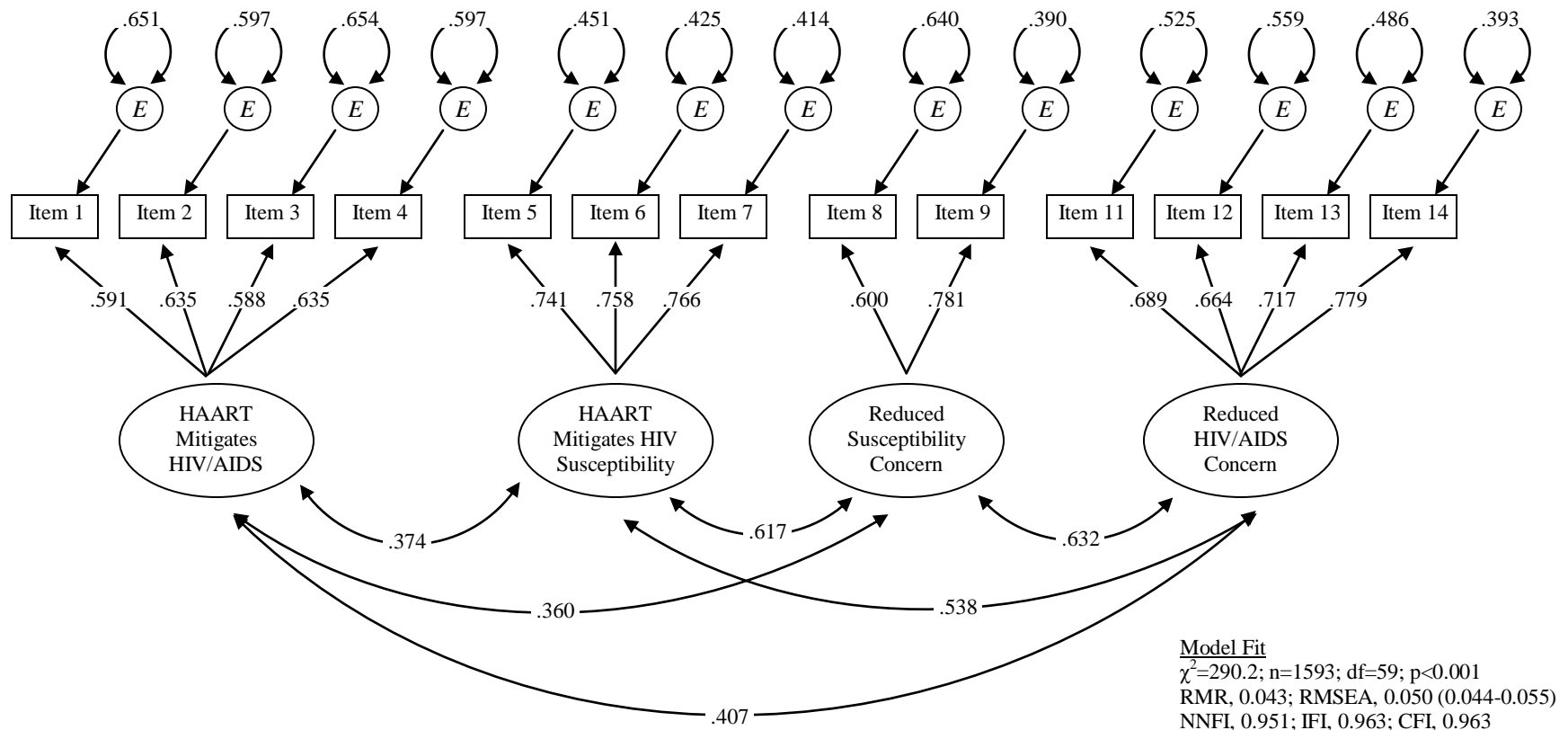
Parameter	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 11	Item 12	Item 13	Item 14
Unstd. loading[b]	0.6873	0.7090	0.7379	0.7642	0.8628	0.8708	0.8221	0.6260	0.6794	0.6379	0.5478	0.6665	0.7580
Standard error	0.0318	0.0304	0.0344	0.0328	0.0277	0.0272	0.0254	0.0286	0.0251	0.0222	0.0200	0.0221	0.0225
T-test value	21.6	23.3	21.5	23.3	31.1	32.0	32.4	21.9	27.0	28.7	27.4	30.2	33.7
Variance explained	34.9%	40.3%	34.6%	40.3%	54.9%	57.5%	58.6%	36.0%	61.0%	47.5%	44.1%	51.4%	60.7%

[a]In this model, standardized factor loadings are interpreted as correlations between the factor and the item; unstandardized factor loadings are interpreted as regression coefficients that estimate the direct effects of the factor on the item.
[a]Unstandardized factor loading.

Figure 4.3. Original hybrid model; latent constructs in circles, measured variables in rectangles, 1-headed arrows from constructs and variables are standardized path values, disturbance (D) and error (E) parameters are unexplained variance.[a]

HAART Mitigates HIV/AIDS

HAART Mitigates HIV Susceptibility

Reduced Susceptibility Concern

Reduced HIV/AIDS Concern

Lifetime Risk Index

Recent Risk Index

.178 .140 .611 .607 .092 .333 .159 .850 .541 .503

D D E
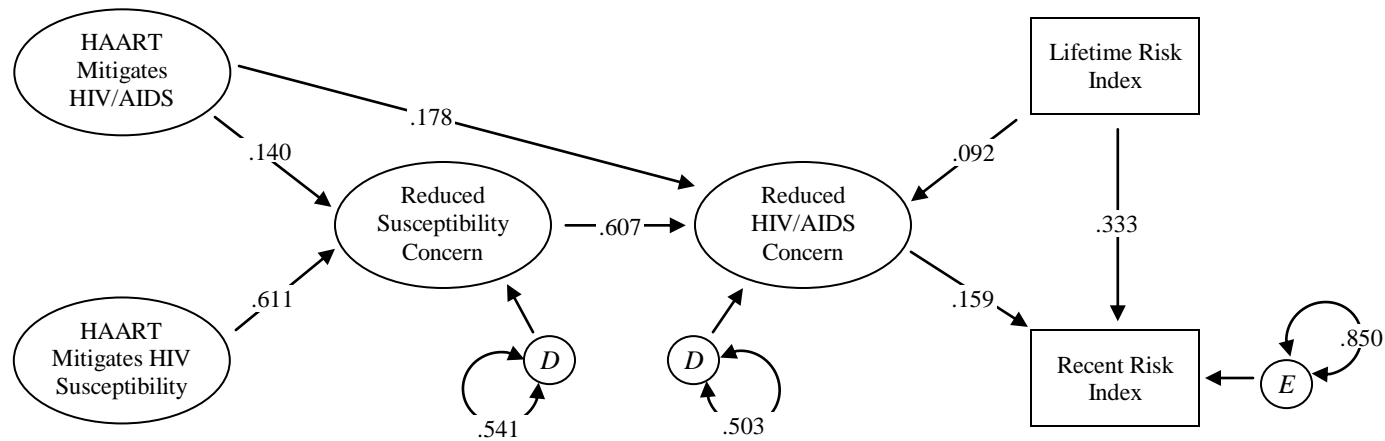
Model Fit
χ^2=338.7; n=1593; df=82; p<0.001
RMR, 0.043; RMSEA, 0.044 (0.040-0.049)
NNFI, 0.949; IFI, 0.960; CFI, 0.960

Direct Effects	Unstandardized Path Value[a] All Cities	(range)[b]	Std. Error All Cities	T-test Value All Cities	(range)[b]	Variance Explained All Cities	(range)[b]
Mitigates HIV/AIDS → Reduced Susceptibility Concern	0.1287	(0.0863–0.1722)	0.0338	3.81	(1.70–3.81)[c]	--	
Mitigates Susceptibility → Reduced Susceptibility Concern	0.4868	(0.4070–0.5516)	0.0306	15.92	(9.03–13.36)[d]	--	
Reduced Susceptibility Concern	--		--	--		45.9%	(38.8–54.4%)
Mitigates HIV/AIDS → Reduced HIV/AIDS Concern	0.1903	(0.0794–0.3054)	0.0369	5.15	(1.47–5.60)[c]	--	
Reduced Susceptibility Concern → Reduced HIV/AIDS Concern	0.7068	(0.5219–0.9334)	0.0480	14.73	(8.87–11.76)[d]	--	
Lifetime Risk Index → Reduced HIV/AIDS Concern	0.0361	(0.0218–0.0499)	0.0092	3.92	(1.61–3.72)[c]	--	
Reduced HIV/AIDS Concern	--		--	--		49.7%	(40.1–62.0%)
Lifetime Risk Index → Recent Risk Index	0.3441	(0.3178–0.3762)	0.0242	14.22	(9.20–10.84)[d]	--	
Reduced HIV/AIDS Concern → Recent Risk Index	0.4192	(0.2706–0.6092)	0.0684	6.13	(2.74–5.95)[d]	--	
Recent Risk Index	--		--	--		15.0%	(11.8–18.4%)

[a]Standardized and unstandardized path values are interpreted as standardized and unstandardized multiple regression coefficients, respectively.
[b]Of 20 possible combinations of samples from 3 YMS cities; range of 3-city sample sizes: 717-876.
[c]Statistically significant in all but 2 combinations; no city combination yielded >1 non-significant path value.
[d]Statistically significant (P<0.05) in all 20 combinations of samples.

Figure 4.4. Fit indices and parameter estimates for direct causal paths (C, D, E, F) of alternative hybrid models, and paths A and B of the original hybrid model restricted to MSM with very low and some perceived HIV risk.

HAART Mitigates HIV/AIDS

Lifetime Risk Index

Reduced Susceptibility Concern

Reduced HIV/AIDS Concern

B

HAART Mitigates HIV Susceptibility

C

E

F

A

D

Recent Risk Index

Models	Unstandardized Path Value	Standard Error	Path T-test Value	Var. Expl.[a] Recent Risk	χ^2	RMR	RMSEA (90%CI)	NNFI	IFI	CFI	χ^2 Difference Test
Original	--	--	--	15.0%	338.7; df, 82	0.043	0.044 (0.040-0.049)	0.949	0.960	0.960	Reference
Original + C D E F	--	--	--	15.7%	313.8; df, 78	0.041	0.044 (0.039-0.049)	0.951	0.964	0.964	24.9; df 4; *P*<0.01
Paths C D	C 0.187; D -0.011	C 0.039; D 0.096	C 4.8; D -0.1	--	--	--	--	--	--	--	--
Paths E F	E -0.239; F 0.037	E 0.142; F 0.091	E -1.7; F 0.4	--	--	--	--	--	--	--	--
Original + C	C 0.187	C 0.039	C 4.8	15.1%	317.9; df, 81	0.042	0.043 (0.038-0.048)	0.952	0.963	0.963	20.8; df 1; *P*<0.01
Very low perceived HIV risk (n=675)											
Original	A 0.240; B 0.004	A 0.095; B 0.012	A 2.5; B 0.4	10.5%	176.1; df, 82	0.045	0.041 (0.033-0.050)	0.956	0.966	0.965	Reference
Original − A	B 0.004	B 0.012	B 0.4	9.5%	182.5; df, 83	0.054	0.042 (0.034-0.051)	0.954	0.964	0.964	6.4; df 1; *P*<0.05
Some perceived HIV risk (n=918)											
Original	A 0.424; B 0.051	A 0.092; B 0.014	A 4.6; B 3.6	14.0%	260.3; df, 82	0.048	0.049 (0.042-0.055)	0.938	0.952	0.951	Reference
Original − A	B 0.051	B 0.014	B 3.6	11.6%	281.6; df, 83	0.070	0.051 (0.045-0.058)	0.931	0.946	0.946	21.3; df 1; *P*<0.01

[a]Variance explained

Note: unstandardized path values are interpreted as unstandardized multiple regression coefficients.

Figure 4.5. Final hybrid model restricted to 675 MSM with very low perceived HIV risk; latent constructs in circles, measured variables in rectangles, 1-headed arrows from constructs and variables are standardized path values, disturbance (D) and error (E) parameters are unexplained variance.[a]

HAART Mitigates HIV/AIDS

Lifetime Risk Index

.200

.166

Reduced Susceptibility Concern

Reduced HIV/AIDS Concern

.603

.305

.533

HAART Mitigates HIV Susceptibility

.102

D

.895

D

Recent Risk Index

E

.618

.506
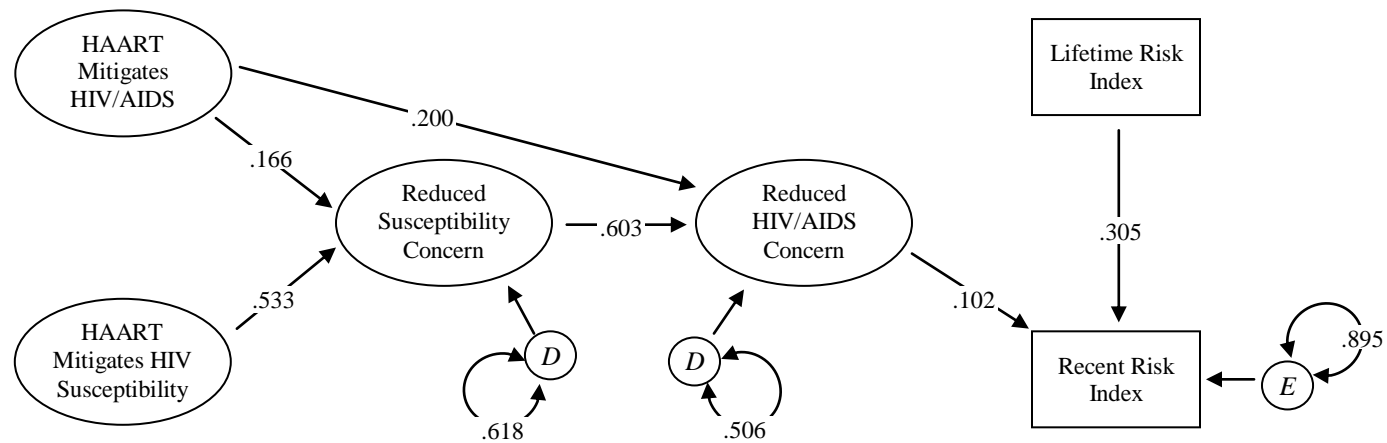
Model Fit
χ^2=176.2; n=675; df=83; p<0.001
RMR, 0.045; RMSEA, 0.041 (0.032-0.049)
NNFI, 0.957; IFI, 0.966; CFI, 0.966

Direct Effects	Unstandardized Path Value[a]	Standard Error	T-test Value[b]	Variance Explained
Mitigates HIV/AIDS → Reduced Susceptibility Concern	0.1543	0.0515	3.00	--
Mitigates Susceptibility → Reduced Susceptibility Concern	0.4096	0.0433	9.47	--
Reduced Susceptibility Concern	--	--	--	38.2%
Mitigates HIV/AIDS → Reduced HIV/AIDS Concern	0.1899	0.0492	3.86	--
Reduced Susceptibility Concern → Reduced HIV/AIDS Concern	0.6141	0.0634	9.69	--
Reduced HIV/AIDS Concern	--	--	--	49.4%
Lifetime Risk Index → Recent Risk Index	0.2351	0.0281	8.35	--
Reduced HIV/AIDS Concern → Recent Risk Index	0.2401	0.0953	2.52	--
Recent Risk Index	--	--	--	10.5%

[a]Standardized and unstandardized path values are interpreted as standardized and unstandardized multiple regression coefficients, respectively.
[b]All values statistically significant ($P<0.05$).

