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Unintended Consequences of HIV Immunization: How Understanding of HIV Vaccines and Vaccine Efficacy May Impact Risk Perception and Behavior Among Gay and Bisexual Men

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Unintended Consequences of HIV Immunization: How Understanding of HIV Vaccines and Vaccine Efficacy May Impact Risk Perception and Behavior Among Gay and Bisexual Men

by

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A thesis submitted in partial satisfaction of the requirements for the degree of Master of Science in Health & Medical Sciences in the Graduate Division of the University of California, Berkeley

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Spring 2008
Unintended Consequences of HIV Immunization:
How Understanding of HIV Vaccines and Vaccine Efficacy May Impact Risk
Perception and Behavior Among Gay and Bisexual Men

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PART ONE: LITERATURE REVIEW

INTRODUCTION

THE HIV PANDEMIC

The Joint United Nations Programme on HIV/AIDS (UNAIDS) 2007 report estimated that 6,800 people were infected everyday with HIV (*AIDS Epidemic Update*, 2007). Worldwide, approximately 33.2 million people were living with HIV, while 2.5 million new HIV infections occurred in the past year. Even though HIV incidence has been declining since the late 1990s, AIDS remains one of the leading global causes of mortality, and it is the primary cause of death in sub-Saharan Africa. Certain high-risk populations, such as men who have sex with men (MSM), continue to be focal points of the epidemic where high transmission rates already exist. Furthermore, these same groups are experiencing emerging epidemics in other areas of the globe (*AIDS Epidemic Update*, 2007). In both the U.S. and abroad, the need for effective HIV prevention measures remains acute.

THE HIV EPIDEMIC AMONG MSM IN THE UNITED STATES

In the U.S., epidemiological trends among MSM continue to be of concern because this group is one of the highest risk populations for HIV. Between 2001 and 2005, new HIV cases among MSM in 33 states and U.S. dependent areas with confidential named–based reporting increased 13% from 16,167 in 2001 to 18,296 in 2005 (Jaffe et al., 2007). While some of this increase may reflect improved surveillance and testing coverage in MSM, a concomitant ten-fold rise in syphilis rates
in the same time period indicates an increase in high-risk sexual behaviors (Jaffe et al., 2007).

The exacerbation of the HIV epidemic is not equally distributed among all subgroups of MSM (Hall et al., 2007). African-American and Hispanic-American MSM have been found to be at increased risk for the virus. African-American MSM had an estimated infection rate of 70.8 per 100,000 people in 2004, five times higher than that in White MSM (14.6 per 100,000). It is estimated that Hispanic-American MSM had an infection rate that was about three times higher (39.0 per 100,000) than White MSM in the same time period (Hall et al., 2007).

Furthermore, younger U.S. MSM populations are increasingly becoming the focus of the epidemic. From 2001 through 2004, HIV rates increased by 14% per annum among 13 to 19 year-olds, 13% per annum in 20 to 24 year-olds, and 3 to 6% in 25 to 29 year-olds. In contrast, the 30 to 39 year-old age group was found to have small decreases in HIV rates (Hall et al., 2007). Even the one older age group with increased HIV rates—40 to 54 year-olds—was at considerably less risk (3 to 6% increase per annum) than the two youngest groups (Hall et al., 2007). While analysis of risk by race, irrespective of age, showed disparities between groups, youth in all racial groups had the highest rates for new infections (Hall et al., 2007).

**The Public Health Need for an HIV Vaccine**

An HIV vaccine is considered one of the best hopes for ending the AIDS pandemic (Chang et al., 2003; Esparza et al., 2003; IAVI, 2005). While recent studies point to the promise of interventions such as circumcision in the reduction of HIV
transmission, no current approach has been proven to eliminate the risk of HIV infection. A vaccine—a biomedical approach for HIV prevention—has been considered essential as an intervention for which success does not depend on diminution of risk behaviors.

Although efforts to find a vaccine have been ongoing since the cause of AIDS was discovered over two decades ago, a safe and efficacious vaccine continues to be elusive. The difficulty in finding a promising candidate has led many to expect that when a vaccine is developed, it will be of low to moderate efficacy (30 to 50%) compared to currently licensed vaccines (Chang et al., 2003; Hu et al., 2003; Gilbert et al., 2003) The willingness of public health institutions to accept an HIV vaccine of lowered efficacy is a shift from other vaccines, which have typically required high efficacy for licensure. For example, the measles, mumps, and rubella vaccine had an efficacy of greater than 90% in preventing overt clinical symptoms in Phase III efficacy trials (Kakakios et al., 1990).

Furthermore, while an HIV vaccine has been considered an important tool in the HIV epidemic as a biomedical—rather than behavioral—intervention, current trends in HIV vaccine research indicate that the consideration of risk behaviors would not be obviated even in the context of HIV immunization. Chang et al. (2003), stated that the public health benefits “could be blunted or lost for vaccines of low to moderate efficacy if risk behaviour increases as a result of an unwarranted sense of protection among the vaccinated individuals” (p. W3).

This unwarranted sense of protection that reduces protective behaviors has been referred to as behavioral disinhibition in the field of HIV prevention. The extent to
which behavioral disinhibition could occur with an HIV vaccine is unclear without the existence of a licensed, efficacious product in use. Some data from the world's first Phase III HIV vaccine trial provides evidence that even a perceived increase in protection from vaccination may have an influence on risk behaviors (Bartholow et al., 2005; Whittington et al., 2006).

The possibility of behavioral disinhibition raises the question of what characteristics of a vaccine—real or perceived—may drive individuals to alter their use of risk-reduction methods. This review of the literature will explore the subject as it relates to HIV vaccines and MSM, an epidemiologically important risk group in the United States. It will begin with trends in HIV vaccine research, the evidence for behavioral disinhibition, and the implications of increased risk behaviors in conjunction with an HIV vaccine of low to moderate vaccine efficacy (VE). Next, the potential drivers for behavioral disinhibition will be discussed, examining the literature on risk perception and risk behaviors among MSM, HIV vaccine perceptions, and the psychological literature on reasoning and decision-making. Finally, this review will identify areas that need to be clarified to understand how an HIV vaccine may influence risk behaviors among MSM.

**Current Vaccine Research**

Gallo (2005) identified many obstacles to the development of an effective HIV vaccine. These included the lack of an animal model, ignorance of the protective component of the immune response, virus strain variation, the difficulty in mounting a durable and rigorous vaccine-induced immune response, and the ability of HIV to
integrate into its host genome. While the study of these issues has advanced the understanding of HIV biology, these barriers have thus far stymied the development of an efficacious vaccine.

Earlier goals for an HIV vaccine focused on the achievement of sterilizing immunity, an immunity that prevents HIV from establishing an infection in the body and that has conventionally been thought to depend on neutralizing antibodies (Gallo, 2005; Letvin, 2006). Current research has focused instead on cellular immunity, which works to destroy cells already infected with the virus (Letvin, 2006). According to Follman et al. (2007), vaccines based on this concept, known as cell-mediated immunity (CMI) vaccines, “are widely expected to have little effect on acquisition of HIV but may result in a favorable shift in the battle between virus and T-cells among individuals who become infected after vaccination” (p. 49).

Considered here are two implications stemming from the use of these vaccines. First, CMI vaccines, rather than being used for the prevention of infection, could be used to delay HIV disease progression and perhaps reduce the infectiousness of an individual with HIV. Secondly, CMI vaccines would prevent infection only minimally, if at all, resulting in a low to moderate VE. It has been posited that low to moderate efficacy vaccines could have utility in targeted risk groups (Chang et al., 2003; Esparza et al., 2003; IAVI, 2005). Modeling of the HIV transmission rates associated with vaccine administration has predicted that their use could have a positive impact when taking into account both reduced susceptibility of unvaccinated individuals and reduced infectiousness of vaccinated ones (Anderson & Hanson, 2005). However, the use of these same vaccines could have serious consequences if
risk behaviors increase as a result of a vaccine intervention.

**Behavioral Disinhibition**

In the fields of psychology and economics, behavioral disinhibition is more commonly referred to as risk compensation. This concept states that a change in the expected costs or benefits of various activities affects behavior (Hemenway, 1993). A decrease in costs or increase in benefits may induce individuals to take more risks when things are made safer. Conversely, an increase in costs or a decrease in benefits may induce individuals to avoid risk. It is hypothesized that the magnitude of the compensatory response depends both on the perceived reduction of risk as well as the perceived increase in benefits (Hemenway, 1993). It is important to note that this hypothesis says nothing about the accuracy of the perceptions.

Empirical data have revealed two interesting facets regarding risk compensation. First, the compensatory response to a change in perceived risk is greater in the long term than in the short term. There are several reasons why smaller amounts of behavior change would be seen in the beginning, from ingrained habits to environmental factors that may constrain change (Hemenway, 1993). For example, an individual perceiving a recent decreased risk for HIV may not immediately alter his consistency of condom use due to factors such as habituation to using condoms or few available opportunities for unsafe sex. However, as this person continues to live with a perceived decreased HIV risk, lapses in condom use may behaviorally become easier or altered circumstances in that person's life (e.g., moving to an area with a large gay population) may permit more opportunities for unsafe sex.
Second, empirical evidence demonstrates that compensatory responses to risk are expected to be larger when the likelihood of an event is altered compared to an altered severity of an event. For example, data have shown that drunk driving is better deterred by an increase in the probability of arrest than by the threat of longer jail sentences (Hemenway, 1993); the increase in risk probability (i.e., higher likelihood of arrest) leads to more risk compensation than the increased severity of consequences (i.e., longer jail sentences). Applying this evidence to HIV vaccines would suggest that a vaccine that reduces the chance of infection would result in some amount of behavioral disinhibition, since the severity of consequences (i.e., acquisition of AIDS) would have less effect on behavior than the likelihood of HIV infection. This discussion comes from data on risk compensation in the context of crime, safety, and economics. These same principles may not hold true when applied to sexual behavior, where different dynamics come into play.

**Modeling of HIV Vaccine-Induced Behavioral Disinhibition**

If the first HIV vaccine will be of low efficacy, then existing research suggests considerable challenges for the development of an effective vaccine intervention, especially due to behavioral disinhibition. Perceived protective benefits of a vaccine could negate a vaccine’s potential for controlling the HIV epidemic by increasing risk behaviors. For example, computer models show that the HIV epidemic would worsen if risk behaviors increased due to a vaccine campaign (Anderson & Hanson, 2005; Blower & McLean, 1994).

In modeling the spread of sexually transmitted diseases (STDs), the reproductive
rate ($R_0$) is the average number of secondary infections of an STD arising from a new case, and is an indicator of the rate of STD transmission (Holmes, 1995). The three determinants of the rate of spread are the average risk of infection per exposure ($\beta$); the average rate of sexual partner change within the population ($c$); and the average duration ($D$) of the infectious period for individuals with the STD. Thus, $R_0 = \beta \times c \times D$. When $R_0 > 1$, there will be a net gain in the number of new cases arising from an existing case of an STD and the disease will spread. At $R_0 < 1$, the disease transmission cannot sustain itself because there are not enough new cases to replace current cases of an STD. When the population prevalence of an STD is at equilibrium, then $R_0 = 1$, indicating that the number of new cases will occur at a rate of replacement for current cases of an STD, leaving the epidemic static (Holmes, 1995).

Blower and McLean predicted the impact of an HIV vaccine on the $R_0$ of HIV using a model based on data from the San Francisco Young Men’s Health Study (SFYMHS) (Blower & McLean, 1994). They calculated the impact of different levels of risk behavior and different levels of VE on the $R_0$ of HIV among San Francisco MSM. Using HIV eradication as the endpoint, their model demonstrated that with a high rate of HIV transmission ($R_0 = 2$), a 60% efficacious vaccine would be able to eradicate an HIV epidemic in San Francisco with 80% coverage of the population if risk behavior did not increase. To provide context for the significance of 80% coverage, one study, conducted from 1994 – 1998, found that among MSM 30 years of age or under, hepatitis B vaccine coverage was just 9% (MacKellar et al., 2001). The hepatitis B vaccine has been available for over two decades, and MSM, a high-
risk group for the hepatitis B virus, have been a targeted group for hepatitis B virus immunization (Mast et al., 2006).

Eradication of the HIV epidemic with the same 60% efficacious vaccine would be virtually impossible with just a 20% increase in risk behaviors (Blower & McLean, 1994). Blower and McLean modeled risk behavior changes as changes in $\beta c$, the product of condom use frequency ($\beta$) and the rate of acquisition of receptive anal intercourse partners ($c$). The baseline value of $\beta c$ was calculated from SFYMH5 seronegative respondents and standardized at $\beta c = 1$. In the model, the value $\beta c$ was varied from 0 to 2. With $\beta c \geq 1.2$, a 20% increase, the authors state that "it is also possible that if risk behavior increased as a consequence of a mass vaccination campaign, then not only may it become impossible to eradicate the HIV epidemic, but mass vaccination may have the perverse outcome of increasing the severity of the epidemic" (Blower & McLean, 1994, p. 1453).

In contrast, Anderson and Hanson (2005) focused their models on the reduction of HIV prevalence rather than the more demanding endpoint of epidemic eradication. Even with low efficacy CMI vaccines and an increase in sexual risk behaviors (although the type of sexual behaviors is undefined in their model, an increased level of risk behaviors is quantified as $r \geq 1$), HIV prevalence could be reduced as long as $R_0$ among the vaccinees was less than $R_0$ among the unvaccinated (Anderson & Hanson, 2005). Anderson and Hanson’s findings support the utility of CMI vaccines, even in the face of behavioral disinhibition.
EXISTING EVIDENCE OF HIV VACCINE-INDUCED DISINHIBITION

While computer models have attempted to quantify the effect of behavioral disinhibition on HIV transmission, without the existence of a licensed HIV vaccine, it is impossible to know the magnitude of this response or how widespread it may be in vaccinated individuals. Some researchers have attempted to elucidate this subject through surveys of attitudes in populations at risk.

One study in Baltimore indicated that 37% of injection drug users interviewed believed that their peers would rely primarily on an HIV vaccine for protection rather than other risk reduction measures such as the avoidance of needle sharing (Vlahov et al., 1994). A factor analysis of survey responses from MSM at a Mardi Gras event in Sydney, Australia, revealed that one of the recurrent themes in HIV vaccine attitudes was the prospect of sexual freedom (Van De Ven et al., 2002). One limitation of these studies is that subjects were asked to predict behavior due to a hypothetical HIV vaccine.

VAX004 — The World’s First HIV Vaccine Efficacy Trial

Because there is no HIV vaccine, work on behavioral disinhibition, while necessary, can only be exploratory and speculative. Much insight in this area, however, has been provided by data from the Vaxgen clinical trial VAX004, the first Phase III efficacy trial of an HIV vaccine. VAX004 was a randomized, double-blind, placebo-controlled efficacy trial of a bivalent rgp120 HIV-1 subtype B vaccine. The trial was conducted at 61 sites in the United States (n = 57), Canada (n = 3), and the Netherlands (n = 1). Five thousand ninety-five MSM and 308 women at risk for HIV infection were
enrolled from June 1998 through November 1999 (Bartholow et al., 2005). Although the product was ultimately determined to have insufficient efficacy for licensure, many data were collected about participants' sexual risk behaviors.

While the overall proportion of MSM reporting unprotected anal intercourse (UAI) decreased from baseline at 36 months of participation, men who consistently perceived an assignment to the vaccine arm or who had inconsistent perceptions of study assignment (i.e., vaccine or placebo arm) were more likely than men who perceived assignment to placebo to report engaging in UAI ($p < 0.05$ for both perceived assignment to vaccine arm or inconsistent perceptions of study assignment) (Bartholow et al., 2005). Post-trial analysis of data from the same study demonstrated that participants who became HIV positive during the study showed a trend of increasing unprotected anal intercourse (UAI) after 18 months of participation. Since these participants did not know whether they had received experimental vaccine or placebo, the investigators speculated that being HIV negative at 18 months increased participant optimism of being a recipient of the experimental vaccine, with a resultant increase in risk behaviors (Bartholow et al., 2005).

More direct indications of behavioral disinhibition arose in a comparison study between vaccine trial participants in VAX004 and a control group receiving the exact same behavioral intervention. In this comparison, VAX004 participants were more likely to have had insertive UAI with their last three partners than controls (46.2% vs. 40.3%, $p < 0.05$). VAX004 participants were also more likely than controls to have had receptive UAI with an HIV positive partner at their last sexual encounter when they perceived that person to be on antiretroviral therapy (ART) (2.6% vs. 1.0%, $p < 0.05$).
although this relationship disappeared when controlling for perceived ART use (Whittington et al., 2006). In addition to having more receptive UAI with HIV positive partners, VAX004 participants were also more likely than controls to report a primary HIV-positive partner. Thus, receptive UAI by VAX004 participants may reflect a belief of decreased infectiousness of their HIV-positive partners when on ART rather than disinhibition caused by the vaccine (Whittington et al., 2006).

Overall, some evidence for increased risk behaviors was seen in the VAX004 group, although the data are scant. Some risk behaviors, such as receptive UAI with a HIV positive partner, could be explained by factors other than behavioral disinhibition (e.g., perceived ART use). There are several possible reasons why a stronger effect of behavioral disinhibition may not have been seen. Study and control groups were not completely comparable: VAX004 participants were somewhat older and less racially diverse and reported higher educational levels than controls. VAX004 participants were significantly more likely to have a primary male partner than controls (52.6% vs. 42.9%, p < 0.01), and controls had a significantly higher number of partners (p<0.05) (Whittington et al., 2006). Therefore, controls may have been riskier to begin with, making it harder to detect an effect of behavioral disinhibition among VAX004 participants. Finally, as part of a randomized clinical trial, VAX004 participants had no assurances they received a vaccine, and they did not know whether or not it was efficacious; thus, it would have been harder for VAX004 participants to calculate their change in risk due to this experimental vaccine. Although the authors conclude that “adverse effects of vaccine trial participation on sexual behavior were not suggested by our findings” (Whittington et al., 2006, p. 237), the study’s findings of some higher
risk behaviors among VAX004 participants is interesting and deserves more exploration.