Figure 4.6. Final hybrid model restricted to 918 MSM with some perceived HIV risk; latent constructs in circles, measured variables in rectangles, 1-headed arrows from constructs and variables are standardized path values, disturbance (D) and error (E) parameters are unexplained variance.[a]
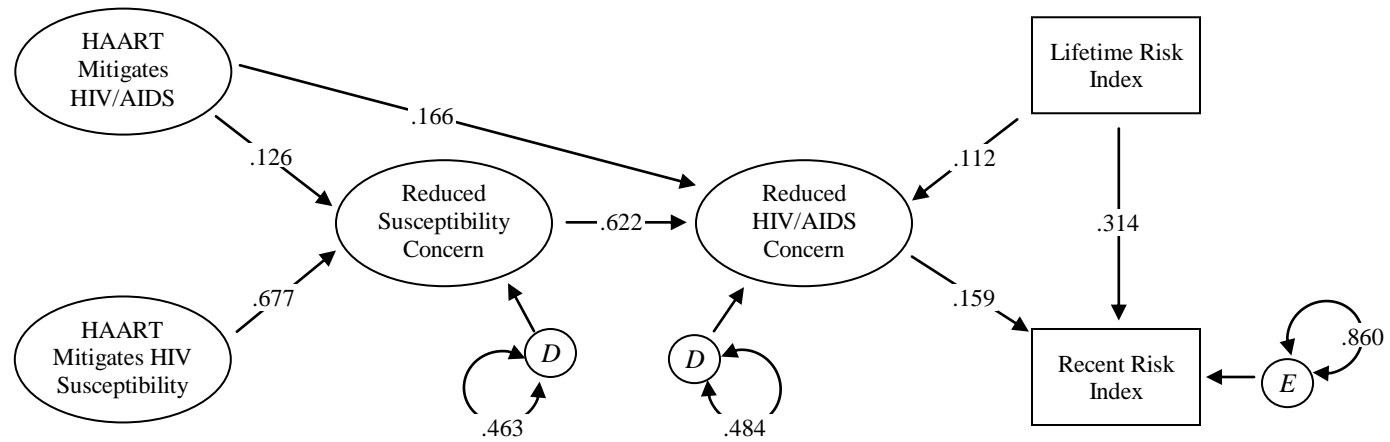
Model Fit
χ^2=260.3; n=918; df=82; p<0.001
RMR, 0.048; RMSEA, 0.049 (0.042-0.055)
NNFI, 0.938; IFI, 0.952; CFI, 0.951

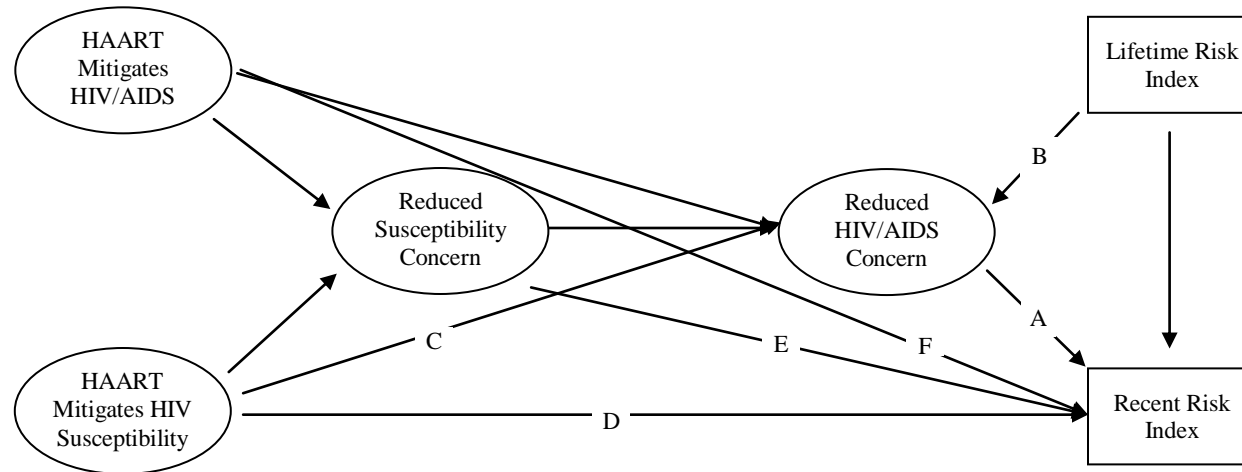| Direct Effects	Unstandardized Path Value[a]	Standard Error	T-test Value[b]	Variance Explained
Mitigates HIV/AIDS → Reduced Susceptibility Concern	0.1134	0.0444	2.56	--
Mitigates Susceptibility → Reduced Susceptibility Concern	0.5501	0.0428	12.85	--
Reduced Susceptibility Concern	--	--	--	53.7%
Mitigates HIV/AIDS → Reduced HIV/AIDS Concern	0.1877	0.0526	3.57	--
Reduced Susceptibility Concern → Reduced HIV/AIDS Concern	0.7836	0.0692	11.33	--
Lifetime Risk Index → Reduced HIV/AIDS Concern	0.0509	0.0140	3.64	--
Reduced HIV/AIDS Concern	--	--	--	51.6%
Lifetime Risk Index → Recent Risk Index	0.3797	0.0378	10.03	--
Reduced HIV/AIDS Concern → Recent Risk Index	0.4240	0.0920	4.61	--
Recent Risk Index	--	--	--	14.0%

[a]Standardized and unstandardized path values are interpreted as standardized and unstandardized multiple regression coefficients, respectively.
[b]All values statistically significant ($P<0.05$).

CHAPTER 5

HIV/AIDS COMPLACENCY AND HIV INFECTION AMONG YOUNG MEN WHO HAVE

SEX WITH MEN, AND THE RACE-SPECIFIC INFLUENCE OF

UNDERLYING HAART BELIEFS [1]

Abstract

Background: Among men who have sex with men (MSM) in the U.S., the influence of HIV/AIDS complacency and beliefs about the efficacy of highly active antiretroviral therapy (HAART) on HIV-infection risk is unknown.

Methods: We analyzed data from a 1998-2000 cross-sectional six-city survey of 1,575 MSM aged 23-29 years who had not previously tested HIV positive to assess these plausible influences overall and by race/ethnicity.

Findings: Measured as strong endorsement for reduced HIV/AIDS concern due to HAART, HIV/AIDS complacency was associated with reporting ≥10 male sex partners [odds ratio (OR), 2.94; 95% confidence interval (CI), 2.12-4.07], unprotected anal intercourse (OR, 2.06; 95%CI, 1.51-2.81), and HIV infection (adjusted OR, 2.35; 95%CI, 1.38-3.98). Strong endorsement of the belief that HAART mitigates HIV/AIDS severity was more prevalent among black (21.8%) and Hispanic (21.3%) than white (9.6%) MSM (p<0.001), and was more strongly associated with HIV infection among black (AOR, 4.65; 95% CI, 1.97-10.99) and Hispanic (AOR, 4.12; 95% CI, 1.58-10.70) than white (AOR, 1.62; 95% CI, 0.64-4.11) MSM.

Conclusions: Young MSM who are complacent about HIV/AIDS because of HAART are more likely to engage in risk behavior and acquire HIV. Programs that target HIV/AIDS complacency among MSM as a means to reduce HIV incidence should consider potential race-specific effects of underlying HAART beliefs.

Introduction

The influence of beliefs and attitudes about highly active antiretroviral therapy (HAART) on HIV risk behavior among men who have sex with men (MSM) has been the subject of considerable research since the late 1990s (Dilley et al. 1997; Remien et al., 1998; Kalichman et al., 1998, 2007a, 2007b; Kelly et al., 1998; Van de Ven et al., 1999, 2000; Elford et al., 2000, 2002, 2003; Vanable et al., 2000; Huebner & Gerend, 2001; Ostrow et al., 2002; International Collaboration on HIV optimism, 2003; Koblin et al., 2003; Williamson & Hart, 2004; Halkitis et al., 2004; Huebner et al., 2004; Stolte et al., 2004a; van der Snoek et al., 2005; Sullivan et al., 2007; Bakeman et al., 2007). From this body of research, nearly all studies that evaluated HIV/AIDS complacency, measured as reduced HIV/AIDS concern because of HAART, found that it is associated with increased risk behavior among MSM who had not previously tested HIV positive (acquisition behavior) 1990s (Van de Ven et al., 1999; Elford et al., 2000, 2002, 2003; Vanable et al., 2000; Ostrow et al., 2002; Koblin et al., 2003; Williamson & Hart, 2004; Huebner et al., 2004; Stolte et al., 2004a; Kalichman et al., 2007b). Despite these consistent findings, however, three important gaps in understanding remain.

Foremost among these gaps, the influence of HIV/AIDS complacency and plausible underlying HAART-efficacy beliefs on HIV-infection risk has not been reported and is unknown among MSM in the United States. Moreover, although three reports suggest that MSM of black or Hispanic race/ethnicity are more likely than white MSM to endorse optimistic HAART beliefs, the importance of these beliefs in explaining considerable racial disparities in HIV-infection risk is unknown (Kalichman et al., 2007a; Sullivan et al., 2007; Koblin et al., 2003). Evaluating plausible effects on HIV infection, rather than risk behavior, is critical because risk behaviors are often inadequate proxies for sexually transmitted infections including HIV,

particularly among MSM (Peterman et al., 2000; Bingham et al., 2003; Harawa et al., 2004; Millett et al., 2007).

Second, the literature is unclear on the causal mechanism that might explain observed behavioral associations. Longitudinal studies in The Netherlands found that MSM who were less concerned about HIV/AIDS because of HAART were more likely to subsequently engage in acquisition behavior (Stolte et al., 2004a; van der Snoek et al., 2005). The causal path from reduced concern to heightened risk behavior is central to several theories including the health-belief model (HBM) and protection-motivation theory (PMT). Under HBM/PMT, persons who endorse stronger beliefs about reduced susceptibility to or severity of a disease will be less concerned about that disease and are thus less motivated to engage in behaviors that protect against it (Becker, 1974; Prentice-Dunn & Rogers, 1986).

In contrast, reports from serial cross-sectional studies in England (Elford et al., 2002, 2003 and Scotland (Williamson & Hart, 2004), and a longitudinal study in the United States (Huebner et al., 2004) suggest that reduced HIV/AIDS concern because of HAART is a consequence of acquisition behavior. The causal path from acquisition behavior to reduced concern is central to cognitive dissonance (CDT) and similar theories. Under CDT, persons who recognize that their behavior is inconsistent with internalized beliefs or attitudes will modify those beliefs or attitudes to avoid the stress or other negative emotions caused by that dissonance (Aronson, 1969).

Finally, the literature is unclear on the importance of specific beliefs that presumably underlie HAART-related HIV/AIDS complacency. For example, of 13 studies that evaluated the belief that HAART mitigates HIV susceptibility, six found that this belief was not independently associated with acquisition behavior (Elford et al., 2000, 2002, 2003; Ostrow et al., 2002; Koblin

et al., 2003; Williamson & Hart, 2004). Moreover, of six studies that evaluated the belief that HAART mitigates HIV/AIDS severity, none found that this belief was associated with acquisition behavior, contrary to HBM/PMT expectations (Kalichman et all, 1998, 2007b; Van de Ven, 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a).

Understanding whether HIV/AIDS complacency is associated with both acquisition behavior and HIV infection, the directionality of observed associations, and potential race-specific effects of underlying HAART-efficacy beliefs is important for informing new programs that target HIV/AIDS complacency as a means to reduce the considerable incidence of HIV among MSM, particularly those who are black (CDC, 2009c).

To help address these needs, this report uses data from the second phase of CDC's Young Men's Survey (YMS) to evaluate whether HIV/AIDS complacency among young MSM plausibly increases risk for HIV infection expected under HBM/PMT, and whether two underlying HAART-efficacy beliefs have similar effects on observed infection risks among MSM who are black, Hispanic, and white.

Methods

YMS methods have been described previously (MacKellar et al., 1996). In summary, the second phase of YMS was conducted from 1998 through 2000 of men who attended MSM-identified venues (e.g., bars, dance clubs, parks, street locations in retail areas, etc.) in Baltimore, Maryland; Dallas, Texas; Los Angeles, California; Miami, Florida; New York, New York; and Seattle, Washington. Formative research was conducted to construct monthly sampling frames of the days, times, and venues attended by young MSM. From these sampling frames, 12 or more venues and their associated day/time periods were selected randomly and scheduled as

recruitment events each month. During recruitment events, men were approached consecutively to assess their eligibility. Men aged 23 to 29 years who resided in a locally defined area and who had not previously participated in the second phase of YMS were eligible and encouraged to participate. Participants had blood drawn for HIV testing, and were interviewed using a standard questionnaire, provided counseling and referral for care, and reimbursed $50 for their time. Specimens were tested at local laboratories with FDA-approved assays. The YMS protocol was approved by institutional review boards at CDC, and at state and local institutions that conducted the survey.

Measures

One standard questionnaire was used in all cities to measure socio-demographic characteristics, sexual behaviors, perceived risk for HIV infection, and HAART-efficacy belief and HIV/AIDS complacency constructs. Sexual risk behaviors were assessed since sexual debut (lifetime) and in the six months preceding the survey interview (recent). Perceived risk for infection was measured with the following item: "Using this card, choose a number that best describes how likely it is that you are HIV positive today." The card included 6 possible responses (1, very unlikely; 2, unlikely; 3, somewhat likely; 4, likely; 5, very likely; 6, HIV positive). For multivariate analyses, response values 1-2 were combined into one category labeled "low" and values 3-6 were combined into one category labeled "moderate-high." Responses were dichotomized into these categories because of observed homogeneity of HIV-infection rates in response categories 1 and 2, and because very few MSM reported values ≥ 4.

Based in part from previous research, 11 items were used to measure the following three constructs: belief that HAART mitigates HIV/AIDS severity, belief that HAART mitigates HIV

susceptibility, and reduced HIV/AIDS concern because of HAART (Table 5.1) (Vanable et al., 2000; Ostrow et al., 2002). The 11 items were administered in a separate section of the questionnaire on knowledge and beliefs about HAART, which was defined as the "new combination-drug treatments for HIV and AIDS that include protease inhibitors." Responses were measured on a 5-point scale ranging from (1) strongly disagree to (5) strongly agree. The 11 items were only administered to participants who reported being aware of HAART and having never tested for HIV or having last tested HIV negative.

Confirmatory factor analysis (CFA) and Cronbach's coefficient alpha were used to assess the validity and reliability of the three posited constructs. For CFA, all items were constrained to load on only hypothesized constructs (factors), error variances were not allowed to correlate, and all factors were free to correlate (Kline, 2005). Based on a sample size of 1,575 MSM, the three-factor model demonstrated adequate fit [root mean square residual, 0.045; root mean square error of approximation, 0.054 (90% confidence interval, 0.047- 0.060); comparative fit index, 0.964]; all factor loadings were statistically significant with t-values ≥ 21.4; and HAART belief and complacency constructs explained 34.6% to 61.1% of observed variance of respective items. Cronbach's coefficient alpha was 0.704 for the belief that HAART mitigates HIV/AIDS severity (items 1-4), 0.799 for the belief that HAART mitigates HIV susceptibility (items 5-7), and 0.804 for reduced HIV/AIDS concern because of HAART (items 8-11) (Table 5.1).

To evaluate associations with risk behavior and HIV infection, responses to items corresponding to each construct were summed into a composite score. For each construct, composite scores were dichotomized into two endorsement levels labeled "weak-moderate" and "strong." Strong endorsement represented approximately the 10th decile of the composite-score

response distribution for each construct. Composite scores were dichotomized to facilitate interpretation, and because behavioral and infection outcomes were similar within each category.

Univariate and Bivariate Analyses

All data analyses were conducted using SAS version 9.1 (SAS Institute Inc., Cary, NC). The univariate distributions of recruitment outcomes, socio-demographic characteristics, and sexual behaviors were first evaluated overall and by survey city. Next, we evaluated bivariate associations between strong endorsement of each of the three HAART constructs and age group, race/ethnicity, HIV infection, and the following two recent risk behaviors: reporting ≥10 male oral or anal sex partners and engaging in UAI with HIV-positive or unknown-status male partners. These behavioral outcomes were chosen because they had the highest adjusted hazards for incident HIV infection in a large contemporary cohort of MSM (Koblin et al., 2006). Odds ratios (OR) and 95% confidence intervals (CI) are reported for statistically significant associations with demographic variables, and for behavioral and HIV-infection outcomes regardless of statistical significance.

Associations with behavioral outcomes are reported for the entire sample and among MSM who perceived they were "very unlikely" to be HIV infected. Analyses were restricted to this lowest risk-perception group to assess evidence of the plausible direction of observed associations. If CDT alone explains the associations, risk behaviors should *not* be associated with the three HAART constructs among MSM who perceive themselves at very low risk because the only driver of the associations (i.e., cognitive dissonance) should be very weak in this group (Aronson, 1969; Huebner & Gerend, 2001; Huebner et al., 2004). In contrast, if HBM/PMT operates at least in part, associations should be observed within the very low risk

perception group and in the entire sample (Becker, 1974; Rosenstock, 1974; Rogers, 1975; Prentice-Dunn & Rogers, 1986).

Multivariate Analyses

Logistic regression analyses were next performed to assess independent associations between HIV infection and the three HAART constructs. The effect of these constructs on HIV-infection risk is presumed to be mediated at least partially through risk behaviors and partner-selection practices that were not measured in our survey. The following variables known to be associated with HIV infection were also included in the full logistic regression model: YMS city, age group, race/ethnicity, education, previous incarceration, interval since last HIV-negative test result, ≥10 male oral or anal sex partners and engaging in UAI with HIV-positive or unknown-status male partners in the prior 6 months, and two behavioral proxies: ever diagnosed with an STD and perceived risk for being HIV infected (Valleroy et al., 2000; Koblin et al., 2006; MacKellar et al., 2007a). To assess potential race-specific effects and evidence for the directionality of associations, we evaluated effect modification (moderation) by race/ethnicity and perceived risk for infection.

Assessment of Moderation and Derivation of the Final Model

To assess moderation, the full model included six two-way interaction terms between the three HAART constructs and race-ethnicity and perceived risk for being HIV infected. The fully adjusted model was then reduced by the manual stepwise elimination of interaction terms with *P* >0.15 and all other variables with *P* >0.05. A lenient elimination threshold for interaction terms was used given the lower power to detect statistically significant interactions (Hosmer &

Lemeshow, 1989). In order of highest to lowest *P*-values, stepwise elimination proceeded first with interaction terms and then with variables not included in those interaction terms that were retained for the final model. Variables were only excluded from models after meaningful confounding of retained covariates was ruled out.

Evidence for Directionality of Associations

Evidence for the directionality of associations was obtained from evaluating moderation by perceived risk for being HIV infected. If CDT alone explains observed associations, interaction terms that include perceived risk for infection should be statistically significant, and associations between HIV infection and the three HAART constructs should be restricted to MSM who perceive themselves at risk for HIV (Aronson, 1969; Huebner & Gerend, 2001; Huebner et al., 2004). In contrast, if HBM/PMT operates at least in part, these associations should be reasonably homogenous across risk-perception groups (i.e., corresponding interaction terms should be statistically insignificant) (Becker, 1974; Rosenstock, 1974; Rogers, 1975; Prentice-Dunn & Rogers, 1986).

<div align="center">Results</div>

Recruitment

At 181 venues in the six cities, staff enrolled 3,137 (57.6%) men of 5,443 identified as eligible. Proportionally more men aged 23 to 26 years enrolled compared with men 27 to 29 years (58.9% vs. 54.7%; χ^2, 9.13; $P < 0.01$). Statistically significant differences were not observed in the proportion of men enrolled by race/ethnicity. Of the 3,137 participants, the following were removed from analyses: 53 (1.7%) duplicates; 13 (0.4%) who gave contradictory

responses or who were impaired by alcohol or drugs; 11 (0.4%) who reported never having sex; 121 (3.9%) who reported never having sex with men; 199 (6.3%) who reported previously testing HIV positive (n=104), indeterminate (n=5), or who either didn't know their last HIV-test result (n=89), or who refused to report their last result (n=1); 1,055 (33.6%) who reported either being unaware of HAART (n=1,047) or who had missing information on awareness of HAART (n=8); 20 (0.6%) who were not HIV tested at the time of their interview; and 90 (2.9%) who either reported not knowing, had missing responses, or refused to respond to one or more construct items (n=88) or to the measure on perceived risk for being HIV infected (n=2). Analyses were restricted to the remaining 1,575 HIV-tested MSM who reported being aware of HAART, and had either never previously HIV tested or had last tested HIV negative.

Participant Characteristics

Of the 1,575 MSM, 876 (55.0%) were 26-29 years of age; and 100 (6.3%) were Asian, 197 (12.5%) black, 286 (18.2%) Hispanic, 935 (59.4%) white, and 57 (3.6%) were of other race/ethnicity (Table 5.2). Most MSM reported receiving at least some technical or college education, being part- or full-time employed, and having previously tested for HIV. Although few MSM perceived themselves at risk for being HIV infected, many reported having $\geq$20 lifetime and $\geq$10 recent male oral or anal sex partners, ever being diagnosed with an STD, and recently engaging in UAI with an HIV-positive or HIV-unknown-status male partner; 120 (7.6%) tested HIV positive at the time of their YMS interview (Table 5.2).

Associations with Race/ethnicity & Risk Behavior

Strong endorsements of the three HAART constructs did not vary by age; the two

HAART-efficacy beliefs, but not reduced HIV/AIDS concern, did vary by race/ethnicity (Figure

5.1). Compared with white MSM, black (OR, 2.62; 95%CI, 1.75-3.92) and Hispanic (OR, 2.55;

95%CI, 1.78-3.64) MSM were more likely to strongly endorse the belief that HAART mitigates

HIV/AIDS severity. Compared with black MSM, white MSM were more likely to strongly

endorse the belief that HAART mitigates HIV susceptibility (OR, 2.17; 95%CI, 1.22-3.85).

Differences between Hispanic and white MSM on strong endorsement of the belief that HAART

mitigates HIV susceptibility were not statistically significant (white vs. Hispanic: OR, 1.36;

95%CI, 0.90-2.07) (Figure 5.1).

Among all participants, strong endorsements of the three HAART constructs were

associated with reporting $\geq$10 male sex partners; strong endorsements of the belief that HAART

mitigates HIV/AIDS severity and reduced HIV/AIDS concern were also associated with

engaging in UAI (Table 5.3). Excluding the belief that HAART mitigates HIV susceptibility,

similar magnitudes of associations were observed among MSM who perceived themselves at

very low risk for being HIV infected (Table 5.3).

Association with HIV Infection

In bivariate analyses, HIV infection was associated with strong endorsements for the

belief that HAART mitigates HIV/AIDS severity and reduced HIV/AIDS concern (Table 5.4).

In logistic regression analyses, these associations remained statistically significant after

adjustment for YMS city, age group, education, having tested HIV negative within the past year,

and perceived risk for being HIV infected (Table 5.4). HIV infection was not associated with

strong endorsement of the belief that HAART mitigates HIV susceptibility (Table 5.4), and this non-significant association was not moderated by either race/ethnicity (P= 0.92) or perceived risk for being infected (P=0.74) in the full logistic regression model.

In the full model, the significant association between HIV infection and reduced HIV/AIDS concern also was not moderated by either perceived risk for being infected ($P = 0.68$) or race/ethnicity ($P = 0.61$). The significant association between HIV infection and the belief that HAART mitigates HIV/AIDS severity was not moderated by perceived risk for being infected ($P = 0.91$) but was moderated by race/ethnicity ($P = 0.14$). In the final reduced model, the adjusted HIV-infection odds for strong endorsement of this belief was approximately 2.9 (4.65/1.62) and 2.5 (4.12/1.62) fold higher among black and Hispanic MSM, respectively, compared with white MSM (Table 5.5).

Discussion

In a six-city study of MSM who had not previously HIV tested or who last tested HIV negative, we found that HIV/AIDS complacency, measured as reduced HIV/AIDS concern because of HAART, was associated with both HIV infection and sexual behaviors known to be associated with HIV incidence among MSM. Contrary to expectations under cognitive dissonance theory, these observed associations were not restricted to men who recognized that their behaviors placed them at risk for HIV.

Thus, in accordance with the Health Belief Model and Protection Motivation Theory, our findings suggest that young MSM who are complacent about HIV/AIDS because of HAART are less motivated to consistently enact protective sexual behavior, and as a result, are more likely to acquire HIV. Our findings are supported by 11 of 13 studies that found similar reduced

HIV/AIDS concern constructs were associated with acquisition behavior (Van de Ven et al., 1999; Elford et al., 2000, 2002, 2003; Vanable et al., 2000; Ostrow et al., 2002; Koblin et al., 2003; Williamson & Hart, 2004; Huebner et al., 2004; Stolte et al., 2004a; Kalichman et al., 2007b), and by the only study found of its kind, with subsequent STD/HIV infection among MSM in the Netherlands (van der Snoek et al., 2005). The two studies that did not observe associations were either conducted in the year following first availability of HAART (Kalichman et al., 1998) or included only MSM ≤25 years of age (Bakeman et al., 2007).

Belief that HAART Mitigates HIV/AIDS Severity

We also found that (1) young black and Hispanic MSM were more likely than young white MSM to endorse strongly the belief that HAART mitigates HIV/AIDS severity; (2) strong endorsement of this belief was associated with our two measures of acquisition behavior; and (3) the association between this belief and HIV infection among young black and Hispanic MSM was very strong (AOR ~ 4.0) and over twice that observed among young white MSM. With respect to (1), three studies also found that MSM of minority race/ethnicity were more likely than white MSM to endorse HAART-optimism beliefs (Koblin et al., 2003; Kalichman et al., 2007a; Sullivan et al., 2007), including the belief that HAART is a cure for AIDS (Koblin et al., 2003).

Finding (2) stands in contrast to six studies that did not observe associations between acquisition behavior and the belief that HAART mitigates HIV/AIDS severity among MSM (Kalichman et al., 1998, 2007b; Van de Ven, 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a). Excluding the report by Koblin and colleagues (2003) that included only MSM <23 years of age, however, all remaining studies recruited relatively few minorities,

did not report findings stratified by race/ethnicity, and may have had insufficient power in aggregate analyses to detect associations that may be more relevant among minority MSM.

Our measures also required subjects to appraise their personal likelihood of a quality life taking HAART, assuming they had acquired HIV. In contrast, all six studies assessed how subjects perceived HAART in curing or reducing the severity of HIV/AIDS specifically in other persons or without regard to self. It is possible that our personalized items were able to measure a belief construct more salient to reduced personal concern about HIV/AIDS and risk behavior.

Finally, because behavioral measures do not typically include partner risks, absence of observed behavioral associations does not rule out associations with sexually transmitted infections including HIV, particularly among MSM (Peterman et al., 2000; Bingham et al., 2003; Harawa et al., 2004; Millett et al., 2007). Notably, our measures of risk behavior did not predict HIV infection when evaluated in the presence of perceived risk for being infected, a measure that may have taken both behavior and partner risks into account.

Belief that HAART Mitigates HIV Susceptibility

Similar to other studies, we also observed that strong endorsement of the belief that HAART mitigates HIV susceptibility was associated with acquisition behavior ($\geq$10 recent male sex partners) (Kalichman et al., 1998, 2007a, 2007b; Van de Ven et al., 1999; Vanable et al., 2000; Huebner & Gerend, 2001; Halkitis et al., 2004). The lack of association with HIV infection could be attributed, in part, to the fact that white MSM, at substantially lower HIV-infection risk in our sample, were more likely to strongly endorse this belief compared with black MSM, who were at substantially higher infection risk (only 14 black MSM strongly endorsed this belief). Although proportionally more white MSM who strongly endorsed this

belief (n=133) tested HIV positive compared with weak-moderate endorsers (n=803), our study lacked sufficient power to detect differences between these two groups (White MSM: % HIV+ strong vs. weak-moderate, 5.3% vs. 3.4%; OR, 1.59; 95%CI, 0.68-3.74).

Limitations

The findings in this report are subject to several important limitations. First, because our survey was restricted to 23-29 year-old men who attended MSM-identified venues in six cities, our findings may not generalize to MSM who are younger or older, who reside in other cities, and who do not attend MSM-identified venues. Second, although our participation rate (58% of eligible men) was not unreasonable for a venue-based study that required HIV testing, our findings may be subject to recruitment biases of unknown direction and magnitude. Third, because YMS was cross-sectional, evidence for the directionality of plausible causal associations can only be inferred from contrasting theoretical expectations. Our findings, thus, do not rule out the possibility that observed associations could be attributed, in part, to attitudinal or belief modification expected under CDT, as suggested by several studies (Elford et al., 2002, 2003; Williamson & Hart, 2004; Huebner et al., 2004). Fourth, it is unknown whether observed associations with HAART-efficacy belief and HIV/AIDS complacency constructs would attenuate when evaluated in the presence other theoretically important determinants (e.g., stigma, depression, homophobia, etc.). The importance of other potential determinants is notable because both racial disparities and resurgence in HIV incidence among MSM preceded the availability of HAART (Lemp et al., 1994; Valleroy et al., 2000; Hall et al., 2008). Finally, because our study was conducted 2-4 years after HAART first became available, it is unknown

whether our findings remain relevant in explaining HIV-infection risk in contemporary samples of young MSM.

Implications for Research & Prevention

Although the subject of considerable speculation, the determinants of both racial disparities and increasing HIV incidence among MSM in the United States remain unknown (Millett et al., 2007; Hall et al., 2008). One study in Amsterdam suggests that only 8%-13% of new acquisition behavior among MSM might be attributed to HAART optimism (Stolte et al., 2004a; Elford, 2004), and thus, some have argued that prevention efforts should address more important determinants (Elford, 2004). The relevance of this population-attributable behavioral risk to population-attributable infection risk, however, is unknown.

Our findings suggest that among young MSM, HAART-related HIV/AIDS complacency and efficacy beliefs may be important determinants for both acquiring new HIV infection and for racial/ethnic differences in that acquisition. For programs that target HIV/AIDS complacency as a means to reduce HIV incidence (CDC, 2009c), our findings suggest that messages that counter beliefs that HAART mitigates HIV/AIDS severity may be more effective for young black and Hispanic MSM, and messages that counter beliefs that HAART mitigates HIV susceptibility may be more effective for young white MSM. However, research is needed to evaluate what messages might be effective in reducing HIV-acquisition risks by countering beliefs about HAART that are now recognized as essentially true (Montaner et al., 2006; Antiretroviral Therapy Cohort Collaboration, 2008; Attia et al., 2009; Sullivan et al., 2009b; Donnell et al., 2010).

Although we found that many young men in our sample were not yet aware of HAART, because of widespread media and direct-to-consumer drug advertisements, HAART awareness has probably increased considerably since the time of our study (Altman, 1996; Lyco et al., 1996; Klausner et al., 2002; Kallen et al., 2007). The prevalence of HAART-efficacy beliefs and corresponding complacent attitudes may also have increased, as has been suggested in two recent reports (Kalichman et al., 2007a; 2007b). Thus, new research is needed to evaluate the current prevalence of HAART-efficacy beliefs and HIV/AIDS complacency among contemporary samples of MSM, and whether these beliefs and attitudes increase HIV-acquisition risk equally by race/ethnicity. Given the dramatic improvement in HAART to prolong quality life (Antiretroviral Therapy Cohort Collaboration, 2008), compelling evidence that HAART reduces HIV transmission (Montaner et al., 2006; Attia et al., 2009; Sullivan et al., 2009b; Donnell et al., 2010), and the growing HIV epidemic among MSM in the United States, particularly among men who are young, black, and Hispanic (Hall et al., 2008; CDC 2008b, 2008c), our findings suggest this research may be particularly important for HIV prevention.

Table 5.1. Measures of HAART-efficacy beliefs and reduced HIV/AIDS concern.

<div style="text-align:center;">Constructs and Items*</div>

HAART Mitigates HIV/AIDS Severity Belief

1. If I became infected with HIV today, I probably wouldn't get AIDS given the combination drug treatments that are available.

2. If I got infected with HIV today I could live a long and healthy life by taking the combination drug treatments that are available.

3. HIV is now a manageable disease much like diabetes.

4. If I became HIV infected today, the combination drug treatments would prevent me from getting AIDS for many years.

HAART Mitigates HIV Susceptibility Belief

5. I would be less likely to get infected by an HIV positive partner with undetectable virus than a HIV positive partner with detectable virus.

6. If I were having anal sex with an HIV-positive man and his condom broke, it would be less risky for me if he had no detectable virus.

7. If my partner had a low viral load it would be less risky for me to have receptive anal sex with him than if he had a high viral load.

Reduced HIV/AIDS concern

8. Because of the combination drugs available for HIV, I am less concerned about becoming infected.

9. Because of the combination drugs available for HIV, I'm not as concerned about slipping and having unsafe sex.

10. With the good news about combination drugs for HIV, I worry less about having sex with partners that might be HIV-positive.

11. I'm not as concerned about HIV infection now that there are combination drugs available for HIV.

*Response range for each item: 1 (strongly disagree) to 5 (strongly agree).

Table 5.2. Characteristics of 1,575 23-29 year-old MSM who were aware of HAART and who had never tested for HIV or last tested HIV negative, six U.S. cities, 1998-2000.

Characteristic	Baltimore	Dallas	Los Angeles	Miami	New York	Seattle	All
Recruitment							
Venues #	19	26	40	32	38	26	181
Participation rate %*	58	60	55	58	59	54	58
Records analyzed #	271	245	246	235	229	349	1575
Age %							
23-25	50.6	45.7	41.9	44.7	47.6	41.0	45.0
26-29	49.4	54.3	58.1	55.3	52.4	59.0	55.0
Race/ethnicity %							
Asian	4.1	1.6	10.6	2.1	10.5	8.6	6.3
Black	19.6	13.1	10.2	5.5	27.9	2.9	12.5
Hispanic	4.8	20.0	15.0	47.7	24.4	5.4	18.2
White	67.5	63.7	60.6	40.4	31.9	79.9	59.4
Other	4.1	1.6	3.7	4.3	5.2	3.2	3.6
Highest level of education %							
At least some college	84.5	82.4	84.6	85.9	87.8	88.2	85.7
Employment %							
Part or full time	89.7	95.9	79.3	84.2	83.0	88.8	87.0
Jailed or imprisoned %							
Ever	21.0	26.1	20.1	17.9	26.2	12.9	20.2
Last HIV-test result %							
Negative	90.8	92.7	91.9	93.2	90.4	90.3	91.4
Negative <1 year ago	57.2	59.6	59.8	59.6	54.1	62.8	59.1
Risk behaviors %							
≥20 lifetime male oral or anal sex part.	45.8	60.4	64.2	62.6	53.7	54.2	56.4
Ever diagnosed with an STD	22.9	29.0	28.0	28.1	30.6	27.5	27.6
≥10 recent male oral or anal sex part.[†]	12.6	16.3	20.7	20.0	17.9	15.8	17.0
UAI with HIV+ or unk.-status male[†]	19.9	29.0	27.6	16.6	28.8	20.9	23.6
Perceived risk for being HIV infected %							
Moderate-high	12.9	20.8	16.3	17.0	19.7	11.2	15.9
Strong endorsement of beliefs/attitude %							
HAART mitigates HIV susceptibility	12.2	13.9	11.8	11.9	12.2	13.8	12.7
HAART mitigates HIV/AIDS severity	12.6	19.2	11.4	17.4	19.2	5.7	13.6
Reduced HIV/AIDS concern	10.3	19.2	12.6	14.5	13.1	10.6	13.1
Test result at survey interview %							
HIV positive	10.0	13.1	4.5	6.8	12.2	1.7	7.6

*Of men identified as eligible.
[†]In the prior six months.
HAART, highly active antiretroviral therapy; UAI, unprotected anal intercourse; STD, sexually transmitted disease.

Table 5.3. Associations between risk behaviors in the prior 6 months and endorsement of HAART-efficacy beliefs and reduced HIV/AIDS concern among 1,575 23-29 year-old MSM who were aware of HAART and who had never tested for HIV or last tested HIV negative, overall and among MSM who perceived themselves at very low risk for HIV, six U.S. cities, 1998-2000.

Endorsement of HAART Beliefs and Attitude	≥10 Partners*			UAI[†]		
	n	(%)	OR (95% CI)	n	(%)	OR (95% CI)
Total (n=1575)	268	(17.0)	--	371	(23.6)	--
HAART mitigates HIV susceptibility belief						
Weak-moderate (n=1375)	217	(15.8)	Reference	316	(23.0)	Reference
Strong (n=200)	51	(25.5)	1.83 (1.29-2.59)	55	(27.5)	1.27 (0.91-1.78)
HAART mitigates HIV/AIDS severity belief						
Weak-moderate (n=1361)	217	(15.9)	Reference	303	(22.3)	Reference
Strong (n=214)	51	(23.8)	1.65 (1.17-2.33)	68	(31.8)	1.63 (1.19-2.23)
Reduced HIV/AIDS concern						
Weak-moderate (n=1368)	199	(14.6)	Reference	296	(21.6)	Reference
Strong (n=207)	69	(33.3)	2.94 (2.12-4.07)	75	(36.2)	2.06 (1.51-2.81)
Very low perceived HIV risk (n=668)[§]	60	(9.0)	--	91	(13.6)	--
HAART mitigates HIV susceptibility belief						
Weak-moderate (n=574)	48	(8.4)	Reference	80	(13.9)	Reference
Strong (n=94)	12	(12.8)	1.60 (0.82-3.15)	11	(11.7)	0.82 (0.42-1.60)
HAART mitigates HIV/AIDS severity belief						
Weak-moderate (n=575)	43	(7.5)	Reference	73	(12.7)	Reference
Strong (n=93)	17	(18.3)	2.77 (1.50-5.10)	18	(19.4)	1.65 (0.93-2.92)
Reduced HIV/AIDS concern						
Weak-moderate (n=602)	45	(7.5)	Reference	77	(12.8)	Reference
Strong (n=66)	15	(22.7)	3.64 (1.90-6.98)	14	(21.2)	1.84 (0.97-3.47)

*Male oral or anal sex partners in prior 6 months.
[†]Unprotected anal intercourse with an HIV-positive or unknown-status male partner in prior 6 months.
[§]Representing the lowest possible response "1, very unlikely" to the question: "Using this card, choose a number that best describes how likely it is that you are HIV positive today."
HAART, highly active antiretroviral therapy; OR, odds ratio; CI, confidence interval.