**Potential Models for HIV Vaccine-Induced Behavioral Disinhibition**

The use of antiretroviral agents like tenofovir as HIV pre-exposure prophylaxis (PrEP), may be a comparable model for HIV vaccine behavioral disinhibition. There are some reports that tenofovir is already being used to prevent HIV infection among HIV-negative MSM at circuit parties, sex clubs, and bathhouses in combination with “club drugs” such as sildenafil (trade name Viagra®)—a drug prescribed for erectile dysfunction, but reportedly misused as a male sexual performance enhancer—and methylenedioxymethamphetamine (MDMA or “ecstasy”) (Liu et al., 2006). Clinical trials are currently underway to test the safety and efficacy of this approach (Liu et al., 2006). It is clear that data are needed to understand how behavioral disinhibition may operate in the context of an HIV vaccine. The study of tenofovir’s effect on risk behaviors may yield useful data for the understanding of behavioral disinhibition.

**The Influence of Vaccine Efficacy on Acceptability**

As stated above, the essential problem of studying HIV vaccine-induced behavioral disinhibition is that there is no such vaccine in use. The uniqueness of HIV makes it hard to find comparable models that help predict what would happen with an HIV vaccine. Surveys of individual attitudes are not dependable, as people are generally unable to predict how they may behave in the future (Weinstein, 1982, 1984, 1980, 1989). Nevertheless, existing research may illuminate important factors to
consider when investigating behavioral disinhibition due to HIV vaccines. While studies have identified different factors influencing vaccine acceptability—type of vaccine, number of injections, side effects—the common theme was a concern about VE (Newman et al., 2004; Zimet et al., 1997; Liau & Zimet, 2001; Liau et al., 1998). In fact, research surveying individual attitudes on a hypothetical HIV vaccine has shown that vaccine acceptability increases with efficacy (Newman et al., 2006; Liau & Zimet, 2001; Liau et al., 1998; Zimet et al., 1997; Webb et al., 1999). These studies found that survey respondents required at least 80 to 90% efficacy for acceptance of HIV immunization. Vaccines with efficacy of 50% had significantly lower acceptability scores (Liau & Zimet, 2001; Liau et al., 1998; Webb et al., 1999). Most of these studies sampled undergraduate students in an introductory psychology class, who were at low risk of HIV. Furthermore, these students were being asked for their attitudes about a product that does not yet exist. These results may not be fully generalizable to communities at risk. Nevertheless, the results do raise some important issues.

The lay public’s high attention to VE can also be looked at as the primary variable in the risk-benefit calculus for vaccine acceptance or rejection. As discussed earlier in this section, the magnitude of risk compensation—or behavioral disinhibition—depends partly on the perceived change in risk and the perceived change in benefits that follow some event (Hemenway, 1993). The attention to VE suggests that individuals may use that quantity to assess a potential change in risk. Yet, no study has explored how individuals understand the concept of VE. Furthermore, none of the HIV vaccine acceptability studies reviewed explained how
VE was defined for participants, making it difficult to understand what study participants were evaluating (Lally et al., 2006; Liau & Zimet, 2000, 2001; Liau et al., 1998; Webb et al., 1999; Zimet et al., 2000; Zimet et al., 1997; Rudy et al., 2005; Newman et al., 2006). Clarifying how individuals conceptualize VE could illuminate how assessments of risk are made in relation to HIV vaccines. In turn, better understanding this decision-making process may provide insight into the potential drivers of HIV vaccine-related behavioral disinhibition.

It may be important to account for behavioral disinhibition in any HIV vaccine intervention, however, its potential to reduce vaccine effectiveness does not ensure an exacerbation of the HIV epidemic with a low efficacy vaccine. In his discussion of risk compensation, Hemenway importantly points out that risk compensation "does not imply that the overall level of safety will not be raised, only that it will not be increased as much as if compensatory actions had not been taken" (Hemenway, 1993, p. 213). Careful consideration of behavioral disinhibition in HIV vaccine implementation, however, can help ensure that vaccine effectiveness—the benefit seen in real-world application—will approach its efficacy, a vaccine's maximal potential as seen in clinical trial.

**Vaccine Efficacy, Statistical Reasoning, and Numeracy**

*Vaccine Efficacy*

As discussed earlier, studies have shown that the higher the efficacy possessed by an HIV vaccine, the greater the interest people had in it (Newman et al., 2006; Liau & Zimet, 2001; Liau et al., 1998; Zimet et al., 1997; Webb et al., 1999). It is unclear
how the lay public interprets this statistical measure, yet understanding of statistics, or a lack thereof, may influence an individual’s risk perception and risk decisions. A review of the literature of statistical reasoning and numeracy suggest that VE may be a difficult concept for the general public to grasp, with potential implications for risk decision making.

It is known that the general population has difficulty interpreting probabilities. In Gigerenzer et al. (2005), the investigators assessed people’s understanding of probabilistic weather forecasts. Study participants chose from multiple-choice responses to the meaning of a 30% chance of rain, which included (1) rain in 30% of the geographic area, (2) rain for 30% of the day, and the correct response, (3) out of 100 days like the one forecasted, rain will occur on about 30 of them. Overall just 55.9% of respondents chose the correct answer. When given the opportunity to provide their own definition, some people stated that a 30% chance represented the amount of rain that would fall and “3 out of 10 meteorologists believe it will rain.” The authors commented on these results, stating that:

“Many risk experts and meteorologists promote quantitative probabilities because they believe that numbers are more precise and convey more information to the public than qualitative risk statements. This is only partly true. Quantitative probabilities will continue to confuse the public as long as experts do not spell out the reference class when they communicate with the public.” (G. Gigerenzer et al., 2005, p. 629)

A reference class is essentially the denominator of any statistic; in the “30% chance of rain” example, the reference class is “days like the one forecasted.” Without this reference class, it is impossible to know what the statistic refers to, yet it is often omitted.
Vaccine efficacy is a measure of relative risk, which is the proportion of diseased people exposed to a factor divided by the diseased people who are unexposed to a factor. In the case of VE, the exposure factor is the vaccine. Within an efficacy trial, VE is expressed by the equation:

\[ VE\% = 1 - \frac{AR_v}{AR_u} \times 100 = (1 - RR) \times 100 \]

where AR equals the infection rate in the vaccinated (AR_v) and the unvaccinated(AR_u) (Orenstein et al., 1988; Halloran et al., 1991). The equation above is a comparison of the infection rates between the vaccinated and the unvaccinated. Assuming that the infection rate in the vaccinated is less than or equal to that in the unvaccinated, VE is expressed as a percentage between 0 and 100. For example, if the infection rate in controls was 2.8 cases per 100 person-years in the unvaccinated, but 1.4 cases per 100 person-years in the vaccinated, than the VE equal 50%, which is a decrease by half in the rate of infection.

The difficulty with the interpretation of VE measures is that VE is an inherently ambiguous statistic. First, its reference class—unvaccinated individuals—is left unstated. Lacking knowledge of the reference class makes it impossible to whom the statistic refers, and therefore, makes it difficult to make assessments of risk.

Furthermore, the specific definition of VE will depend on the study endpoint, which will determine what a vaccine is efficacious against. In a Phase III vaccine efficacy trial required for product licensure, that endpoint is disease infection rates and is used to evaluate unproven vaccines, such as the HIV vaccine. However, an investigator may establish a different endpoint depending on study objectives. For example, in a trial
assessing the safety and efficacy of an attenuated rotavirus vaccine, several endpoints were established to meet different study objectives:

"The primary efficacy end point was the prevention of severe rotavirus gastroenteritis, according to the case definition, from two weeks after the second dose (i.e., after completion of the full vaccination course) until one year of age. The secondary end points were efficacy against severe rotavirus gastroenteritis defined according to the Vesikari scale, efficacy against gastroenteritis associated with specific circulating rotavirus types, and efficacy against severe rotavirus gastroenteritis occurring after the first dose" (Ruiz-Palacios et al., 2006, p.13).

Because of the aforementioned development of CMI vaccines with likely partial efficacy, alternate endpoints are being considered for HIV vaccines as well, including vaccine efficacy for delaying the progression to AIDS (Follmann et al., 2007). Nevertheless, efficacy for the prevention of infection is the gold-standard used in randomized clinical trials and will be used in subsequent discussion of HIV VE.

Given that VE can be defined several different ways, it is not to be unexpected that the public may interpret it in a variety of manners. For someone unfamiliar with the derivation of VE, the statistic could mean that fifty percent of the population is protected, which is how most people would interpret other relative risk measures (Gigerenzer, 2002).