Table 5.4. Crude and adjusted associations with HIV infection among 1,575 23-29 year-old MSM who were aware of HAART and who had never tested for HIV or last tested HIV negative, six U.S. cities, 1998-2000.*

Characteristics	Total	HIV positive n	(%)	OR (95% CI)	AOR[†] (95% CI)
Total	1575	120	(7.6)	---	--
Age group					
23-25	709	42	(5.9)	Reference	Reference
26-29	866	78	(9.0)	1.57 (1.07-2.32)	1.74 (1.10-2.76)
Race/ethnicity					
White	935	34	(3.6)	Reference	--[§]
Black	197	54	(27.4)	10.00 (6.29-15.91)	--
Hispanic	286	24	(8.4)	2.43 (1.41-4.17)	--
Other	157	8	(5.1)	1.42 (0.65-3.13)	--
Highest level of education achieved					
At least some college	1348	83	(6.2)	Reference	Reference
High school or less	225	37	(16.4)	3.00 (1.98-4.55)	1.73 (1.03-2.90)
Ever jailed or imprisoned					
No	1255	72	(5.7)	Reference	--
Yes	317	48	(15.1)	2.93 (1.99-4.32)	--
Interval since last HIV test					
Not tested / HIV negative ≥1 year ago	644	65	(10.1)	Reference	Reference
HIV negative <1 year ago	931	55	(5.9)	0.56 (0.38-0.81)	0.61 (0.39-0.95)
Ever diagnosed with an STD					
No	1141	74	(6.5)	Reference	--
Yes	434	46	(10.6)	1.71 (1.16-2.51)	--
Male oral or anal sex partners in last six months					
0-4	1073	77	(7.2)	Reference	--
5-9	234	18	(7.7)	1.08 (0.63-1.84)	--
≥ 10	268	25	(9.3)	1.33 (0.83-2.13)	--
UAI with HIV-positive/unknown-status male					
No	1204	77	(6.4)	Reference	--
Yes	371	43	(11.6)	1.92 (1.30-2.84)	--
Perceived risk for being HIV infected					
Low	1325	55	(4.2)	Reference	Reference
Moderate-high	250	65	(26.0)	8.11 (5.49-11.99)	6.57 (4.14-10.41)
Endorse HAART mitigates HIV susceptibility					
Weak-moderate	1375	106	(7.7)	Reference	--
Strong	200	14	(7.0)	0.90 (0.51-1.61)	--
Endorse HAART mitigates HIV/AIDS severity					
Weak-moderate	1361	71	(5.2)	Reference	--[§]
Strong	214	49	(22.9)	5.40 (3.62-8.04)	--
Endorse reduced HIV/AIDS concern					
Weak-moderate	1368	86	(6.3)	Reference	Reference
Strong	207	34	(16.4)	2.93 (1.91-4.49)	2.35 (1.38-3.98)

*Associations based on manual stepwise logistic regression analysis that included all table variables in the full model and survey city (see Methods).
[†]Associations also adjusted for survey city.
[§]Interaction (see Table 4).
HAART, highly active antiretroviral therapy; OR, odds ratio; AOR adjusted odds ratio; CI, confidence interval; STD, sexually transmitted disease; UAI, unprotected anal intercourse in the prior six months.

Table 5.5. Crude and adjusted associations between HIV infection and endorsement of the belief that HAART mitigates HIV/AIDS severity among 1,575 23-29 year-old MSM who were aware of HAART and who had never tested for HIV or last tested HIV negative, six U.S. cities, 1998-2000, by race/ethnicity.*

Endorsement of belief that HAART mitigates HIV/AIDS severity	Total	HIV positive		OR (95% CI)	AOR (95% CI)
		n	(%)		
Black (n=197)					
Weak-moderate	154	28	(18.2)	Reference	Reference
Strong	43	26	(60.5)	6.88 (3.30-14.36)	4.65 (1.97-10.99)
Hispanic (n=286)					
Weak-moderate	225	13	(5.8)	Reference	Reference
Strong	61	11	(18.0)	3.59 (1.52-8.48)	4.12 (1.58-10.70)
White (n=935)					
Weak-moderate	845	27	(3.2)	Reference	Reference
Strong	90	7	(7.8)	2.56 (1.08-6.05)	1.62 (0.64-4.11)

*Other race/ethnicity not reported because only 8 infections were observed in this multi-racial group. Associations are adjusted for all variables included in the final logistic regression model (Table 3).

HAART, highly active antiretroviral therapy; OR, odds ratio; AOR, adjusted odds ratio; CI, confidence interval.
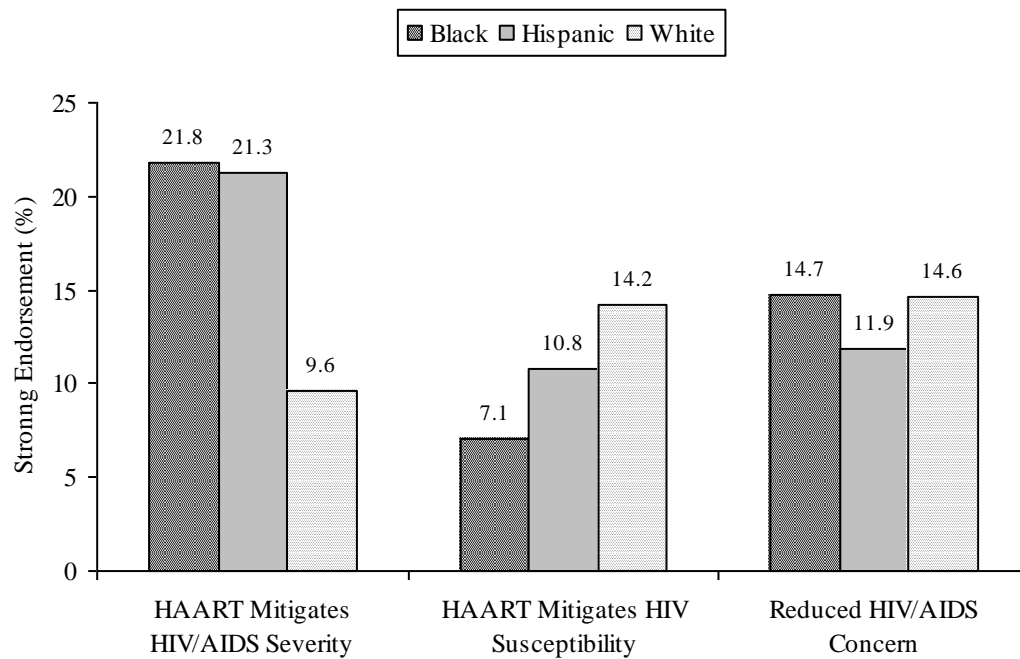
Figure 5.1. Strong endorsement of HAART-efficacy beliefs and reduced HIV/AIDS concern constructs among 23-29 year-old black (n=197), Hispanic (n=286), and white (n=935) MSM who were aware of HAART and who had never tested for HIV or last tested HIV negative, six U.S. cities, 1998-2000.

CHAPTER 6

REASONS FOR NOT TESTING, TESTING INTENTIONS, AND POTENTIAL USE OF AN

OVER-THE-COUNTER RAPID HIV TEST IN AN INTERNET SAMPLE OF

MSM WHO HAVE NEVER TESTED FOR HIV [1]

Abstract

Background: Correlates of main reasons for not testing, HIV testing intentions, and potential use of an over-the-counter rapid HIV test (OTCRT) among men who have sex with men who have never tested for HIV (NTMSM) are unknown.

Methods: We evaluated these correlates among 946 NTMSM from six U.S. cities who participated in an internet-based survey in 2007.

Findings: Main reasons for not testing were low perceived risk (LPR) (32.2%), structural barriers (SB) (25.1%), and fear of testing positive (FTP) (18.1%). LPR was associated with having fewer unprotected anal intercourse (UAI) partners and less frequent use of the internet for HIV information; SB was associated with younger age and more UAI partners; FTP was associated with black and Hispanic race/ethnicity, more UAI partners, and more frequent use of the internet for HIV information. Strong testing intentions were held by 25.9% of all NTMSM and 14.8% of those who did not test because of LPR. Among NTMSM who were somewhat unlikely, somewhat likely, and very likely to test for HIV, 47.4%, 76.5%, and 85.6% would likely use an OTCRT if it was available, respectively.

Conclusions: Main reasons for not testing vary considerably among NTMSM, a minority of whom hold strong testing intentions. To facilitate HIV testing, programs should expand interventions and services tailored to address this variation. If approved, OTCRT might be used by many NTMSM who might not otherwise test for HIV.

Introduction

Entering the fourth decade of HIV/AIDS, the considerable individual and public-health benefits of regular HIV testing and early HIV diagnosis has been well established (CDC, 2006c; Marks et al., 2006; Walensky et al., 2007; Antiretroviral Therapy Cohort Collaboration, 2008). Of persons at risk for HIV, men who have sex with men (MSM) arguably have the most to benefit from testing. Annual HIV incidence among MSM has increased steadily since the early 1990s, attributed in part, to the high proportion of HIV-infected MSM who are unaware of their infection (CDC, 2005a; MacKellar et al., 2005; Marks et al., 2006; Hall et al., 2008). Although national guidelines recommend that MSM test for HIV annually, many test only infrequently, and of those <25 years of age, many have never tested for HIV (Maguen et al., 2000; MacKellar et al., 2002; CDC, 2005a; MacKellar et al., 2005; CDC, 2006c; Sumartojo et al., 2008; Mimiaga et al., 2009). As a consequence, nearly half of HIV-infected MSM may be diagnosed late in the course of their HIV disease (CDC, 2009b).

Although considerable research has explored factors associated with ever, repeat, and recent testing among MSM in the United States, no reports have focused on those who have never tested for HIV (NTMSM) (Heckman et al., 1995; McFarland et al., 1995; Phillips et al., 1995; Roffman et al., 1995; Povinelli et al., 1996; Campsmith et al., 1997; Kalichman et al., 1997; Leaity et al., 2000; Maguen et al., 2000; Spielberg et al., 2001; Kellerman et al., 2002; MacKellar et al., 2002; Fernandez et al., 2003; Spielberg et al., 2003; CDC, 2005a; MacKellar et al., 2005; CDC, 2006a; MacKellar et al., 2006a; Mimiaga et al., 2007; Sumartojo et al., 2008; Mimiaga et al., 2009). Thus, information on potential modes of delivery, relevant content, and priority of interventions to facilitate testing of NTMSM are not available. For example, although the internet is a promising new mode to deliver test-promotion interventions, the proportion of

NTMSM who use the internet for HIV-related information and who might be accessible to these interventions is unknown (Mikolajczak et al., 2008; Moskowitz et al., 2009; Noar et al., 2009a). Similarly, although outreach testing programs at MSM venues reach many high-risk MSM, the types of venues attended by NTMSM is also unknown (Bingham et al., 2008; Bowles et al., 2008; Murrill et al., 2008; Raymond et al., 2008).

While several studies suggest that the main reasons for not HIV testing among MSM are perceived low risk for infection, fear of testing positive, and structural barriers such as not knowing where or not having the time or resources to test, the variation of these reasons among age, race/ethnic, risk, and intervention-accessible subgroups of NTMSM is unknown (Campsmith et al., 1997; Kellerman et al., 2002; MacKellar et al., 2002; CDC, 2005a; MacKellar et al., 2005; CDC, 2006a; Mimiaga et al., 2007; Mimiaga et al., 2009). Information about the variation of main reasons for not testing might help programs target more relevant test-promotion interventions and services for these important subgroups (Armitage et al., 2000; Hullett, 2006; Noar et al., 2009b).

Although most MSM eventually test for HIV, the magnitude and correlates of intentions to test in the upcoming year is also unknown for NTMSM (CDC, 2006a). Information on subgroups of NTMSM who are less likely to test might help prevention programs prioritize test-promotion interventions for MSM at greater risk for delayed testing and late HIV diagnosis. Finally, an over-the-counter rapid HIV test (OTCRT) is currently being evaluated and may soon be available in the U.S. market (Blood Products Advisory Committee, 2009; OraSure Technologies Inc., 2009). Information on the potential use of an OTCRT among NTMSM, particularly among those who report weak testing intentions, might help establish research needs on how OTCRT, if approved, might be used to increase the uptake of HIV testing.

To help meet these information needs, we evaluated among NTMSM who participated in the Centers for Disease Control and Prevention's Web-based HIV Behavioral Surveillance (WHBS) (1) the magnitude and characteristics of subgroups that might be accessible to prevention services via the internet or at MSM venues; (2) the distribution of main reasons for testing in age, racial/ethnic, risk, and prevention-accessible subgroups; and (3) the magnitude and correlates of intentions to test for HIV in the upcoming year and to use an OTCRT if it became available.

Methods

Recruitment

Conducted in collaboration with six public health departments in 2007, WHBS was an internet-based survey of risk and preventive behaviors of MSM who reported residing in the following metropolitan (project) areas: Baltimore, Maryland; Boston, Massachusetts; Dallas, Texas; Los Angeles, California; New York, New York; and San Francisco, California. Banner ads were used to recruit persons who accessed MSM web sites in project areas or who searched for MSM-associated web sites, venues, or activities (terms) via Google, Yahoo, or other internet search engines.

Designed and approved by each participating health department, banner ads appeared systematically (e.g., every 3rd person) to persons who accessed project-area web sites or who searched for MSM-associated terms. The banner ads briefly explained the purpose of the survey, encouraged men to participate, and provided a link to the WHBS web page. When an internet user clicked on the link, the user was assigned a unique survey identification number (ID) and was sent directly to the WHBS eligibility web page.

Persons who reported being male at birth, at least 18 years of age, and residing in one of the project areas were WHBS eligible. Eligible persons were sent directly to a consent web page designed and approved by the health department of the reported city of residence. Ineligible persons were sent directly to a web page containing information about local HIV services. Ineligible persons could not use the "back" arrow on their internet browser to re-enter the site and their assigned ID expired immediately. At the consent web page, eligible persons were asked to check a box stating that they read the information about WHBS and agreed to participate in a 10- to 15-minute anonymous survey without reimbursement.

Survey questions appeared on separate pages and participants were required to submit their responses to proceed to the next page. Participants could view and make corrections to any of their previous answers, and they could refuse to answer any survey question by selecting a "refuse to answer" option. Participants had to complete the survey during one session. If they exited the site, the record was flagged as incomplete, the ID immediately expired, and they could not re-enter the site using the same ID.

Measures

The survey assessed participant characteristics within the following 7 domains: (1) demographics (age, race/ethnicity, highest level of education achieved, sexual identity); (2) attendance at 12 types of MSM venues (e.g., bars, dance clubs, sex establishments); (3) internet usage and purpose (e.g., hours per week, to meet sex partners); (4) risk behavior (e.g., drug use; number of internet, unprotected anal sex (UAI), and total male sex partners; diagnosis of a sexually transmitted disease); (5) exposure to HIV-prevention services (e.g., attending an in-person risk-reduction session, visiting websites for information about HIV and safer sex,

participating in online HIV-prevention chat sessions); (6) HIV testing and the most important (main) reason for not testing (e.g., low perceived risk); and (7) HIV-testing intentions. All variables within domains 2-6 were assessed in the year before the date of interview.

Two HIV-testing intentions were measured using the same 4-point response scale ("very likely," "somewhat likely," "somewhat unlikely," "very unlikely"). Intention to test for HIV was assessed with the following question: "How likely is it that you'll get tested for HIV in the next 12 months?" All participants except those who responded "very unlikely" were asked to respond to the second intention measure: "A new type of HIV home testing kit may soon be available in drug stores or by mail. This new home test kit would use a swab from your mouth (no blood) and would let you know at once if you were infected with HIV. If the new home test kit were available, how likely is it that you would use it?" Strong intention to test in the next year or to use an OTCRT was defined as responding "very likely" to the respective question.

Analyses

All analyses were conducted using SAS version 9.1 (SAS Institute Inc., Cary, NC). The univariate distribution of demographic characteristics, internet usage, venue attendance, risk behavior, exposure to HIV-prevention services, main reasons for not testing, and testing intentions were first evaluated by city of residence. Because similar distributions were observed across cities, all subsequent analyses were conducted on the combined dataset.

Contingency table analyses using chi-squared tests, Cochran-Armitage trend tests, or odds ratios (OR) and 95% confidence intervals (CI) were performed to evaluate correlates of (1) attending ≥ 2 types of MSM venues, (2) visiting at least one website for HIV information, (3) main reasons for not HIV testing, and (4) strong intention to test for HIV in the next year and to

use an OTCRT if it became available. The distributions of the three most frequently reported main reasons for not testing are provided in figures for the following identified correlates: age-group, race-ethnicity, number of male UAI partners (0, 1, >1), and number of times website(s) were visited for HIV information (0, 1, >1).

Logistic-regression analyses were conducted to identify independent correlates of strong intention to test for HIV. Variables selected for inclusion in the full logistic-regression model included age group, race/ethnicity, and level of education, and other variables that were associated ($P < 0.05$) with strong intention in contingency-table analyses. A manual, stepwise procedure was used to remove statistically non-significant variables from the model only after meaningful confounding ($\geq 10\%$ change in adjusted OR) of retained covariates was ruled out. We report crude and adjusted OR and 95%CI for variables included in the full and final models, respectively.

To evaluate correlates of strong intention to use an OTCRT, contingency-table analyses were stratified by strength of intention to test for HIV in the next year (available strata: "very likely," "somewhat likely," "somewhat unlikely"). Strong intention to use an OTCRT was not reported for all strata combined because it was not assessed among NTMSM who reported that it was very unlikely they would test for HIV and because the two intention variables were strongly correlated.

Results

Analytical Restrictions

Of 13,785 internet users screened as eligible, 7,296 (52.9%) completed the survey. Of those who completed the survey, 6,015 (82.4%) identified as male and reported having sex with

another man in the previous 12 months. Of the 6,015 MSM, 1,038 (17.3%) reported that they had never tested for HIV—of whom 87 (8.4%) reported not knowing whether they would test for HIV in the next year and 5 (0.5%) refused to report their HIV-testing intentions. Analyses were restricted to the 946 NTMSM on whom analyzable responses to HIV-testing intentions were obtained.

Participant Characteristics

Of the 946 NTMSM, most were <25 years of age, white, and college educated; nearly all identified as gay or bisexual; many used the internet to socialize and meet sex partners; and most had attended multiple types of MSM venues; 123 (13.0%) reported not attending any MSM venue in the past year (Table 6.1). Attendance at ≥ 2 types of venues (79.0% overall) did not vary significantly by age-group ($P= 0.082$), race/ethnicity ($P=0.053$), UAI ($P=0.080$), or main reason for not testing ($P= 0.070$). Many NTMSM reported attending dance clubs (54.9%), bars (49.1%), and sex establishments (34.1%); few reported attending gay-pride events (12.3%) and raves or circuit parties (11.2%).

Many NTMSM reported having multiple male sex partners and UAI, and although few had participated in in-person or online HIV-prevention sessions, approximately half had received free condoms and nearly half used the internet to obtain information about HIV and safer sex (Table 6.1). Visiting at least one website for HIV information (47.4% overall) did not vary significantly by age-group ($P= 0.364$), race/ethnicity ($P=0.707$), and UAI ($P= 0.982$).

Reasons for Not Testing

Main reasons for not testing for HIV in the past year were low perceived risk for infection (32.2%), structural barriers (25.1%), fear of testing positive (18.1%), and worry about loss of confidentiality (5.8%) (Table 6.1). Of the 305 NTMSM who had not tested because of low perceived risk in the past year, during that year, 34.9% had used non-injection drugs, 52.5% had >1 male internet partners, 56.4% had ≥2 male sex partners, and 37.4% had UAI. Of the 237 NTMSM who reported structural barriers as their main reason for not testing, 42.2%, 27.4%, 25.3%, and 5.1% reported not knowing where, or not having the money, time, or transportation to test, respectively.

Age-group. Low perceived risk was the most frequently reported main reason for not testing for all age groups (Figure 6.1). Reporting structural barriers as a main reason for not testing decreased with increasing age (trend test, *P*<0.001). Not testing because of low perceived risk (*P*=0.319) and fear of testing positive (*P*=0.689) did not vary significantly by age group.

Race/ethnicity. The most frequently reported main reason for not testing was fear of testing positive among black NTMSM, low perceived risk and structural barriers among Hispanic NTMSM, and low perceived risk among white NTMSM (Figure 6.1). Compared with white NTMSM, proportionally more black (14.8% vs. 37.0%; OR, 3.38; 95% CI, 2.04-5.60) and Hispanic (14.8% vs. 21.3%; OR, 1.56; 95% CI, 1.02-2.39) NTMSM reported fear of testing positive as a main reason for not testing. Not testing because of low perceived risk (*P*=0.406) and structural barriers (*P*=0.106) did not vary significantly by race/ethnicity.

Male UAI partners. The most frequently reported main reason for not testing was low perceived risk among NTMSM who did not report UAI, low perceived risk and structural barriers among NTMSM who reported one UAI partner, and structural barriers and fear of

testing positive among NTMSM who reported multiple UAI partners (Figure 6.2). Reporting low perceived risk decreased (trend test, $P<0.001$), and reporting structural barriers (trend test, $P=0.008$) and fear of testing positive (trend test, $P<0.001$) increased, with increased number of UAI partners.

Use of the internet for HIV information. The most frequently reported main reason for not testing was low perceived risk among NTMSM who did not visit websites for HIV information, and low perceived risk and structural barriers among NTMSM who visited a website once for this purpose (Figure 6.2). Similar frequencies for the three main reasons for not testing were reported among NTMSM who visited websites more than once for HIV information. Reporting low perceived risk decreased (trend test, $P=0.018$) and reporting fear of testing positive increased (trend test, $P<0.001$) with increased use of the internet to obtain information about HIV. Reporting structural barriers did not vary significantly with increased use of the internet ($P=0.384$).

Intention to Test for HIV

Approximately one-quarter of NTMSM reported that it was very likely they would test for HIV in the next year (Table 6.1); 31.7%, 16.2%, and 26.2% reported that it was somewhat likely, somewhat unlikely, and very unlikely they would test for HIV, respectively. In the final logistic-regression model, increased adjusted odds for strong testing intention were observed among NTMSM aged 18-24 years or of black or Hispanic race/ethnicity, and among NTMSM who reported attending multiple types of MSM venues, participating in an in-person HIV-prevention session, visiting websites for HIV information more than once, using non-injection

drugs, having multiple male sex partners, and main reasons for not testing other than low perceived risk (Table 6.2).

Potential Use of an OTCRT

Compared with NTMSM who were somewhat unlikely to test for HIV in the next year, proportionally more NTMSM who were somewhat likely (47.4% vs. 76.5%; OR, 3.62; 95% CI, 2.39-5.49) and very likely (47.4% vs. 85.6%; OR, 6.60; 95% CI, 4.09-10.66) to test reported strong intentions to use an OTCRT if it was available. In stratified analyses, two correlates of strong intention to use an OTCRT were observed (Table 6.3).

Among 152 NTMSM who reported that it was somewhat unlikely to test for HIV in the next year, NTMSM who reported not testing in the past year because of low perceived risk were less likely than all other NTMSM to hold strong intentions to use an OTCRT. Among 243 NTMSM who reported that it was very likely they would test for HIV in the next year, NTMSM who engaged in UAI were more likely than NTMSM who did not engage in UAI to hold strong intentions to use an OTCRT (Table 6.3).

Discussion

In a internet survey of MSM from six U.S. cities in 2007, we found that of a large sample of MSM who had never tested for HIV, most were under 25 years of age, many reported considerable HIV risks in the past year, and only one-quarter reported strong intentions to test for HIV in the upcoming year. Many NTMSM, however, attended multiple types of MSM venues and used the internet for HIV-related information, and are thus plausibly accessible to outreach-

testing services and online interventions. Interestingly, even among NTMSM with low testing intentions, many reported they would use an over-the-counter rapid HIV test if it was available.

Similar to surveys that included ever-tested MSM, we also found that low perceived risk, structural barriers, and fear of testing positive were the most frequently reported main reasons for not testing, and that concern about loss of confidentiality was infrequently reported as a main reason (Campsmith et al., 1997; Kellerman et al., 2002; MacKellar et al., 2002; CDC, 2005a; MacKellar et al., 2005; CDC, 2006a; Mimiaga et al., 2007; Mimiaga et al., 2009). We also found, however, that the distribution of the three most important reasons for not testing varied considerably by demographic, risk, and internet-use characteristics. Thus, to facilitate HIV testing of diverse NTMSM, only a minority of whom hold strong testing intentions, our findings suggest that prevention programs should expand testing services and interventions tailored to address this variation (Armitage et al., 2000; Hullett, 2006; Noar et al., 2009b).

Low Perceived Risk

Low perceived risk was the most frequently reported main reason for not testing among NTMSM of all age groups, and of white and Hispanic race/ethnicity. However, many NTMSM who reported low perceived risk as a main reason for not testing also reported considerable drug-use and sexual risks, and among NTMSM who reported 1 male UAI partner in the past year, low perceived risk remained the most frequently reported reason for not testing. Notably, very few (14.8%) NTMSM who reported low perceived risk as the main reason for not testing in the past year held strong intentions to test for HIV in the upcoming year.

Many NTMSM who had 1 male UAI partner may have perceived being at low risk because their UAI partners were main partners or because they "knew" their UAI partners were

HIV-negative (Kippax et al., 1997; Hoff et al., 1997; Davidovich et al., 2000; Crawford et al., 2001; Guzman et al., 2005; Frost et al., 2008). These NTMSM, however, remain at substantial HIV risk because of the high prevalence of undiagnosed HIV infection among MSM, and that many undiagnosed, HIV-infected MSM unintentionally disclose being "HIV-negative" and engage in UAI because they perceive themselves or their partners at low risk for infection (CDC, 2005a; MacKellar et al., 2005; Koblin et al., 2006; MacKellar et al., 2006b; Gold & Karantzas, 2008; Jin et al., 2009; Sullivan et al., 2009a).

Collectively, these findings underscore the need for targeted test-promotion efforts for NTMSM who report not testing because of low perceived risk, particularly for those who engage in UAI. Interventions designed to heighten uncertainty of risk and perceived vulnerability might persuade some NTMSM who do not test because of perceived low risk; however, these interventions may only be effective when coupled with messages that convey the value of early HIV diagnosis on personal health and well being, and that have explicit information on when and where free HIV testing is available (Witte & Allen, 2000; McOwan et al., 2002; Hullett, 2006).

Many MSM may also report being at low risk as a rationalization for avoiding testing and as a coping strategy to reduce the stress and fear from knowingly engaging in HIV risks (Aronson, 1969; Offir et al., 1993; Mikolajczak et al., 2006; Mimiaga et al., 2007; Gold & Karantzas, 2008). Because messages designed to increase perceived vulnerability may threaten self-image and induce defensiveness (Witte & Allen, 2000; Sherman et al., 2000), prevention programs should also consider alternative promotional strategies. Though further research is necessary, interventions that preserve self-image, induce hypocrisy, or incorporate affective outcomes such as anticipated regret have been effective in reducing risk behaviors and might also be effective in increasing the uptake of testing among NTMSM (Aronson et al., 1991; Stone

et al., 1994; Richard et al., 1996; Sherman et al., 2000; Thompson et al., 2002; Sandberg & Conner, 2008).

Fear of Testing Positive

Fear of testing positive was the most frequently reported main reason for not testing among NTMSM who were of black race and who reported multiple male UAI partners, two groups of NTMSM at considerable risk for undiagnosed HIV infection (CDC, 2005a; MacKellar et al., 2005; Koblin et al., 2006; CDC, 2008c). These findings underscore the need for programs to investigate and address underlying causes of fears about testing HIV positive, particularly for these important subgroups.

Although heightened risk perception probably helps explain fear of testing positive among NTMSM with multiple UAI partners, one study suggests that risk perceptions of young black and white MSM are similar (MacKellar et al., 2005; MacKellar et al., 2007a). Compared with young white MSM, however, young black and Hispanic MSM might be less aware of the efficacy and safety of highly active anti-retroviral therapy, and of the availability of medical care for those with limited resources (Koblin et al., 2003). Thus, prevention programs should consider increasing awareness of the benefits of early HIV diagnosis and care, and of available supportive services, particularly targeting NTMSM of black and Hispanic race/ethnicity and who report multiple UAI partners.

Structural Barriers

Not surprisingly, structural barriers were frequently reported as a main reason for not testing among younger and Hispanic NTMSM, groups that may have fewer resources to test or

that might be less integrated in MSM communities and less aware of free HIV-testing services. We also found that structural barriers was one of two most frequently reported main reasons for not testing among NTMSM who reported UAI, suggesting that expanded delivery of testing services might benefit those NTMSM most in need of testing.

We were encouraged that most NTMSM attended multiple types of MSM venues and that attendance at multiple venues was associated with strong testing intentions. Attendance at diverse MSM venues could be a proxy for increased social integration within MSM communities or for greater acceptance or openness about homosexuality, factors known to be associated with HIV testing (MacKellar et al., 2002; CDC, 2003b; MacKellar et al., 2006a; Mimiaga et al., 2007; Sumartojo et al., 2008). Our findings suggest that expanding community-based testing at MSM venues such as dance clubs, bars, and sex establishments, particularly those attended by young and Hispanic MSM, might be particularly helpful to facilitate testing of NTMSM who haven't tested because of structural barriers.

Implications for Internet-based Interventions

We were also encouraged that approximately half of NTMSM used the internet for HIV-related information and that internet use for this purpose was associated with strong testing intention. Thus, internet-based test-promotion programs might be effective in facilitating testing of many NTMSM (Mikolajczak et al., 2008; Moskowitz et al., 2009). Prevention programs should also consider how their websites might be adapted to facilitate testing of NTMSM. Home pages, for example, might encourage users who haven't tested in the past year to enter portals specific to a main reason for not testing. Users entering these portals could then be provided more personally relevant information and motivational messages. Because structural barriers

were a prevalent reason for not testing, prevention websites should also provide "one-click"

access to pages that have information in both English and Spanish on the locations and hours of

operation of free testing services.

Limitations

The findings in this report are subject to several important limitations. First, since our

survey was restricted to an internet sample of MSM from six US cities, our findings may not

generalize to NTMSM who do not use the internet or who reside in other cites. Second, we were

unable to evaluate the magnitude and direction of recruitment bias because the number and

characteristics of NTMSM who saw banner ads and who chose not to enter the WHBS website is

unknown.

Third, the validity of our intention measures to predict testing behavior is unknown.

Because our measures did not include test costs or appeals for a realistic appraisal of testing

intentions, it is possible that our reported intentions might over-estimate testing behavior,

particularly for OTCRT which may be expensive to purchase (Brown et al., 2003). To help

reduce bias, we provided the most conservative estimate our data allowed by excluding

"somewhat likely" responses from our defined intention outcomes.

Fourth, because our survey was cross-sectional, identified correlates of testing intentions

may not be causal. For example, prior exposure to in-person or online prevention services may

reflect the fact that MSM with stronger testing intentions were more likely to seek out these

services. Finally, we were unable to report potential use of an OTCRT among those NTMSM

who held the weakest testing intention.

Public Health Significance & Potential Uptake of OTCRT

Our finding that approximately one in six (17%) predominately young MSM had never tested for HIV, similar to 22 % of 15-25 year-old MSM surveyed in 10 U.S. cities in 1999 and 16% of 18-24 year-old MSM in 15 U.S. cities in 2003-2005, is remarkable in light of considerable investments in the past two decades to increase testing among MSM (CDC, 2006a; Sumartojo et al., 2008; Sutton et al., 2009). Although we were encouraged that strong testing intention was associated with black and Hispanic race/ethnicity and increased risk behavior, findings that might be attributed, in part, to these investments, more effective efforts are clearly needed (Sutton et al., 2009). Recent policy changes and new social-marketing campaigns will hopefully reduce the delay in testing among NTMSM; however, new HIV testing applications could also play an important role (CDC, 2006c; CDC, 2009c; Sutton et al., 2009).

In our large sample of NTMSM, many reported they would use an OTCRT if it was available, even among those who thought it was unlikely they would test in the upcoming year under currently available options. That an OTCRT might be used among many NTMSM who might not test otherwise is plausible given the large uptake of rapid tests in the U.S., and that an inexpensive home test that provides accurate and rapid results are test attributes with the highest reported preference among MSM (Spielberg et al., 2001; Phillips et al., 2002; Spielberg et al., 2003; San Antonio-Gaddy et al., 2006; Spielberg et al., 2005a). Thus, our findings and those of others suggest potential value in evaluating public-health applications of OTCRT, if approved, to increase the uptake of testing among MSM. In the interim, to help reduce late HIV diagnoses and transmissions attributed to undiagnosed infection, prevention programs should expand delivery of interventions and services tailored to address the diversity of reasons for not testing among NTMSM.

Table 6.1. Characteristics of an internet sample of 946 MSM who have never tested for HIV, six U.S. cities, 2007.

Characteristic (%)	Baltimore (n=79)	Boston (n=136)	Dallas (n=156)	Los Angeles (n=205)	New York (n=263)	San Francisco (n=107)	All (n=946)
Age group							
18-24	77.2	75.0	73.1	79.5	73.4	72.9	75.2
25-34	13.9	17.6	16.0	16.6	18.6	20.6	17.4
≥ 35	8.9	7.4	10.9	3.9	8.0	6.5	7.4
Race/ethnicity							
Black	17.7	7.4	4.5	5.9	11.8	6.5	8.6
Hispanic	2.5	7.4	18.6	35.6	15.2	22.4	18.8
White	63.3	79.4	65.4	46.3	63.5	54.2	61.3
Other/unknown	16.5	5.9	11.5	12.2	9.5	16.8	11.3
Highest level of education achieved							
At least some college	70.9	65.4	68.6	63.9	73.0	68.2	68.5
Sexual identity							
Heterosexual/straight	2.5	0.7	2.0	1.0	1.5	0.0	1.3
Bisexual	13.9	19.1	17.0	27.7	20.4	18.4	20.5
Homosexual/gay	81.0	80.1	80.4	71.3	77.3	80.6	77.6
No. of types of MSM venues attended*†							
0-1	22.8	25.0	23.1	16.6	22.8	15.9	21.0
2-6	45.6	54.4	53.8	50.7	45.6	50.5	49.9
7-12	31.6	20.6	23.1	32.7	31.6	33.6	29.1
Internet usage*							
Average ≥20 hours/week	40.5	39.7	34.6	43.9	36.5	41.1	39.1
To meet people at free web sites, daily	31.6	32.4	31.4	31.2	37.6	32.7	33.4
To meet sex partners, at least once	48.7	57.6	53.9	48.2	58.3	52.8	53.9
Risk behaviors*							
Injected drugs	0.0	0.0	0.6	0.5	1.1	0.9	0.6
Used non-injection drugs	41.8	39.3	28.1	33.8	46.4	35.8	38.1
≥1 internet male sex partners	60.8	69.9	66.5	59.8	67.8	64.5	65.2
≥4 total male sex partners	43.0	39.7	43.6	40.5	48.3	36.4	42.8
UAI with ≥1 male partners	52.6	60.7	57.8	57.8	42.9	58.5	53.7
Diagnosed with an STD	2.5	4.4	3.2	5.9	6.5	1.9	4.7
HIV prevention exposures*							
Attended in-person session‡	3.8	9.6	10.3	14.1	10.6	11.2	10.7
Received free condoms	43.0	51.9	32.5	57.1	60.5	56.1	52.0
Visited website(s) for HIV info.	31.6	50.4	48.4	47.6	49.0	49.5	47.4
Visited website(s) for safer sex info.	31.2	36.3	46.8	47.8	46.7	45.2	44.0
Approached online by prev. worker	5.1	16.2	3.9	17.6	14.6	10.6	12.5
Participated in online prev. session	6.3	8.2	6.4	6.3	4.2	4.8	5.8

*In the past 12 months.
†Social organizations, retail businesses, fitness clubs, restaurants, bars, dance clubs, circuit parties, house parties, parks and beaches, street locations, gay pride or similar events, sex establishments.
‡Either individual- or group-based risk-reduction session facilitated by a prevention-program worker or counselor.