*Reasoning with Statistics and Probabilities*

There are different perspectives on how people reason and make mistakes with statistical reasoning. One view asserts that problems the general public has with probabilities can be reduced if quantities are stated as frequencies (Gigerenzer, 2002). According to Gigerenzer, human minds are adapted to natural frequencies, (e.g., 5 out
of 1,000) making it difficult for individuals to interpret probabilities, especially since probabilities often obscure the reference class they describe (e.g., the rain forecast discussed above is ambiguous in what it is describing, and people draw their own conclusions) (Gigerenzer, 2002). When ambiguity exists, the mind instinctively tries to create certainty from it, and the mind’s perceptual system automatically sells its “best guess” of what it thinks is happening. With probabilities, the mind is more often than not wrong in its guess (Gigerenzer, 2002).

An alternate view—the “dispositionist” approach—states that most individuals, rather than base probabilities on statistical evidence, use inferred causal dispositions or situational propensities, meaning that something inherent to the situation creates the probability, rather than the frequency of an event (Teigen et al., 1999). From this perspective, a soccer team has a high probability of winning because it is a good team, and not because it has a past history of winning many games; unprotected sex is risky because it can transmit sexually transmitted diseases and not because it has a higher rate of STDs than sex with condoms. In a study by Teigen et al. (1999), participants were less likely to choose a frequentist reason for a probability than a dispositionist reason, and they were more likely to give verbal explanations for probabilities rather than frequentist explanations. For example, a participant was more likely to have stated that there was a 90% chance that an appendix operation was successful because it is a simple surgery (dispositionist), rather than stating that 90 out of 100 surgeries occur without complication (frequentist). The authors hypothesize that thinking about risk in terms of the range of possibilities (e.g., appendectomies are simple, the surgery is common, most doctors are experienced at appendectomies) may be more effective for
understanding risk than thinking in terms of failure probability (Teigen et al., 1999).

A “heuristics and biases” view holds that heuristics or “rules of thumb” are used for statistical reasoning in order to reduce the complex task of assessing probabilities. A number of heuristics and biases have been proposed to explain how individuals perform statistical reasoning. While useful, these heuristics can also lead to severe and systematic errors in reasoning when the heuristic diverges greatly from statistical principles (Tversky & Kahneman, 1974). Tversky and Kahneman (1974) were instrumental in elaborating many of these heuristics, three of which (representativeness, availability, and adjustment and anchoring) will be discussed here.

The representativeness heuristic is a heuristic where a probability of an event depends on a stereotype of the sample or event. When an individual has a preconception of A, if B is similar to his or her preconception, B is judged as having a high probability of belonging to A. Conversely, if B is seen to be unlike A, then the probability that it belongs to A is deemed low. Individuals tend to hew to this heuristic, even when it violates principles of probability. For example, when a coin flipped seven times lands on heads, individuals tend to predict that the next flip will result in tails, even though the probability remains one-half. This is referred to as the “Gambler’s Fallacy” or the violation of the law of independent events. Because individuals have a stereotype of equal heads and tails with repeated coin tosses, when the distribution of results skews towards one result or the other, the representativeness heuristic leads them to believe the process will be self-correcting, adhering to their stereotype of coin toss results (Tversky & Kahneman, 1974).

The representativeness heuristic can also lead to base-rate neglect, where if an event
is similar to an individual’s stereotype of a class, that person will judge that event as belonging to that class, even if the prior probabilities—or base-rate frequencies—make it statistically unlikely that it can belong. For example, John has been described as:

"very shy and withdrawn, invariably helpful, but with little interest in people, or in the world of reality. A meek and tidy soul, he has a need for order and structure, and a passion for detail" (Tversky & Kahneman, 1974, p. 1124).

However, it is already known that John belongs to a group comprised of 70 farmers and 30 librarians. Even though it is probabilistically more likely that John is a farmer, most individuals would neglect the base-rates of farmers and librarians, and predict that John is a librarian because of his description.

The availability heuristic describes how individuals judge the probability of an event based on the ease by which similar instances or occurrences are brought to mind. When an occurrence is easily retrievable, it may bias an individual to believe that it is relatively common or numerous. Yet, this retrievability may actually be due to factors such as salience, recency of a prior occurrences, and one’s ability to conduct an effective search of possibilities. For example, one may assess the risk of prostate cancer among older men based on one’s acquaintances. An individual may judge the effectiveness of condoms considering only friends’ stories of condoms breaking and slipping. In trying to recall street names containing the letter “r”, one may conduct an ineffective search by thinking of names beginning with “r” and not those with the letter in the middle or the end of the name (Tversky & Kahneman, 1974).

The adjustment and anchoring heuristic is a rule of thumb where individuals “anchor”
to a piece of information and adjust their interpretation of subsequent values to that anchor. Individuals start with an initial value that is adjusted to the final answer, but adjustments are typically insufficient. As a result, different starting points yield different results. For example, in one study, subjects were asked to estimate the number of African countries in the United Nations (U.N.), after spinning a wheel with the numbers 0 to 100. Although participants adjusted towards the correct number, those who spun lower numbers on the wheel had lower estimates, and those who spun higher numbers had higher estimates for the number of African countries in the U.N. (Tversky & Kahneman, 1974). The discussion of these three heuristics highlighted their failings, but Tversky and Kahneman (1974) state that individuals are usually economical and effective in making judgments in situations of uncertainty. Nevertheless, Nisbett et al. (1983) state that these “failings seem particularly clear and particularly important in people's reasoning about social behavior” (p. 341).

While this review cannot resolve the differences between these schools of thought, all the views discussed do indicate that the public, in general, has difficulty with statistical reasoning. For a complex concept like VE, it is reasonable to assume that most would have difficulty with this as well.

Numeracy Among the Lay Public

Medical literature on patient communication shows that problems with reasoning with numbers are not limited to experiments in cognitive psychology. The literature is replete with examples demonstrating how infrequently patients understand the statistical information that is given to them. While the previous section showed
possible ways that individuals may draw improper inferences from probabilities, problems with numeracy—understanding and manipulating numbers—can further hamper one’s ability to make decisions based on risk.

A study on vaccine acceptance showed that individuals had a difficult time interpreting probabilities about adverse events (Kaplan et al., 1985). Subjects were told that their risk of death from influenza was 1/1,000 but their risk of developing Guillain-Barré syndrome due to an influenza vaccine was randomly 1/1,000; 1/10,000; or 1/100,000. Participants were then asked whether they would accept such a vaccination. While the correct interpretation of adverse event frequencies (which

![Graphs showing vaccine acceptability versus frequency of adverse events.](image)

**Figure 1. Interpreting Probabilities for Small Events.** Data from Kaplan et al. (1985) demonstrate how individuals have problems interpreting extremely small or extremely large numbers. Study participants were asked how the frequency of the adverse event (AE) Guillain-Barré would influence their acceptance of an influenza vaccine. A correct interpretation of AE (Graph (a)) shows the expected effect of AE on acceptability, with acceptability increasing exponentially with exponentially decreasing AE. Instead, acceptability was more likely to increase linearly with an exponentially decreasing AE, suggesting that AE was interpreted in a logarithmic fashion (Graph (b)). (Adapted from Kaplan et al. 1985)
decreased exponentially by powers of 10) would lead to an expected exponential increase in acceptability (Figure 1a), the vaccine acceptability for the different levels of adverse effects followed a log-linear pattern (Figure 1b), similar to the pattern of the exponents of the probabilities of developing Guillain-Barré syndrome (i.e., \(10^3, 10^4, 10^5\)). This result suggested that participants had difficulty interpreting probabilities that became exponentially smaller (Kaplan et al., 1985).

A study by Hux and Naylor (1995) involved communicating the efficacy of chronic medical therapy for the prevention of myocardial infarction (MI) randomly in different, but equivalent incident rate comparison formats: relative-risk reduction (RRR), absolute-risk reduction (ARR), and number needed to treat (NNT). RRR is equivalent to VE. ARR is the difference in incidence rates between the two study arms. NNT is the number of individuals that need to be treated in order to prevent one case of a disease. NNT is calculated as the inverse of ARR. Participants were asked to assent to preventive MI therapy based on information presented in these three different formats. Eighty-eight percent of participants agreed to take the medication when stated as RRR. NNT had the lowest acceptance at 31%. ARR acceptance was 42%. The authors note that RRR is often favored over ARR when event rates are extremely low (Hux & Naylor, 1995). When the probability of an event is low, even a small decrease in an event can cause a great increase in the RRR. For example, if the incidence of a disease is 2 per 100,000 annually, and those receiving drug treatment have an incidence of 1 per 100,000 in the same time period, the RRR is 50%, whereas the ARR is 1 per 100,000. This tendency is indicative of the cognitive bias base-rate neglect, where individuals ignore prior probabilities (i.e., 2 per 100,000) in considering the
chances of an event. In the Hux and Naylor study, participant choices were heavily influenced by the presentation of equivalent values in different efficacy formats, providing evidence that efficacy measures are poorly understood by the public, due in part to biases such as base-rate neglect.