Table 6.1. (Continued).

Characteristic (%)	Baltimore (n=79)	Boston (n=136)	Dallas (n=156)	Los Angeles (n=205)	New York (n=263)	San Francisco (n=107)	All (n=946)
Main reason for not testing for HIV*							
Low perceived risk for HIV	30.4	36.8	28.2	34.1	31.6	31.8	32.2
Structural barriers[±]	34.2	25.0	26.9	22.4	24.7	21.5	25.1
Fear of testing positive	12.7	16.2	20.5	21.5	18.3	14.0	18.1
Worried about loss of confidentiality[§]	8.9	4.4	7.1	7.3	4.6	3.7	5.8
Test for HIV in the next year							
Very likely	25.3	22.1	23.1	26.3	28.5	28.0	25.9
Somewhat likely	27.8	28.7	39.1	28.3	34.2	28.0	31.7
Somewhat unlikely	15.2	21.3	18.6	14.1	12.9	18.7	16.2
Very unlikely	31.6	27.9	19.2	31.2	24.3	25.2	26.2

[*]In the past 12 months.

[±]Didn't know where or didn't have the time, transportation, or money to test for HIV.

[§]From being reported to the government, someone learning result, or losing friends, family, job, or insurance.

UAI, unprotected anal intercourse; STD, sexually transmitted disease

Table 6.2. Crude and adjusted associations with strong intention to test for HIV in the next year*
in an internet sample of 946 MSM who have never tested for HIV, six U.S. cities, 2007.

Characteristics	Total	Intention n (%)		OR (95% CI)	AOR (95% CI)
Total	946	245	(25.9)	---	--
Age group					
≥ 35	70	10	(14.3)	Reference	Reference
25-34	165	38	(23.0)	1.80 (0.84-3.84)	1.90 (0.83-4.37)
18-24	711	197	(27.7)	2.30 (1.15-4.58)	2.14 (1.00-4.58)
Race/ethnicity					
White	580	127	(21.9)	Reference	Reference
Black	81	37	(45.7)	3.00 (1.86-4.84)	3.41 (2.00-5.81)
Hispanic	178	54	(30.3)	1.55 (1.07-2.26)	1.52 (1.01-2.28)
Other/unknown	107	27	(25.2)	1.20 (0.75-1.94)	1.30 (0.78-2.17)
Highest level of education achieved					
High school or less	298	75	(25.2)	Reference	--
At least some college	648	170	(26.2)	1.06 (0.77-1.45)	--
Sexual identity					
Heterosexual/straight	12	2	(16.7)	Reference	--
Bisexual	191	47	(24.6)	1.63 (0.35-7.72)	--
Homosexual/gay	724	189	(26.1)	1.77 (0.38-8.13)	--
Number of types of MSM venues attended[†‡]					
0-1	199	30	(15.1)	Reference	Reference
2-6	472	128	(27.1)	2.10 (1.35-3.25)	1.84 (1.15-2.93)
7-12	275	87	(31.6)	2.61 (1.64-4.15)	2.18 (1.32-3.61)
Attended in-person HIV-prevention session[†±]					
No	845	208	(24.6)	Reference	Reference
Yes	101	37	(36.6)	1.77 (1.15-2.73)	1.74 (1.08-2.81)
Times visited website(s) for HIV information[†]					
0	492	96	(19.5)	Reference	Reference
1	214	51	(23.8)	1.29 (0.88-1.90)	1.17 (0.78-1.76)
>1	229	95	(41.5)	2.92 (2.07-4.13)	2.48 (1.72-3.59)
Most important reason for not HIV testing[†]					
Low perceived risk for HIV	305	45	(14.8)	Reference	Reference
All other reasons[§]	641	200	(31.2)	2.62 (1.83-3.75)	2.06 (1.40-3.04)
Used non-injection drugs[†]					
No	589	137	(23.3)	Reference	Reference
Yes	357	108	(30.3)	1.43 (1.06-1.92)	1.40 (1.01-1.94)
Total male sex partners[†]					
1	254	38	(15.0)	Reference	Reference
2-3	287	75	(26.1)	2.01 (1.30-3.10)	1.59 (1.00-2.52)
≥4	405	132	(32.6)	2.75 (1.84-4.11)	1.87 (1.20-2.92)
Unprotected anal intercourse with male partner(s)[†]					
No	434	98	(22.6)	Reference	--
Yes	504	142	(28.2)	1.34 (1.00-1.81)	--

*Strong intention is defined as responding "very likely" to the following question: "How likely is it that you'll get tested for HIV in the next 12 months?" Adjusted associations based on logistic regression analysis (see Methods).
[†]In the past 12 months
[‡]Social organizations, retail businesses, fitness clubs, restaurants, bars, dance clubs, circuit parties, house parties, parks and beaches, street locations, gay pride or similar events, sex establishments.
[±]Either individual- or group-based risk-reduction session facilitated by a prevention-program worker or counselor.
[§]Structural barriers, fear of testing positive, worried about loss of confidentiality, other reasons; categories combined because of observed homogeneity in frequency of reported strong HIV testing intentions.
OR, odds ratio; AOR, adjusted odds ratio; CI, confidence interval.

Table 6.3. Strong intention to use an over-the-counter rapid HIV test (OTCRT)* (assuming availability) in an internet sample of MSM who have never tested for HIV, by strength of intention to test for HIV in the next year, six U.S. cities, 2007.

| | Strength of Intention to Test for HIV[†] | | |
| | Somewhat Unlikely Use OTCRT | Somewhat Likely Use OTCRT | Very Likely Use OTCRT |
Characteristic	n/N (%)	n/N (%)	n/N (%)
Total	72/152 (47.4)	228/298 (76.5)	208/243 (85.6)
Age group			
18-24	54/104 (51.9)	183/236 (77.5)	169/195 (86.7)
≥25	18/48 (37.5)	45/62 (72.6)	39/48 (81.2)
Race/ethnicity			
Black	5/9 (55.6)	18/24 (75.0)	35/36 (97.2)
Hispanic	9/21 (42.9)	41/55 (74.6)	48/54 (88.9)
White	52/111 (46.8)	138/182 (75.8)	104/127 (81.9)
Highest level of education achieved			
High school or less	24/40 (60.0)	74/94 (78.7)	63/74 (85.1)
At least some college	48/112 (42.9)	154/204 (75.5)	145/169 (85.8)
Sexual identity			
Bisexual	16/31 (51.6)	48/60 (80.0)	38/47 (80.9)
Homosexual/gay	51/114 (44.7)	176/232 (75.9)	162/187 (86.6)
Number of types of MSM venues attended[‡±]			
0-1	13/30 (43.3)	48/62 (77.4)	23/28 (82.1)
2-6	43/78 (55.1)	121/158 (76.6)	112/128 (87.5)
7-12	16/44 (36.4)	59/78 (75.6)	73/87 (83.9)
Visited website(s) for HIV information[‡]			
No	40/81 (49.4)	111/141 (78.7)	79/95 (83.2)
Yes	30/68 (44.1)	115/155 (74.2)	126/145 (86.9)
Most important reason for not HIV testing[‡]			
Low perceived risk for HIV	22/60 (36.7)[§]	59/80 (73.7)	38/45 (84.4)
All other reasons	50/92 (54.3)	169/218 (77.5)	170/198 (85.9)
Total male sex partners[‡]			
1	19/46 (41.3)	50/68 (73.5)	32/37 (86.5)
2-3	26/44 (59.1)	81/102 (79.4)	62/75 (82.7)
≥4	27/62 (43.6)	97/128 (75.8)	114/131 (87.0)
Unprotected anal intercourse with male partner(s)[‡]			
No	30/68 (44.1)	114/150 (76.0)	77/97 (79.4)[§]
Yes	42/84 (50.0)	114/148 (77.0)	126/141 (89.4)

*Strong intention is defined as responding "very likely" to the following question: "A new type of HIV home testing kit may soon be available in drug stores or by mail. This new home test kit would use a swab from your mouth (no blood) and would let you know at once if you were infected with HIV. If the new home test kit were available, how likely is it that you would use it?"
[†]Intention to use an OTCRT was not assessed of participants who reported that it was very unlikely they would test for HIV in the next year; analyses excluded 5 participants who did not know if they would use an OTCRT.
[‡]In the past 12 months.
[±]Social organizations, retail businesses, fitness clubs, restaurants, bars, dance clubs, circuit parties, house parties, parks and beaches, street locations, gay pride or similar events, sex establishments.
[§]$P<0.05$

Figure 6.1. Distribution of the three most important reasons for not testing in the past year in an internet sample of 946 MSM who have never tested for HIV, by age group and race/ethnicity, six U.S. cities, 2007.

*Didn't know where or didn't have the time, transportation, or money to test for HIV.
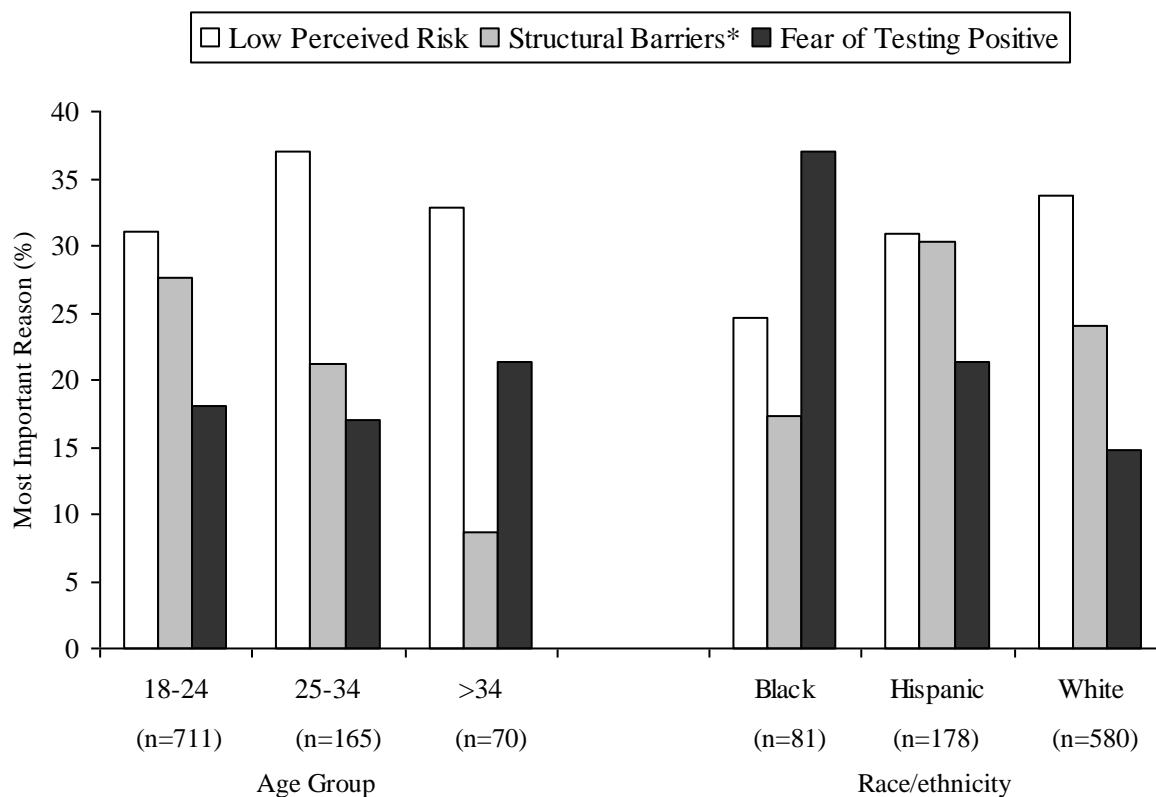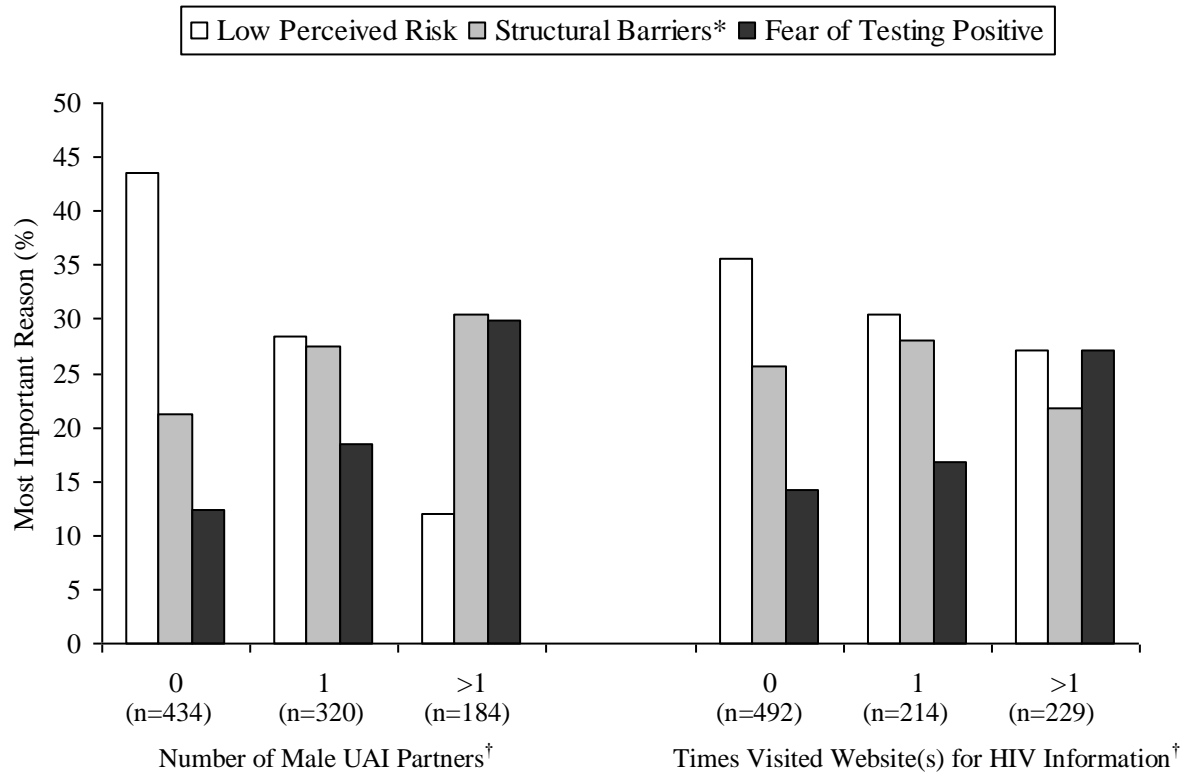
Figure 6.2. Distribution of the three most important reasons for not testing in the past year in an internet sample of 946 MSM who have never tested for HIV, by number of male UAI partners and use of the internet to obtain HIV information, six U.S. cities, 2007 (categories do not add to 946 because of missing data).

*Didn't know where or didn't have the time, transportation, or money to test for HIV.

†In the past 12 months.

UAI, unprotected anal intercourse

CHAPTER 7

OUTCOMES OF HYPOTHESES, CONCLUSIONS, & RECOMMENDATIONS FOR

RESEARCH & PREVENTION

Review of Research Needs, Aims, & Methods

Notwithstanding three decades of prevention efforts, HIV incidence has steadily increased among MSM in the U.S. since the early 1990s, reaching an estimated 30,000 new infections in 2006, more than the estimated number of incident infections among heterosexuals and injection drug users combined (Hall et al., 2008). Estimates of the prevalence of undiagnosed HIV infection among MSM in many cities, particularly of those who are young and black, exceed HIV prevalence estimates in many Sub-Saharan African countries with generalized HIV epidemics (WHO, 2003; CDC, 2005a; MacKellar et al., 2005). Clearly, more research is needed to help inform prevention programs to reduce HIV transmissions and prevalence of undiagnosed infection among young MSM.

To help meet these needs, this dissertation evaluated (1) evidence that HIV/AIDS complacency, measured as reduced HIV/AIDS concern due to HAART, mediates the effects of two HAART-efficacy beliefs on sexual risk behavior (manuscript 1) and HIV-infection risk (manuscript 2), and (2) characteristics of MSM who have never tested for HIV including their reasons for not testing, testing intentions, and potential use of an over-the-counter, rapid HIV test (manuscript 3). The dissertation, thus, addresses both primary and secondary prevention research needs in the population most affected by HIV/AIDS in the United States.

Based on data from a venue-based cross-sectional survey of young MSM from six cities, the first manuscript used structural equation modeling to evaluate a theoretically-based, causal

HAART-efficacy belief, HIV/AIDS complacency, and risk behavior model. Using the same data, the second manuscript used multivariate logistic regression to evaluate the magnitude, plausible direction, and racial/ethnic homogeneity of associations between undiagnosed HIV infection and HIV/AIDS complacency and HAART-efficacy belief constructs, after adjustment for important demographic and risk covariates. Thirteen primary hypotheses were evaluated in analyses reported in these two manuscripts.

Using data from a separate internet-based survey of MSM from six U.S. cities, the third manuscript used exploratory contingency-table and logistic-regression analyses to evaluate socio-demographic and behavioral correlates of reasons for not testing, and strong intentions to test in the next year including use of an over-the-counter, rapid HIV test. A priori hypotheses were not posed for these analyses because the survey was not designed to evaluate a theoretical model and because very limited information was available in the literature on MSM who have never tested for HIV.