While Hux and Naylor indirectly studied patient understanding of efficacy by examining how different efficacy formats affected perceptions, Sheridan et al. (2003) more directly assessed patient understanding of these measures. The investigators conducted an investigation testing patient comprehension of health statistics by asking participants to correctly interpret treatment efficacy stated as RRR, ARR, or NNT. First, participants were given two treatment options of differing efficacy in one of the three formats (RRR, ARR, or NNT), and asked to choose the more efficacious option. Next, those participants were asked to calculate the risk of disease while taking the treatment chosen. The group who had data presented as RRR more often chose the more efficacious treatment of the two presented (60%). However, only 21% could then correctly calculate the risk of disease using the more effective treatment. Furthermore, all participants were given a numeracy test with three questions (e.g., the expected number of heads in 1,000 coin tosses). Overall, 41% failed to answer any of the numeracy test questions correctly. Sheridan et al. (2003) concluded that because “even patients who receive the ‘simplest’ risk presentation formats had difficulty comparing and calculating treatment benefit information, this study again raises questions about whether patients can independently make informed medical decisions using written quantitative information” (p. 890).

Gigerenzer and Edwards (2003) tried to reduce the difficulties that people had
with medical statistics by studying alternate ways of presenting single event probabilities, conditional probabilities, and relative risks. The authors assert that relative risks (RR) are especially prone to errors in interpretation. They state that the "confusion produced by relative risks has received more attention in the medical literature than that of single event or conditional probabilities" (Gigerenzer & Edwards, 2003, p. 742). As discussed earlier, VE is a type of relative risk measure. Not explicit in relative risk measures is a comparison between two groups who developed a disease. However, many in the public believe it refers to healthy people like themselves. In addition, as discussed earlier, the reference class of these measures is often unclear (Gigerenzer & Edwards, 2003). The authors conclude that errors in RR interpretation can be minimized by expressing the statistic as absolute risk, which may be easier to interpret because of the expression of the latter as a natural frequency (Gigerenzer & Edwards, 2003). For example, an earlier illustration of a 50% efficacious vaccine showed infection rate in controls was 2.8 cases per 100 person-years in the unvaccinated, but 1.4 cases per 100 person-years in the vaccinated. An ARR expression of this 50% efficacious vaccine would be an HIV risk reduction of 1.4%, with a 1.4% overall HIV risk after vaccination. Although Gigerenzer and Edwards (2003) posit that ARR measures increase clarity for patients, this seems to contradict the findings of Sheridan et al. (2003), where participants correctly chose the more efficacious treatment option more frequently when stated as RRR than when stated as ARR.

Besides statistical understanding, there are other aspects of VE that may be misunderstood, leading to incorrect assessments of personal risk. It is often left
unstated in the popular media that the VE measure—as a product of a randomized clinical trial—assumes equal exposure between vaccinated and unvaccinated groups (Halloran et al., 1991). However, HIV exposure in the real world is highly influenced by an individual’s behavior, where a person can increase or decrease exposure based on types and number of sexual encounters and risk reduction strategies used. An individual who has an exposure that is different than that in the clinical trial—via behavioral disinhibition, for example—will have a different infection risk based on the amount and frequency of exposure (Halloran et al., 1991). Furthermore, not clearly stated in the efficacy measure is that it is a population-based statistic that cannot be extrapolated to the individual level for personal risk assessment.

**Cognitive Processes and Perception of Risk**

Having the statistical reasoning skills alone is not likely to be sufficient to form a realistic self-risk assessment when considering an HIV vaccine. The capacity to cognitively process information about vaccines may limit understanding or an individual may not have the motivation to carefully reason through how an HIV vaccine may affect his or her personal risk for HIV. Relevant cognitive psychology will be reviewed here in an attempt to understand how individuals perform personal risk assessments.

*Fuzzy-Trace Theory*

According to Reyna, human rationality is constrained because of limitations in human information processing (Reyna, 2004). To conserve limited mental resources,
people can reason with mental processes that are “fast and frugal” or more intense, when the task demands it (Reyna, 2004). *Fuzzy-Trace Theory* explains these two processes and how people reason about risk using a dual-process model. When individuals attempt to remember something, they form two types of mental representations: *verbatim* and *gist representations*. Verbatim representations are precise representations of information that rapidly become unavailable to long-term memory. In contrast, gist representations capture an enduring “fuzzy” representation, which includes the conceptual and emotional meaning of an experience. Although both can be retrieved and used for reasoning, adults tend to rely on gist representations (Reyna, 2004).

For correct reasoning to occur, a gist representation must be stored correctly and retrieved appropriately (Reyna, 2004). *Fuzzy-Trace Theory* identifies four domains leading to risk estimation biases: knowledge deficits, representational biases, retrieval failures, and processing interference (Reyna & Adam, 2003). Knowledge deficits include a lack of adequate information to make a judgment about risk. Representational biases are errors that occur when forming mental representations of risk; because risk representations are likely to be gist-based and imprecise, they can lead to biases that underestimate or overestimate risk (*e.g.*, forming the representation that condoms protect against all STDs, and forgetting that some STDs are transmitted through skin-to-skin contact). Retrieval failures are failures of insight to recognize that certain facts are relevant for a reasoning task. Finally, processing interference are problems applying facts coherently to a reasoning task, even when a person in competent and has accurate knowledge to do so. Processing interference often occurs
when an individual is required to process many classes and thus gets overwhelmed by
the mechanics of processing (e.g., Reasoning through “all A are B, and some B are C”
and concluding that “some A are C.”).

There are many examples in the Fuzzy-Trace Theory literature on the difficulties
individuals have in using statistics for making risk assessments. One study with
physicians showed how faulty encoding of gist representations can lead to errors
(Reyna & Adam, 2003). In this study, Reyna and Adams predicted that physicians
would underestimate the risk of STD and overestimate the effectiveness of condoms.
The researchers’ predictions were based on the premise that estimating STD risk
involved managing multiple factors, or gists, and that created processing interference
in retrieving the correct representation for reasoning. The researchers successfully
predicted that condom effectiveness would be overestimated because of the imprecise
gist that condoms limit fluid-borne infections; however this same gist failed to account
for STDs spread by skin-to-skin contact, such as human papillomavirus (Reyna &
Adam, 2003). Thus, even among individuals knowledgeable in health, errors in risk
assessment occur that are independent of one’s store of information. The literature also
shows that this processing can become more accurate and efficient with experience.
For example, more experienced physicians have been shown to process fewer domains
of information to assess MI risk than less-experienced physicians, indicating that the
former are better at creating gist representations for MI risk (Reyna & Lloyd, 2006).

According to Fuzzy-Trace Theory, populations at risk for HIV may have
difficulty in accurately assessing their risk with an HIV vaccine. Knowledge deficits
and representational biases could lead to gist representations for vaccines that are

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inaccurate or imprecise. For example, if people's experiences with vaccines have been with high efficacy ones such as hepatitis B virus vaccine, then their gist representation for a vaccine might include the idea that "a vaccine keeps people from getting infected," implying that all vaccines work completely. Knowledge deficits could allow the public to subsume low-efficacy HIV vaccines into their current gist representation for other, more highly-ef ficacious immunizations. This representation will need to be overcome if the first HIV vaccines have a low VE, and is a potential point of health education on HIV vaccines. A more appropriate gist may be "an HIV vaccine lowers the chances of getting HIV."

Motivated Reasoning and Optimistic Bias

Although individuals may have the ability to understand and manipulate information about complex subjects, research in cognitive psychology has found that one must engage the relevant cognitive processes or heuristics in order to come to the correct conclusion. Whether or not an individual uses the correct processes can be affected by his or her motivation, independent of statistical reasoning skills, or the ability to form accurate representations.

In this context, Kunda (1990) defines motivation as "any wish, desire, or preference that concerns the outcome of a given reasoning task" (p. 480). Motivation may affect reasoning by allowing one to rely on a biased set of cognitive processes that are engaged to form decisions. This reliance would affect tasks such as forming impressions, determining one's beliefs and attitudes, selecting and evaluating evidence, and making decisions (Kunda, 1990). Depending on the motive, an
individual may desire to arrive at either an *accurate* conclusion or a *particular* conclusion. He or she will then use strategies that allow him or her to come to an accurate conclusion, or will employ those strategies that are more likely to result in a desired conclusion (Kunda, 1990).

Research has shown that when people strive to be accurate, they tend to expend more cognitive effort and to attend to relevant information more carefully (Kunda, 1990). The expenditure of this effort relies on weighing the cognitively energetic cost of arriving at an accurate conclusion versus the benefits resulting from this input of required energy. In other words, people must first determine what accuracy is worth before they decide it is a desirable goal. However, this begs the question of whether those motivated to be accurate actually can be more accurate simply by effort alone. Indeed, research shows that people motivated to be accurate use more complex strategies, and use fewer errors in reasoning, such as less anchoring, when making probability judgments (Kunda, 1990).

On the other hand, while it may seem that a lack of effort would allow someone to arrive at a desired (or directional) conclusion, “people do not seem to be at liberty to conclude whatever they want to conclude merely because they want to” (Kunda, 1990, p. 482). Kunda (1990) claims that people motivated to arrive at a particular conclusion attempt to be rational and to construct a justification of their desired conclusion that could persuade another. They draw the desired conclusion only if they can summon the evidence necessary to warrant it. In other words, they maintain an “illusion of objectivity” that is still constrained by reality.

Indeed, studies have shown how individuals can be motivated to reason towards
a particular conclusion, but can be forced to accept an undesired reality when the
evidence warrants it. In one study, undergraduate psychology students tested their
saliva for the invented enzyme “thioamine acetylase (TAA)” (Ditto & Lopez, 1992;
Ditto et al., 2003). All students were told they were TAA-deficient, however, one
group of students was told prior to testing that having TAA-deficiency had healthy
consequences, while the other was led to believe it had unhealthy effects. It was
postulated that the latter group would require more information to accept the test result
because it was inconsistent with their preferences. Indeed, those students told that
TAA-deficiency had unhealthy consequences were found to be more skeptical and
required more information to accept the test result, but eventually did. The TAA-
deficiency test result was also found to be more unexpected among the “TAA-
deficient” students (Ditto et al., 2003). The authors concluded that personally negative
information was given more attention than positive information—which was accepted
at face value—and that negative information was more likely to lead to motivated
reasoning (Ditto & D. F. Lopez, 1992; Ditto et al., 2003).

The work of Weinstein found similar themes as the studies above. Weinstein
(1980, 1982, 1984) looked at how people use the illusion of objectivity to prove to
themselves that they somehow have a greater probability than others of experiencing a
positive event. Weinstein refers to this as optimistic bias. Optimistic bias results from a
complex heuristic of competing factors whenever an individual assesses personal risk.
For example, the more undesirable an event, the stronger an individual’s tendency to
believe that his or her risk is lower than average. Conversely, the more desirable the
event, the stronger one believes he or she will experience that event. Bauman and
Siegel (1987) found this tendency among MSM, who perceived themselves to be less vulnerable to HIV than their peers. Counterbalancing this tendency is the propensity to believe that one’s risk is *greater than average* for an undesirable event when the population probability of that event is high (e.g., MSM risk for HIV infection) (Weinstein, 1982). Thus, these examples illustrate that optimistic bias may be a significant barrier to a realistic understanding of one’s own risk (Weinstein, 1980, 1982, 1984).

Optimistic bias may be a motivator to help an individual generate directional conclusions, and individuals may employ different strategies to effect different goals. Kunda cites *cognitive dissonance* and *biased memory search* as two strategies for effecting directional goals (Kunda, 1990). Cognitive dissonance theory holds that when one freely engages in behavior that has foreseeable negative consequences, an individual has the choice either to see himself or herself as bad or foolish, or to change his or her belief about the behavior. Faced with this threat to self-image, one may change his or her belief about the behavior to reduce the dissonance (Festinger, 1957). For example, a man who engaged in unprotected, anonymous sex—rather than believing himself to be a risky person—could conclude that his sexual partner was not a dangerous person with whom to have unprotected sex. In reviewing relevant studies, Kunda (1990) concludes that “dissonance is aroused only when one freely chooses to engage in behavior that has foreseeable negative consequences. These conditions suggest that dissonance requires a threat to self: the cognition that one has knowingly chosen to engage in bad or foolish behavior is inconsistent with a self-image as a decent and intelligent person” (p. 484).

In addition to cognitive dissonance, biased memory search is a directional
strategy (i.e., a strategy used to arrive at a desired or particular conclusion) used in evaluating one’s attitudes, traits, and preferences, that could, for instance, allow a person to see him or herself as above average by remembering only successes and not failures. It typically originates from a positive test strategy or hypothesis confirmation bias; people generate hypotheses that are in line with their beliefs and are biased toward seeking instances that will confirm those hypotheses (Kunda, 1990). Weinstein saw this when he stated that “risk factors that involve personal actions constitute a category that appears to be viewed in a consistently one-sided manner” (Weinstein, 1984, p. 433). That is, many individuals tend to have biased recall of their risk reduction actions, but not of their risk increasing actions. Furthermore, an individual demonstrates egocentrism in failing to realize that many others in his demographic group may practice the same risk reduction actions as that individual and still remain above-average in risk, while he continues to perceive his risk as below average (Weinstein, 1984).

In addition to being biased in how one sees him or herself, one may also interpret events differently based on his or her directional goals. “People may interpret their belief that an event has a 60% probability of happening to mean that the event is either slightly likely or somewhat likely to happen, depending on whether they want to view it as likely” (Kunda, 1990, p. 488). Individuals may even choose different statistical heuristics based on their directional goals. In one study cited by Kunda, individuals would consider the base-rate in evaluating likelihoods when advantageous, but ignore it in other cases (Kunda, 1990). In another study, subjects would employ the law of large numbers (i.e., the larger the sample size, the closer the sample value approaches
the expected value) to approximate the true mean when the effort was worth it to them; otherwise they were content with drawing conclusions from a smaller sample size (Kunda, 1990).

Motivated Reasoning and HIV Vaccines

The idea of motivation affecting reasoning has broad implications for how individuals utilize complex health information such as VE. Even if individuals have the ability to comprehend complex information about HIV vaccines, they may form differing conclusions for how this will affect their individual HIV risk. For example, individuals may choose to interpret the VE statistic (e.g., 75% efficacy) based on which interpretation is more beneficial to them (i.e., 75% is highly efficacious or 75% indicates low efficacy). Additionally, individuals may ignore their base-rate risk for HIV infection and conceive of efficacy as protection in absolute terms (e.g., a 75% efficacious vaccine translates into an HIV infection probability of 25%). This type of motivated reasoning may mediate behavioral disinhibition, if directional conclusions about HIV vaccines and risk assessment are what drive increased risk behaviors. Motivated reasoning may moderate behavioral disinhibition if another factor—such as an ignorance of HIV vaccine limitations—is on the causal pathway of increased risk behaviors.

Furthermore, as a very concrete action in risk reduction, HIV vaccination stands to increase optimistic bias and directional reasoning by several mechanisms. First, it may give an individual the perception that avoidance of HIV infection is controllable in unrealistic ways. Alternatively, it may lead individuals to focus on vaccination as an
action that reduces risk, regardless of actions that increase risk. Finally, the individual may fail to appreciate that many in his or her peer group also may have received the vaccine, yet the vaccine will not protect everyone. Because immunity would be viewed as a desirable event, an individual may be prone to believe that he or she is more likely to have vaccine-conferred protection. An HIV vaccine is designed precisely to reduce one’s vulnerability to an adverse event: infection. However, as Kunda’s and Weinstein’s work demonstrate, a concomitant rise in optimistic bias and directional reasoning may lead to an unrealistic appraisal of personal risk, leaving an individual to feel less need to continue safer sex behaviors.

**SUMMARY**

Recent epidemiological data show that an HIV vaccine continues to be needed in the fight against AIDS. MSM are a high-risk group in the U.S. that would benefit from such a vaccine. However, this review of the literature indicates that the intended use of a future HIV vaccine by those at risk for the virus may be at odds with the public health goal of reducing HIV incidence. These data are concerning because they suggest that an HIV vaccine may lead to behavioral disinhibition. Computer models have shown that behavioral disinhibition could actually exacerbate the HIV epidemic with a partially efficacious CMI vaccine, the expected first generation of HIV immunizations.

Lacking an HIV vaccine or a comparable model for an HIV vaccine, behavioral disinhibition is difficult to study. Some data, like those from the Vaxgen Phase III HIV vaccine efficacy trial, suggest that an HIV vaccine may result in behavioral disinhibition. However, it is unknown how an HIV vaccine may alter individual risk
assessment such that it leads to greater risk behaviors. Research in cognitive psychology indicates that people may be optimistically biased to believe that an HIV vaccine will benefit them more than others, and will accept limited evidence to convince them of that protection. Furthermore, Fuzzy-Trace Theory and research on heuristics shows how systematic errors in reasoning may lead one to mistakenly assess self-risk for HIV due to an HIV vaccine. Finally, research has shown that the lay public has difficulty in interpreting statistics, especially relative risk measures such as NNT and VE. Some researchers have suggested that the confusion stems from the fact that relative risk measures are unclear about their reference class.

Even though the public may have trouble understanding VE, many studies have shown that VE is one of the most important factors in the acceptance of a future HIV vaccine. It is reasonable that the public would be interested in VE as a way of assessing the magnitude of benefit from an HIV vaccine. However, given the lack of numeracy with such measures, populations at risk may struggle with accurately assessing their chances for HIV using the VE measure. No literature has been found that addresses public understanding of VE. Although many studies have surveyed the public about their perceptions of VE, none of these studies cited how VE was defined for study participants.