Outcomes of Hypotheses

Hypothesis 1: Stronger endorsements of beliefs that HAART mitigates HIV/AIDS severity and susceptibility to HIV are associated with stronger endorsement of reduced susceptibility concern.

Hypothesis 1 was supported: stronger endorsements of the two posited beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility were statistically significantly associated with stronger endorsement of reduced susceptibility concern.

Hypothesis 2: Greater lifetime behavioral risks and stronger endorsements of HAART-mitigates

HIV/AIDS belief and reduced susceptibility concern are associated with stronger

endorsement of reduced HIV/AIDS concern.

Hypothesis 2 was partially supported: greater lifetime behavioral risks and stronger

endorsements of HAART-mitigates HIV/AIDS belief and reduced susceptibility concern were

statistically significantly associated with stronger endorsement of reduced HIV/AIDS concern.

However, the effect of lifetime behavioral risks on reduced HIV/AIDS concerns was only

statistically significant among MSM who perceived themselves at some risk for HIV. The

associations between reduced HIV/AIDS concern and HAART-mitigates HIV/AIDS belief and

reduced susceptibility concern were statistically significant among both MSM who perceived

themselves at very low and at some risk for HIV.

Hypothesis 3: Greater lifetime behavioral risks and stronger endorsement of reduced HIV/AIDS

concern are associated with greater recent behavioral risks.

Hypothesis 3 was supported: greater lifetime behavioral risks and stronger endorsement of

reduced HIV/AIDS concern were statistically significantly associated with greater recent

behavioral risks. These statistically significant associations were observed in data combined

from all six cities, in both MSM who perceived themselves at very low and at some risk for HIV,

and in all 20 combinations of samples restricted to three survey cities.

Hypothesis 4: Compared with the belief that HAART mitigates HIV/AIDS severity, the belief
that HAART mitigates HIV susceptibility will explain more variation in reduced
HIV/AIDS concern and recent risk behavior.

Hypothesis 4 was partially supported: among MSM who perceived themselves at some
risk for HIV, HAART-mitigates HIV susceptibility belief explained 69% more variation in
reduced HIV/AIDS concern and recent risk behavior than HAART-mitigates HIV/AIDS belief.
Among MSM who perceived themselves at very low risk for HIV, however, both constructs
explained approximately equivalent percentages of variation in reduced HIV/AIDS concern and
recent risk behavior. Attenuation of the effect of the belief that HAART mitigates HIV
susceptibility on risk behavior is reasonable among MSM who perceive themselves at very low
risk for HIV infection.

Hypothesis 5: All direct path coefficients in alternative models that were constrained to zero in
the original model will be small and statistically non-significant.

Hypothesis 5 was partially supported: with the exception of the path from HAART-
mitigates susceptibility belief to reduced HIV/AIDS concern (path C), all direct path coefficients
in alternative models that were constrained to zero in the original model were small and
statistically non-significant. Although path C was statistically significant, adding this one path to
the original model explained only 0.1% additional variation in recent risk behavior (15.0% vs.
15.1%), and as a result, the path was omitted from the final model on grounds of increased
parsimony.

Hypothesis 6: Alternative models will not fit significantly better than the original model.

Hypothesis 6 was refuted: both alternative models that included path C fit statistically significantly better than the original model. However, the fit of the original model was very good, and path C was omitted from the final model as explained above.

Hypothesis 7: The proposed model will demonstrate adequate fit among both MSM who

perceived themselves at very low and at some risk for HIV.

Hypothesis 7 was supported: the proposed model demonstrated very good fit among both MSM who perceived themselves at very low and at some risk for HIV.

Hypothesis 8: In accordance with CDT, path B will be statistically significant only among MSM

who perceived themselves at some risk for HIV.

Hypothesis 8 was supported: in accordance with CDT, the path coefficient from lifetime risk behavior to reduced HIV/AIDS concern (path B), was statistically significant only among MSM who perceived themselves at some risk for HIV.

Hypothesis 9: After adjustment for socio-demographic variables, risk behaviors, and perceived

risk, reduced HIV/AIDS concern due to HAART will be statistically significantly

associated with undiagnosed HIV infection.

Hypothesis 9 was supported: after adjustment for socio-demographic variables, risk behaviors, and perceived risk, reduced HIV/AIDS concern due to HAART was statistically significantly associated with undiagnosed HIV infection.

Hypothesis 10:   The magnitude of association between reduced HIV/AIDS concern and undiagnosed HIV infection will not be statistically significantly different across levels of race and perceived risk for infection.

Hypothesis 10 was supported: the magnitude of association between reduced HIV/AIDS concern and undiagnosed HIV infection was not statistically significantly different across levels of race and perceived risk for infection.

Hypothesis 11:   The magnitude of association between the belief that HAART mitigates HIV susceptibility and undiagnosed HIV infection will be larger than the association between the belief that HAART mitigates HIV/AIDS severity and undiagnosed HIV infection.

Hypothesis 11 was refuted: the association between the belief that HAART mitigates HIV susceptibility and undiagnosed HIV infection was not statistically significant and was of smaller magnitude than the association between the belief that HAART mitigates HIV/AIDS severity and undiagnosed HIV infection.

Hypothesis 12: The magnitude of associations between undiagnosed HIV infection and beliefs

that HAART mitigates HIV/AIDS severity and HIV susceptibility will not be

statistically significantly different across levels of race/ethnicity and perceived

risk for infection.

Hypothesis 12 was partially supported. Perceived risk for infection did not moderate (1)

the non-significant association between the belief that HAART mitigates HIV susceptibility and

undiagnosed infection, and (2) the significant association between the belief that HAART-

mitigates HIV/AIDS severity and undiagnosed infection. Also, race/ethnicity did not moderate

the non-significant association between the belief that HAART mitigates HIV susceptibility and

undiagnosed infection. However, race/ethnicity did moderate the significant association between

the belief that HAART-mitigates HIV/AIDS severity and undiagnosed infection. In the final

reduced model, the adjusted HIV-infection odds for strong endorsement of this belief was

approximately 2.9 and 2.5 fold higher among black and Hispanic MSM, respectively, compared

with white MSM.

Hypothesis 13: Beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility will

be associated with undiagnosed infection when evaluated in the absence of

reduced HIV/AIDS concern and will not be associated with undiagnosed

infection when evaluated in the presence of reduced HIV/AIDS concern.

Hypothesis 13 was refuted: the belief that HAART mitigates HIV susceptibility was not

statistically significantly associated with HIV infection when evaluated in the presence or

absence of reduced HIV/AIDS concern. The belief that HAART mitigates HIV/AIDS severity was statistically significantly associated with undiagnosed HIV infection both in the absence and presence of reduced HIV/AIDS concern.

Conclusions of Manuscripts 1 & 2

Among MSM aged 23-29 years who had not previously tested for HIV or had last tested HIV negative and who were sampled from MSM venues in six U.S. cities 2-4 years after HAART became widely available, the posited causal model demonstrated adequate fit and stability in all 20 combinations of samples from three U.S. cities, and suggests that HIV/AIDS complacency, measured as reduced HIV/AIDS concern because of HAART, mediates the effects of beliefs that HAART reduces HIV/AIDS severity and HIV susceptibility on recent risk behavior.

In analyses stratified on perceived risk for HIV, the model behaved in accordance with theoretical and empirical expectations. Among MSM who perceived themselves at very low HIV risk, the model suggests that heightened lifetime risk behavior (i.e., prior behavior) does not strengthen endorsement of reduced HIV/AIDS concern. This finding is expected because MSM who perceive themselves at very low risk do not identify their prior behavior as risky, and thus have no motivation to modify (i.e., reduce) their concerns about HIV/AIDS (Festinger, 1957; Aronson, 1969).

Within this group of MSM, the model also suggests that stronger endorsement of reduced HIV/AIDS concern increases behavioral risks for HIV. This finding is expected because persons who are less concerned that a disease is severe or are less concerned about being susceptibility to a disease, are less motivated to enact more difficult or less rewarding

behaviors that protect against that disease (e.g., consistently using condoms) (Becker, 1974; Prentice-Dunn & Rogers, 1986).   Thus, in accordance with HBM/PMT/CDT theoretical expectations, among MSM who perceived themselves at very low risk, the model suggests that HIV/AIDS complacency due to HAART acts only as a determinant of risk behavior (Festinger, 1957; Aronson, 1969; Becker, 1974; Prentice-Dunn & Rogers, 1986).

Among MSM who perceived themselves at some risk for HIV, however, the model suggests that heightened lifetime risk behavior strengthens endorsement of reduced HIV/AIDS concern. This finding is expected because MSM who recognize that their behavior places them at harm are motivated to modify their attitude (i.e., reduce their concern for HIV/AIDS) to reduce the stress caused by knowingly engaging in harmful behavior (Festinger, 1957; Aronson, 1969). The model also suggests, as explained above, that stronger endorsement of reduced HIV/AIDS concern increases behavioral risks for HIV. Thus, in accordance with HBM/PMT/CDT theoretical expectations, among MSM who perceived themselves at some risk, the model suggests that HIV/AIDS complacency due to HAART acts both as a consequent and determinant of risk behavior (Festinger, 1957; Aronson, 1969; Becker, 1974; Prentice-Dunn & Rogers, 1986).

Although the amount of variance of recent risk behavior explained by the model was small, particularly among MSM who perceived themselves at very low risk for HIV, reduced HIV/AIDS concern had a moderately strong association with undiagnosed HIV infection. The dissimilar strengths of associations with recent risk behavior and HIV infection is not unexpected since the risk-behavior index used in our survey did not include partner risks and thus has relatively low validity in predicting HIV infection (Bingham et al., 2003; Harawa et al., 2004; Millett et al., 2007; Bingham & Sey, 2009).

Notably, the magnitude of association between reduced HIV/AIDS concern and HIV infection was similar among MSM who perceived themselves at very low and at some risk for HIV, and among MSM who had remotely and recently tested negative for HIV. Under the assumption that unmeasured behaviors mediate the influence of reduced HIV/AIDS concern on HIV-infection risk, the homogeneity of HIV associations across levels of perceived risk suggests that reduced HIV/AIDS concern causes at least some behaviors that lead to HIV infection. That is, if reduced HIV/AIDS concern was only caused by increased risk behavior (as explained above), the association with HIV infection should have been restricted to MSM who perceived themselves at some risk for HIV, in accordance with CDT (Festinger, 1957; Aronson, 1969). The observation that reduced HIV/AIDS concern was also strongly associated with HIV infection presumably acquired within the past year is consistent with the plausibility that reduced HIV/AIDS concern heightens recent risk behavior that can lead to HIV infection.

Analyses conducted for the second manuscript also found that strong endorsement of the belief that HAART mitigates HIV/AIDS severity was more prevalent among black and Hispanic than white MSM, and was more strongly associated with HIV infection among black and Hispanic than white MSM. Thus, in accordance with HBM/PMT/TPB, our findings support the plausibility that HIV/AIDS complacency, shaped in part by beliefs that HAART reduces HIV/AIDS severity and HIV susceptibility, increases HIV acquisition risk among young MSM. Moreover, our findings suggest that racial/ethnic differences in the belief that HAART mitigates HIV/AIDS severity explains, in part, some of the disparities in HIV-infection risks among black, Hispanic, and white MSM.

Potential Reasons for Refuted Hypotheses

Hypothesis 6

Hypothesis 6 (alternative models will not fit significantly better than the original model),

was refuted because of the statistically significant path from the belief that HAART mitigates

HIV susceptibility to reduced HIV/AIDS concern. Although the model posited that the effects of

this belief would be mediated entirely by its corresponding attitude, reduced susceptibility

concern, it was only partially mediated. Assuming that the theory of planned behavior is correct,

it is reasonable to observe incomplete mediation for several reasons.

First, because only two moderately correlated items were used to measure reduced

susceptibility concern, the two items most likely did not adequately measure the full dimension

of the posited mediator.   Depending on sample size and amount of variance shared with the

construct, 3-7 items are recommended to adequately measure latent constructs (MacCallum et

al., 1999). Second, belief and attitude measures were not measured in accordance with TPB

recommendations (Ajzen, 2006). For example, TPB recommends that belief and attitudinal

items shares the same TACT attributes (i.e., behavioral target, action, context, and time) (Ajzen,

2006). Although our belief and attitudinal items were similar, they did not match exactly on

specific behavioral targets and sexual contexts. Also, each belief item did not reflect a

composite of both the outcome expectation (e.g., likelihood of acquiring HIV from a partner on

HAART) and an evaluation of that outcome (degree to which HIV infection is good or bad), as

stipulated by TPB (Ajzen, 2006). Finally, items that measured the posited mediator only

reflected the potency dimension of attitudes (e.g., concerns are reduced because of the potency of

HAART to mitigate HIV/AIDS) (Osgood, 1975; Himmelfarb, 1993), whereas, TPB recommends

that attitudes should be measured on the semantic differential scale that measures all three

attitude dimensions: evaluative (i.e., good vs. bad), potency, and action (Ajzen, 2006). It is possible that the belief items reflected at least some dimension of evaluation that was not captured by the two items that were supposed to measure the mediating attitude.

Hypothesis 11

Hypothesis 11 (HIV infection will be more strongly associated with the belief that HAART mitigates HIV susceptibility than with the belief that HAART mitigates HIV/AIDS severity) was based on consistent findings that HAART-mitigates HIV/AIDS beliefs were not associated with risk behavior (Kalichman et al., 1998, 2007b; Van de Ven et al., 1999; Huebner & Gerend, 2001; Koblin et al., 2003; Stolte et al., 2004a). Similarly, we also found that the belief that HAART mitigates HIV susceptibility explained greater variation in recent risk behavior than the belief that HAART mitigates HIV/AIDS severity among MSM who perceived themselves at some risk for HIV (manuscript 1). However, we found that strong endorsement of the belief that HAART mitigates HIV susceptibility was not associated with HIV infection (manuscript 2).

The lack of association between the belief that HAART mitigates HIV susceptibility and HIV infection could be attributed, in part, to our observation that white MSM, at substantially lower HIV-infection risk, were more likely to strongly endorse this belief compared with black MSM, who were at substantially higher infection risk. Very few black MSM endorsed the belief that HAART mitigates HIV susceptibility. Notably, all studies that found that reduced HIV-susceptibility belief was associated with risk behavior were composed predominately of white MSM (Kalichman et al., 1998, 2007a, 2007b; Van de Ven et al., 1999; Vanable et al., 2000; Huebner & Gerend, 2001; Halkitis et al., 2004).

The finding of a strong association with risk behavior but lack of association with HIV infection illustrates the problem with using behavior as a proxy for HIV-infection risk—which is conditional on having HIV-infected partners. Measures of risk behavior typically do not include adequate measures of partner risks. As a consequence, although white MSM report similar sexual behaviors as black MSM, their risk for HIV infection is considerably lower (Valleroy et al., 2000; Harawa et al., 2004; Millett et al., 2006; Millett et al., 2007).

Hypothesis 13

Hypothesis 13 (reduced HIV/AIDS concern will mediate the effects of both HAART-efficacy beliefs on risk for HIV infection) was refuted because (1) the belief that HAART mitigates susceptibility was not statistically significantly associated with HIV infection, and (2) the association between the belief that HAART mitigates HIV/AIDS severity and HIV infection remained statistically significant (among black and Hispanic MSM), when evaluated in the presence of reduced HIV/AIDS concern. Assuming that TPB is correct that attitudes mediate the effects of beliefs on risk behavior (and subsequently risk for HIV infection), two reasons might account for the lack of evidence for mediation.

First, to improve interpretation of results, analyses performed in the second manuscript categorized interval-level responses of items that measured HAART-related constructs. For example, composite scores for items that measured the belief that HAART mitigates HIV/AIDS severity and reduced HIV/AIDS concern had 16 intervals (value range: 4-20) that were categorized into 2 (weak-moderate and strong). By creating only two categories, considerable information that was used to assess association with risk behavior (manuscript 1) was lost in assessing association with HIV infection (manuscript 2).

Second, lack of evidence for mediation is not unexpected because the outcome on which the mediated belief is posited to act (risk behavior) results only rarely in HIV infection. Thus, although some variance in recent risk behavior is caused, presumably, by the mediated belief that HAART mitigates HIV/AIDS severity, HIV infection is conditional on having partners who are HIV infected. Combined with the loss of information explained above, it is reasonable to expect that some complacency-induced HIV infections could be distributed in strong belief and weak-moderate attitude categories.

Finally, lack of observed mediation may have been attributed, in part, to measurement error. As explained above, items used to measure beliefs did not measure both outcome and evaluative expectations, attitudes were not measured on the semantic differential that assesses all three attitude dimensions, and belief and attitude items lacked complete TACT compatibility (Ajzen, 2006). Although findings in manuscript 1 suggest that reduced HIV/AIDS concern completely mediated belief effects in the combined dataset, insufficient sample sizes of black (n=202) and Hispanic (n=292) MSM prevented testing the model for these specific groups (Kline, 2005). Thus, we were unable to assess whether reduced HIV/AIDS concern completely mediated the effects of the belief that HAART mitigates HIV/AIDS severity on recent risk behavior among the two groups in which an association between this belief and HIV infection was observed.

Conclusions of Exploratory Analyses: Manuscript 3

In an internet-based survey of MSM from six U.S. cities in 2007, we found that of a large sample of MSM who had never tested for HIV, most were less than 25 years of age and many reported considerable HIV risks in the past year. Similar to surveys that included ever-tested

MSM, we also found that low perceived risk, structural barriers, and fear of testing positive were the most frequently reported main reasons for not testing. Few MSM reported concern about loss of confidentiality as a main reason for not having tested for HIV in the past year.

Analyses conducted in the third manuscript also found that the distribution of the three most important reasons for not testing varied considerably by demographic, risk, and internet-use characteristics. Low perceived risk was associated with having fewer UAI partners and less frequent use of the internet for HIV information; structural barriers was associated with younger age and having more UAI partners; and fear of testing positive was associated with black and Hispanic race/ethnicity, having more UAI partners, and greater internet use for HIV information.