It is not essential that the lay public fully understand the concept of VE. However, the general population does need to understand it adequately in order to make accurate personal risk assessments with a future HIV vaccine. If people do not understand what efficacy means, they may not realize that a vaccine could fail to protect them as they believe. As no research has been done to describe how a
population at higher risk for HIV—such as MSM—conceptualize VE, having this knowledge could be crucial information in designing an effective intervention with the first generation of HIV vaccines.
PART TWO: AN INVESTIGATION OF THE UNDERSTANDING OF HIV VACCINES AND VACCINE EFFICACY AMONG GAY AND BISEXUAL MEN

OVERVIEW OF STUDY DESIGN

With a paucity of literature of understanding of vaccine efficacy (VE), an exploratory study was designed to generate hypotheses of how HIV VE understanding may influence use of an HIV vaccine. As an epidemiologically important population for HIV prevention efforts, gay and bisexual men were chosen as a focus of the study. This study sought to generate hypotheses for three research questions.

First, how would gay and bisexual men plan to incorporate an HIV vaccine into their current risk reduction practices? This question addresses how gay and bisexual men would want to change their current HIV avoidant behaviors after receiving an HIV vaccine.

Second, how might VE be understood by gay and bisexual men? The literature points to VE as primary in the acceptance of HIV vaccines, yet there have been no studies of public understanding of VE. This study explores how gay and bisexual men conceive of this construct.

Finally, how would an understanding of VE affect vaccine acceptability? A rational evaluation of VE would require both an understanding of one’s vulnerability to HIV as well as how a vaccine of a given VE would affect that vulnerability. This question seeks to better understand that decision-making process in accepting or rejecting an HIV vaccine based on its efficacy.

This study was conducted using qualitative methodology, interviewing gay and bisexual men in the San Francisco Bay Area with a semi-structured interview format.
supplemented by a demographic questionnaire. Qualitative methods were chosen as a way to obtain an in-depth understanding of a process that has not been well-characterized. As little is known about the public’s understanding of VE, a qualitative study was most appropriate to capture how individuals made sense of VE. In-depth interviews allowed the identification of heretofore unknown themes, which a quantitative study could not have detected without prior assumptions about VE understanding. Thus, qualitative methods were essential for this exploratory study’s objective of forming hypotheses about HIV vaccines and VE understanding among MSM.

**METHODS**

**Recruitment**

Purposeful sampling stratified by HIV-risk was conducted in order to capture variation within the group and to obtain a range of responses related to HIV vaccines on risk-perception and risk-assessment (Patton, 2002). Recruitment procedures were designed to ensure that both high- and low-risk men were enrolled in the sample by targeting venues likely to have representation of both subgroups. The initial goal for the study sample size was 25 men, a number with sufficient variability for qualitative analysis. The decision to enroll greater or fewer study participants than the initial goal was made during interim analysis, based on the criterion of theme saturation.

Recruitment was conducted both actively and passively. During active recruitment, potential subjects were approached at venues where gay and bisexual men were likely to be found, but where contact posed a minimal risk to privacy (e.g., cafés,
clubs, bars, street corners). The study was described to interested individuals and any questions were answered. At these venues, screening, consent, and interviewing were conducted immediately when it was more convenient for the prospective participant. In these instances, study communication ceased following completion of the interview. Passive recruitment involved the use of advertisements posted online and at community STD clinics (Appendix A), where approaching a prospective participant may have posed an unacceptable risk to privacy due to the sensitivity of the venue. Interested individuals themselves initiated contact with the study at a later time.

**Enrollment Screening**

Prospective participants were eligible for the study if they satisfied the following inclusion criteria:

- At least 18 years of age
- A male identified as gay or bisexual
- Presumed HIV negative (Because the study was interested in perceptions, documented HIV status was not required)
- Able to read and understand English

Eligibility screening took place either in-person or over the telephone. To avoid the recording of responses to sensitive questions such as HIV status, screening never took place over email. All documents containing contact information (e.g., email messages, voicemail messages, study screening forms) were destroyed on study refusal or at the conclusion of the study.
Enrollment screening by telephone: When a prospective participant initiated contact by phone or email, enrollment screening took place over the phone. If necessary, a phone number and time to talk was confirmed via the individual's preferred mode of contact (i.e., email or phone). The participant was given a brief screening (Appendix B). If the prospective participant indicated continued interest in the study, the individual was informed about the nature of the screening questions and it was verified that he was comfortable discussing them over the phone at that time. Responses to screening questions were not recorded. If the individual satisfied the inclusion criteria, he was invited to join the study. A meeting time and place were established and contact information confirmed.

Enrollment Screening in Person: If a prospective participant indicated it as his preference, in-person screening and enrollment occurred during active recruitment. In this scenario, study participation was completely anonymous. The prospective participant was screened according to inclusion/exclusion criteria. It was believed that accidental public disclosure of HIV status posed the greatest risk during in-person study screening. The prospective participant was taken to a nearby space away from other people due to the sensitivity of the HIV-status screening question, since it may have become obvious to others that an individual was disqualified because of his HIV status. In addition, two "dummy" questions about cigarette smoking ("Do you smoke cigarettes?") and health visits ("Do you get check ups with your doctor at least every two years?")
were included to obscure reasons for study exclusion. Screening responses were not recorded.

If the participant did not satisfy criteria during screening, but was interested in participating in HIV vaccine research, he was referred to the San Francisco Department of Public Health HIV Research Section for potential study opportunities.

Enrollment

Meeting places were chosen to balance each individual's comfort level and need for privacy. For example, some might have found an institutional setting intimidating, while others may have felt uncomfortable being interviewed in public. The prospective participant could choose to interview at the San Francisco Department of Public Health HIV Research Section or a public venue of his choosing, such as a café or restaurant. Interviews were not conducted at participants' homes.

At the interview location, the consent document was reviewed and any questions were answered. Understanding of study participation by the participant was checked prior to obtaining consent. Prospective participants were also encouraged to take more time to consider participation at a later date, if needed. If the individual agreed to take part in the study, verbal consent was obtained from the participant.

Interview and Questionnaire

The participant was interviewed using the questions in the interview guide. Interviews covered the themes of general vaccine knowledge, understanding of VE.
interest in HIV vaccines, understanding of HIV vaccine function, and anticipated vaccine impact on HIV avoidance and risk behaviors (Appendix C).

The interview was digitally recorded and lasted about one hour. Following the conclusion of the interview, the digital recorder was stopped. The participant was then given a written questionnaire that measured sexual risk perception and collected demographic information (Appendix D). The participant was allowed to respond to this questionnaire in private.

The demographic questions collected information about age, race, county of residence, income, education level, occupation, and primary partner status. Income levels on the demographic questionnaire were based on the 2006 median income levels as determined for the San Francisco Primary Metropolitan Statistical Area by the U.S. Census (Mayor's Office of Housing: 2006 Income Limits For Housing Programs, 2006). Sexual risk perception items were obtained from questions previously developed at the San Francisco Department of Public Health HIV Research Section (S. Buchbinder, personal communication, June 1, 2007).

Both the interview transcript and questionnaire were given an identification number to link these records.

Participant Education

Following the interview and questionnaire, the participant was given an opportunity to ask questions. At this point, the interviewer addressed participant misconceptions about HIV vaccines that arose during the interview (e.g., vaccines cure disease) and provided resources for additional information on HIV vaccines.
Remuneration

Following completion of the interview and questionnaire, participants were given $25 cash as compensation for their time and effort.

Human Subjects

Human subjects approval for the study was obtained from the institutional review boards of both the University of California, San Francisco, and the University of California, Berkeley.

Analysis

The demographic data were linked to the interview data. Participants were stratified into high- and low-risk groups based on their interview and questionnaire responses. Classification of participants into these strata relied on qualitative criteria, took participant narratives into consideration, and did not rely on quantitative thresholds for HIV risk. Subjects were considered high-risk if they reported anonymous sex, unprotected sex, or anal intercourse with people of unknown HIV serostatus; inconsistent condom use; or sex while intoxicated or high on drugs. Subjects were classified as low-risk if they were in exclusively monogamous relationships; reported consistent condom use; or avoided riskier behaviors such as unprotected anal intercourse and injection drug use. These stratifications were used to draw comparisons between risk groups for HIV vaccine perceptions and understanding.
**Qualitative Data Analysis**

The digital recordings of the interviews were transcribed and entered into the qualitative analysis software TAMS Analyzer, version 3.41b4, which was used for analysis of the interview responses (M. Weinstein). A modified version of grounded theory was used to form hypotheses about gay and bisexual men’s understanding of HIV vaccines and VE using an adapted method of Strauss and Corbin (Strauss & Corbin, 1998). All transcripts were read multiple times to identify principal themes of interest based on the study objectives. A list of codes was elaborated based on these initial readings, and these codes were applied to relevant passages in the text. The outputs of this coding process were then reviewed for similarities and differences within and between groups. Finally, quotes representing each domain were reviewed within the context of the full text of the interview to contextualize and confirm their interpretation. Transcripts were analyzed concomitantly with interview administration so that interview questions could be modified to clarify emerging themes in the analyses.

**Quantitative Data Analysis**

A small sample size was sought to achieve qualitative data objectives. The number of participants enrolled was not sufficient to be generalizable to the greater population of gay and bisexual men. Nevertheless, in some limited instances, univariate statistical testing was done as a way of informing understanding of the qualitative differences seen within the sample, especially between high- and low-risk groups. Student’s t-tests to compare means between groups and a z-test for
proportions were conducted when appropriate.