Overall, only one out of four NTMSM reported strong intentions to test for HIV in the upcoming year; among NTMSM who reported not testing in the past year because of low perceived risk, only one out of seven reported strong intentions to test for HIV. Many NTMSM, however, attended multiple types of MSM venues and used the internet for information about HIV, and are thus plausibly accessible to outreach-testing and online intervention services. Nearly all (85.6%) NTMSM who held strong testing intentions also reported they would use an OTCRT if it was available. Interestingly, even among NTMSM with low testing intentions, nearly half (47.4%) reported they would use an OTCRT if it was available.

Research Recommendations

Because the Young Men's Survey was conducted over 10 years ago, the findings from the first two manuscripts may not reflect current determinants of risk among MSM. Extensive media and direct-to-consumer advertising of the improvements in efficacy and safety of HAART, and compelling evidence that HAART substantially reduces HIV transmission in

discordant couples, suggests that HAART awareness and HAART-related HIV/AIDS complacency might have increased since the time of our study (Kalichman et al., 2007a, 2007b; Kallen et al., 2007; Bhaskaran et al., 2008; Antiretroviral Therapy Cohort Collaboration, 2008; Attia et al., 2009; Sullivan et al., 2009b; Donnell et al., 2010). In the context of unexplained increases in HIV incidence among MSM since the early 1990s, the need to replicate our findings in the first two manuscripts is clear. Also, because the influence of HAART attitude and belief constructs is not theoretically limited to MSM, a similar model could also be evaluated for other important groups such as injection drug users (IDU) and high-risk heterosexuals (HRH). Given decreasing or stable HIV incidence trends in these groups, however, replication of our findings among MSM populations should receive highest priority (Hall et al., 2008).

Replication Research

CDC's national HIV behavioral surveillance system (NHBS) is optimally positioned to assess the prevalence and plausible causal influence of HAART-efficacy beliefs and HIV/AIDS complacency on current HIV-acquisition behavior (CDC, 2006a). Conducted in rotating annual cycles, NHBS samples >10,000 MSM, HRH, and IDU from 25 U.S. statistical metropolitan areas every three years. These large samples would permit robust evaluation of HAART-efficacy belief and HIV/AIDS complacency models separately for age, race-ethnic, risk-perception, and geographic segments of each of the three important groups. Although NHBS is cross-sectional, replication of our findings on both risk behavior and HIV-infection risk among demographic and risk-perception segments of each group would provide strong evidence that HIV/AIDS complacency increases risk behavior that heightens risk for acquiring HIV. Moreover, since nearly identical sampling methods were used in YMS and NHBS-MSM, adding

our construct measures to the NHBS questionnaire would permit a reasonable assessment of whether HAART-efficacy beliefs and complacency attitudes have strengthened among MSM in six U.S. cities (MacKellar et al., 1996; MacKellar et al., 2007b).

For replication efforts in NHBS or elsewhere, our measures of three of the four HAART constructs (belief that HAART mitigates HIV/AIDS severity, belief that HAART mitigates HIV susceptibility, reduced HIV/AIDS concern) demonstrated adequate reliability and validity in our sample, and should be considered for use. However, additional items should be developed and tested particularly for groups that were under-represented or that were not evaluated in our study (e.g., Asian MSM, injection drug users, and high risk heterosexual men and women).

For replication surveys designed to inform prevention policies and allocation of resources, our findings suggest that measurement of reduced HIV susceptibility concern may not be needed because it served only to partially mediate the effects of the two HAART-efficacy beliefs on reduced HIV/AIDS concern. However, measurement of the two HAART-efficacy beliefs in addition to reduced HIV/AIDS concern should be considered because of potential race-specific affects of underlying HAART-efficacy beliefs.

If, however, research is conducted to help inform theory, measurement of reduced susceptibility concern should also be considered. For this purpose, new items will need to be developed given that only two moderately correlated items were retained to measure this construct. If the research is conducted to evaluate TPB specifically, then new belief and attitude items, and items that measure other TPB dimensions (e.g., normative beliefs and subjective norm) will need to be developed in accordance with TPB specifications (Ajzen, 2006).

Primary Prevention Research

Because the findings from the first two manuscripts may not reflect current determinants of HIV risk among MSM, they are inadequate, by themselves, to justify expensive prevention trials. However, prevention trials should be considered if contemporary surveys suggest (1) high prevalence of HIV/AIDS complacency and HAART-efficacy beliefs, and (2) strong associations between these constructs and risk behavior or STD/HIV infection. Ideally, a prevention trial would randomize MSM into comparative, theory-based interventions that assess prospectively HIV risk behaviors and STD/HIV infection outcomes. Using HIV incidence alone as the outcome of interest would most likely be cost-prohibitive for a study conducted in the United States. Based, in part, on the findings in this dissertation, the prevention trial could assess the efficacy of interventions designed to reduce HIV/AIDS complacency by countering the two beliefs that HAART reduces HIV/AIDS severity and HIV susceptibility.

Secondary Prevention Research

To help inform secondary prevention programs, findings from the third manuscript underscore the need for research to explain variation of main reasons for not testing and why only a minority of NTMSM hold strong intentions to test for HIV. Because studies conducted in the U.S. have not focused on NTMSM, qualitative research should be considered first to (1) identify the scope of potential determinants of observed variations, (2) develop measures of these potential determinants for use in representative quantitative studies, and (3) inform theory that could be used to map the direct and indirect influences of potential determinants on HIV testing intentions or practices.

Our finding that main reasons for not testing varied demographically suggests that the qualitative research should include sufficient representation of younger and older Asian, black, Hispanic, and white NTMSM. The formative research should focus on potential determinants of (1) fear of testing positive (e.g., are fears based on disease severity, lack of knowledge about the efficacy of HAART or availability of free treatment services, stigmatization or other social consequences of an HIV diagnosis, or other reasons?); (2) low perceived risk (e.g., is low perceived risk attributed to main or casual partners who are presumed or "known" to be HIV negative, beliefs that specific sexual behaviors such as insertive UAI confer protection, perceptions of personal immunity against HIV, or other reasons?); and (3) structural barriers (e.g., to what extent are NTMSM unaware of free testing opportunities, are structural barriers a convenient rationalization for more important reasons for not testing, what are the perceived test-associated costs?).

Given our findings on structural barriers, attendance at public venues and use of the internet, formative research should also assess facilitators and barriers of accepting testing at MSM-identified venues and participating in internet-based HIV testing interventions. Based on the results of the formative research, prospective cohort studies should be considered to evaluate the extent to which identified determinants, preferably, within specific theoretical frameworks (e.g., TPB), explain variation in testing intentions or practices. Again, NHBS is optimally positioned to identify large samples of persons who have never tested for HIV in each of the three major risk groups (CDC, 2006a). Potentially, the NHBS-survey encounter could also serve as the baseline assessment and point of recruitment into these prospective studies of never tested persons.

OTCRT Research

Finally, our findings on potential use of an OTCRT among diverse NTMSM suggest that research on determinants and contexts of use of an OTCRT might be very informative. The magnitude of undiagnosed HIV infections among young minority MSM justifies public investment in this research now so that some guidance on potential public-health applications might be available by the time an OTCRT is approved.

OTCRT research might assess (1) independently of the manufacturer, whether MSM of different age, socio-economic, and racial/ethnic strata can meet FDA-required performance thresholds using device instructional materials alone; (2) magnitude, theoretical determinants, stated reasons, contexts, and adverse events of prospective OTCRT use; and (3) influence of OTCRT use on risk behavior, and ideally, HIV-infection risk. Information on these important domains of investigation could provide timely guidance for public-health policies and programs to promote or apply OTCRT to reduce the prevalence of undiagnosed infection among MSM.

Prevention Recommendations

Given the public-health urgency to reduce HIV incidence among MSM, particularly those who are young and black, some findings from this dissertation should be considered to improve current primary and secondary prevention practices. For example, the national ACT Against AIDS campaign will be implemented in the next two years to reduce HIV/AIDS complacency as a means to decrease risk behaviors, increase HIV testing, and reduce HIV incidence among black and Hispanic MSM (CDC, 2009c). Additionally, $145 million has been re-authorized for FY2010 for the expanded testing initiative designed to reduce undiagnosed infections among

minority and high-risk populations (CDC, 2009d). Waiting for the replication of our findings would be too late to inform these important primary and secondary prevention programs.

To reduce risk behaviors, our findings suggest that programs designed to reduce HIV/AIDS complacency should consider (1) developing and evaluating interventions that counter the presumed influence of beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility on risk behavior; (2) target black and Hispanic MSM predominately with those interventions that address beliefs that HAART mitigates HIV/AIDS severity; and (3) target white MSM predominately with those interventions that address beliefs that HAART mitigates HIV susceptibility. Although we found clear racial/ethnic differences in the prevalence and influence of these beliefs on HIV acquisition risk that justify tailored interventions, given uncertainty on the current relevance of our findings, prevention programs should retain a mixture of interventions that address both beliefs for all racial/ethnic groups of MSM.

Although findings in this dissertation do not offer specific guidance on intervention content, considerable research has evaluated interventions designed to reduce risk behavior by increasing uncertainty of perceived risk and vulnerability, and awareness of the benefits of early diagnosis on health and well being (Armitage & Conner, 2000; Witte & Allen, 2000). These HBM/PMT-based interventions might also be tailored specifically to address beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility. Because we found evidence that concern about HIV/AIDS can be modified (i.e., reduced) by heightened risk behavior, CDT-based interventions should also be considered. Some of these interventions have reduced risk behaviors by inducing hypocrisy (i.e., increasing awareness that actions are contrary to beliefs) or preserving self image to reduce defensiveness and maladaptive coping (Aronson et al., 1991;

Sherman et al., 2000). These interventions might also be tailored specifically to counter dissonance-arousing beliefs about HAART as a means to cope with or justify risk behavior.

Finally, interventions that target emotions (affect) as a means to reduce risk behavior should also be considered. For example, some affect-based interventions have been designed to induce anticipated regret for the personal and social consequences of future behavior that results in acquiring or transmitting disease to loved ones (Richard et al., 1996; Sandberg & Conner, 2008). These interventions, thus, compliment HBM/PMT-based interventions that target cognition as a means to reduce risk behavior. Used in multi-component interventions, complimentary affect- and cognitive-based interventions might interact to be particularly effective at reducing HAART-belief induced or justified risk behavior and heightened risk for HIV infection.

To increase the uptake of HIV testing, prevention programs should consider NTMSM-specific interventions based on our finding that many young MSM had never tested for HIV and that only a minority of NTMSM held strong testing intentions. Also, because we found that many NTMSM within demographic and risk subgroups reported three main reasons for not testing, interventions that target these subgroups should include components that address each main reason: low perceived HIV risk, structural barriers, and fear of testing positive.

However, our findings also suggest that programs consider weighting these components for each subgroup. For example, interventions for NTMSM who have not recently engaged in UAI or who engage in UAI with only main partners should predominately address low perceived risk for HIV. Interventions for black NTMSM and NTMSM who engage in UAI with multiple partners should predominately address fear of testing positive, whereas interventions for young

and Hispanic MSM should predominately address low perceived risk for HIV and structural barriers.

To help reduce structural barriers, our finding that most NTMSM attended multiple venues suggests that expanding community-based testing at dance clubs, bars, and sex establishments, particularly those attended by young and Hispanic MSM, might particularly help NTMSM who haven't tested because of structural barriers. Because we found that many NTMSM used the internet to obtain HIV information, prevention programs should also consider how their websites might be adapted specifically for NTMSM. Websites, for example, might encourage NTMSM to visit pages that specifically address a personally relevant main reason for not testing. Prevention websites should also provide "one-click" access to web pages that have information in English and Spanish on free testing times and locations.

Final Remarks

Although considerable research has evaluated HIV/AIDS complacency and inadequate HIV testing practices as important causes for the growing HIV epidemic among MSM, considerable gaps in understanding remain. This dissertation addresses some of these gaps by providing evidence that among MSM: (1) HIV/AIDS complacency, shaped in part by strong beliefs that HAART mitigates HIV/AIDS severity and HIV susceptibility, both causes and is caused by heightened HIV-acquisition behavior; (2) racial HIV-infection disparities are explained, in part, by racial/ethnic differences in the strength of these HAART-efficacy beliefs and their influence on HIV-infection risk; (3) most who have never tested for HIV report not testing because of low perceived risk, structural barriers, and fear of testing positive, and although many report substantial risk behavior, few have strong testing intentions; and (4) main

reasons for not testing for HIV vary by age, racial/ethnic, and risk subgroups, however, most NTMSM within these subgroups are accessible to prevention services and strongly intend to use an over-the-counter rapid HIV test should it become available.

Given the dramatic improvement in HAART to prolong quality life, compelling evidence that HAART reduces HIV transmission, and the growing HIV epidemic among MSM attributed, in part, to inadequate testing, translating these findings into contemporary prevention practices may be of considerable importance to reducing HIV incidence among MSM. This dissertation hopes to spur new research needed to replicate these findings and to inform the development of effective interventions to reduce HIV-acquisition risks, racial disparities, and undiagnosed HIV infection among MSM.

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APPENDIX

RISK BEHAVIOR INDICES

The lifetime risk behavior index was based on factors significantly associated with prevalent HIV infection (i.e., cumulative risk for HIV) in a multivariate analysis of young MSM by Valleroy and colleagues (2000). In accordance with table 3 of that report, the index was composed of the following 4 variables: number of lifetime male sex partners, ever having anal sex with another male, ever being diagnosed with a sexually transmitted disease (STD), and ever having used needles or "works" to inject non-prescription drugs. The report by Valleroy and colleagues (2000) was used because (1) it represented the largest sample of young MSM obtained during the period just preceding YMS Phase II on whom prevalent HIV infection was assessed, and (2) because identical measures were used in Phase II for each of the 4 variables.

The four variables that composed the subject's lifetime risk behavior index were weighted based on the reported odds ratio (AOR) for prevalent HIV infection, adjusted for age and race/ethnicity: lifetime male partners (5-19 partners vs. < 4 partners; AOR, 1.9; >20 partners vs. < 4 partners; AOR, 3.0), ever engaged in anal sex (yes vs. no; AOR, 5.0), ever diagnosed with an STD (yes vs. no; AOR, 2.4), ever injected drugs (yes vs. no; AOR, 2.0) (Valleroy et al., 2000).

Subjects who reported four or fewer lifetime male partners and no other index risk behaviors represented subjects with baseline risk, and were thus given a score of 1. Index scores for subjects who reported at least one risk behavior represent the sum of adjusted odds ratios for each reported behavior. For example, subjects who did not report ever having

injected drugs, but who reported > 20 lifetime male partners (AOR=3.0), ever having anal sex with men (AOR=5.0), and ever having an STD (AOR=2.4) were given a score of 10.4 (3.0 + 5.0 + 2.4).   Lifetime risk behavior index scores were rounded to the nearest whole number and ranged from 1 to 12.

The recent risk behavior index was based on factors identified as significantly associated with incident HIV infection in a multivariate analysis of MSM reported in table 1 by Koblin and colleagues (2006). In accordance with this report, the index was composed of the following 6 behaviors measured in the preceding 6 months: number of male sex partners; amphetamine use; heavy alcohol use; use of alcohol or drugs before sex; and insertive and receptive UAI separately for HIV-infected or unknown-status male partners (Koblin et al., 2006). The report by Koblin and colleagues (2006) was used because (1) it represented the largest sample of MSM on whom incident HIV infection was assessed during the time period when YMS Phase II was conducted, and (2) because identical or nearly identical measures were used on 4 of the 6 variables (Koblin et al., 2006).

The variables that composed the subject's recent risk behavior index were weighted based on the reported hazard ratios (AHR) for incident HIV infection, adjusted for race/ethnicity, depression, and previous STD (Koblin et al., 2006). The AHR of the four variables on which YMS had identical or nearly identical measures included: number of male partners in the last 6 months (4-9 vs. < 3; AHR, 1.58; > 10 vs. < 3; AHR, 1.81); methamphetamine use in the last 6 months (yes vs. no; AHR, 1.96); heavy (measured daily in YMS) alcohol use in the last 6 months (yes vs. no; AHR, 1.97); and under the influence of alcohol or drugs during sex in the last six months (yes vs. no; AHR, 1.58). Because YMS did not measure insertive and receptive UAI separately for HIV-positive or unknown-status

partners (AHRs ranging from 1.6 to 3.4; Koblin et al., 2006), a weight of 3.0 was assigned for any UAI with an HIV-positive/unknown-status male partner in the last 6 months.

Subjects who reported three or fewer recent male partners and no other index risk behaviors had baseline risk and were thus given a score of 1. Scores for subjects who reported at least one recent risk behavior represent the sum of the assigned adjusted hazard ratios for those behaviors. For example, subjects who reported 11 recent male partners (AHR=1.81), heavy alcohol use (AHR=1.97), and use of alcohol or drugs before sex (AHR=1.58), but no other risks, were given a score of 5.36 (i.e., 1.81 + 1.97 + 1.58). Recent risk behavior index scores were rounded to the nearest whole number and ranged from 1 to 10.

Both indices differentiated MSM at risk for HIV infection who met our analytical restrictions. Compared with MSM who reported low lifetime risk behavior (index score 1-4; n=60), proportionally more MSM with moderate (index score 5-8, n=1036) and high (index score 9-12, n=479) lifetime risk behavior tested positive for HIV at the time of their interview (% HIV+: low, 1.7; moderate, 7.0; high, 9.6; Cochran-Armitage Trend Test; P = 0.017). Compared with MSM who reported lower recent risk behavior (index score 1-5, n=1349), proportionally more MSM who reported higher recent risk behavior (index score 6-10, n=226) tested HIV positive at the time of their interview (% HIV+: lower, 6.7; higher, 13.3; χ^2, 12.0; P=0.0005).