RESULTS

Results will begin with a description of the study sample, including differences seen between high- and low-risk groups. A discussion of themes that emerged from participant interviews will then follow.

DEMOGRAPHICS. A total of 19 subjects were enrolled. The study group was diverse in most respects (Table 1). The mean age was 37.2 years, with a range of 19 to 67 years. The sample was also diverse in terms of race, education, and income. White, African-American, Asian-American, and Hispanic-American groups were represented. It was a well-educated group, with 63% having a bachelor's degree or higher. Yet, the group also was highly represented by those with low income, with 52.6% with annual incomes under $23,750. Overall, the group reported an average of 7.2 sexual partners in the past 12 months, with a range of 1 to 30 partners in that time period. None of the study subjects had been former vaccine trial participants.

Differences were noted between high- and low-risk groups. The high-risk group was both older (47.8 years vs. 30.7 years, \( p < 0.01 \)) and was more highly represented by White men (\( p < 0.05 \)), while the low-risk group had a greater representation of minorities. The high-risk group also reported a greater mean number of sexual partners in the past 12 months (14.1 persons) in comparison to the low-risk group (2.8 persons, \( p < 0.01 \)).
TABLE 1. Demographic and Sexual Behavioral Characteristics for Study Participants Stratified by HIV Risk Level

<table>
<thead>
<tr>
<th></th>
<th>High-Risk (n = 8)</th>
<th>Low-Risk (n = 11)</th>
<th>Overall (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in Years (Mean, Range)</strong></td>
<td>47.8 (35 - 67)*</td>
<td>30.7 (19 - 38)</td>
<td>37.2 (19 - 67)</td>
</tr>
<tr>
<td><strong>Race % (n)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>75%§</td>
<td>27.3%</td>
<td>52.6%</td>
</tr>
<tr>
<td>African-American</td>
<td>25%</td>
<td>18.2%</td>
<td>21.1%</td>
</tr>
<tr>
<td>Asian-American</td>
<td>0%</td>
<td>36.4%</td>
<td>21.1%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>0%</td>
<td>9.1%</td>
<td>5.2%</td>
</tr>
<tr>
<td><strong>Highest Education % (n)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>12.5%</td>
<td>18.2%</td>
<td>15.7%</td>
</tr>
<tr>
<td>Some college</td>
<td>37.5%</td>
<td>27.3%</td>
<td>31.6%</td>
</tr>
<tr>
<td>College</td>
<td>37.5%</td>
<td>27.3%</td>
<td>31.6%</td>
</tr>
<tr>
<td>Post-graduate</td>
<td>12.5%</td>
<td>27.3%</td>
<td>21.1%</td>
</tr>
<tr>
<td><strong>Annual Income % (n)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $23,750</td>
<td>62.5%</td>
<td>45.5%</td>
<td>52.6%</td>
</tr>
<tr>
<td>$39,600 to $63,349</td>
<td>25.0%</td>
<td>27.3%</td>
<td>26.3%</td>
</tr>
<tr>
<td>$63,350 to $79,799</td>
<td>0.0%</td>
<td>18.2%</td>
<td>10.5%</td>
</tr>
<tr>
<td>$79,800 to $99,749</td>
<td>12.5%</td>
<td>9.1%</td>
<td>10.5%</td>
</tr>
<tr>
<td><strong>Sexual partners in the past 12 months (Mean, Range)</strong></td>
<td>14.1 (1 - 30)*</td>
<td>2.8 (1 - 10)</td>
<td>7.6 (1 - 30)</td>
</tr>
</tbody>
</table>

* Indicates significant difference between high and low-risk participants (p < 0.01).
§ Indicates significantly different proportion of White men in high-risk group compared to the low-risk group (p < 0.05).

EMERGING THEMES FROM PARTICIPANT INTERVIEWS. In the discussion of HIV vaccines, several themes emerged in the interviews that were directly related to HIV vaccine understanding and perceptions. Other themes arose that were not explicitly connected to HIV vaccines, but were relevant to how participants perceived HIV risk. These included the perceived ability to control HIV risk; optimistic bias in HIV risk.
perception; and vaccine perceptions and understanding. The last theme included the subthemes of intended use of an HIV vaccine and understanding of vaccine efficacy.

Perceived Ability to Control HIV Risk

One theme that emerged was the ways in which high- and low-risk men talked about HIV risk. High- and low-risk men showed different perceptions of their ability to control HIV risk. In general, high-risk men indicated less perceived control over the sexual behaviors that influenced HIV risk than low-risk men. For example, one high-risk individual said that he could not explain why he engaged in unprotected sex, describing it as a mystery that defied reason:

"I do, occasionally have unprotected sex. Now you might think in your mind, after all that I saw, why would I do that? Well, it’s a good question. I don’t know if I have a good answer. It’s a good question. I didn’t die then. I had a lot more unprotected sex than I do now. I don’t know why. I had no idea why. Do I feel invincible? No. There’s nobody that’s invincible. Do I feel I have an immunity? No. I don’t feel I have that either."

Another high-risk man explained that the impulse to engage in unprotected sex was like a force that could control him completely:

"Because life is like a probability, you know, and if you see somebody that you met like I described, this particular one, this particular case, you get so high that it’s a mechanism that you cannot say no probably. It’s very, very hard to say no. It’s like the adrenaline is up and you felt yourself powerless."

This was in contrast to low-risk men, who identified HIV risk as a source of anxiety that could be reduced by personal action:

"Yeah, I mean, I have to really think about that because I’m not engaging in any risky behaviors. I think it would be more about allaying more of my personal anxieties around HIV. Yeah. Cause I mean I can’t imagine being fucked without a condom. It’s non-negotiable and it always has been for
Another low-risk participant reiterated that perspective, acknowledging that a small part of his HIV risk was uncontrollable, but also describing the several steps he could take to minimize that risk:

"But there is, you know, condoms, like I said, are 99% effective if used correctly, but there’s always a one percent chance that they don’t work, and if there’s fluid transmission, like even accidental, you want to make sure that you’re safe. And it’s, you know, just in a sense that because I’m sexually active and that’s a possibility for me. Like contraction of a disease is possible when there’s the potential for fluid exchange. Like because I’m at risk, because I’m participating in that kind of behavior, I need to do everything that I can to protect myself. And that includes like making wise choices. Like obviously choosing the partners; choosing the right – the behaviors. But that also extends to, like, you know, vaccinations and medicines and things of that nature."

Optimistic bias in HIV risk perception

Interview analysis provided evidence of optimistic bias in HIV risk perception within this sample. One high-risk participant rated his risk of contracting HIV as “less likely” than other MSM, although he reported 30 sexual partners within the last 12 months and described engaging in unprotected insertive anal intercourse:

“No condoms or what have you, but I don’t have anal intercourse. I’m a top, and so my preference is that tops don’t get AIDS, only bottoms get AIDS. So that’s my, you know, my preference.”

The above is an example of frank misunderstanding of risk that leads to optimistic bias. However, this bias can also exist in more subtle ways.

Another high-risk participant considered his risk for HIV to be “much less likely” than other gay and bisexual men, which was the lowest possible rating for
perceived HIV risk. He reported 15 sexual partners in the past 12 months, and in the beginning of the interview, he described himself as having very little risk for HIV:

“Oh, [I am] very low risk. Maybe I’ve had maybe two unprotected sex sessions, you know, in, like, the last three years.”

Later in the interview, this number increased slightly, raising some question about the veracity of his risk reporting:

“I had about 3 slips.”

Further on, the participant reflected on his risk, drawing a comparison with others whom he may have thought had a similar risk for HIV as he:

“I’ve met several young people that did it ‘one time’, that one time and that’s when they caught AIDS. I know one kid that—he used a dirty rig once and never shot up before in his life. He shot up with his friend and caught AIDS. I know one guy boy that had sex one time and the one time he had sex he caught AIDS. So, even though my numbers are small, I know that I’m still spinning a roulette wheel.”

The participant seemed to view the people in the anecdotes as low-risk, like him, but who were unlucky. Consequently, he acknowledged that his own behaviors could place him at risk for HIV, even though he previously described himself as “very low-risk”. Compared to other gay and bisexual men that he knows, he believed himself to be low-risk, neglecting to consider other, even lower-risk gay and bisexual men. It appears that by failing to compare himself to both MSM who are at lower and higher risk than himself, he arrived at a biased estimation of his HIV risk.

These results suggest that a certain proportion of the study sample—especially in the high-risk group—did exhibit optimistic bias. They made comparative risk judgments without considering the risk status of others or using a stereotyped
representation of a high-risk person. Consequently, they assume that they are better off than most others (Weinstein, 1983, 1984).

Analysis of the questionnaires also provided support for optimistic bias within this sample. Participants were asked to rate their lifetime risk for HIV compared to other MSM using a Likert scale (1 = "Much less likely", 5 = "Much more likely"). They were asked the following question: "Using the following scale, compared to other men who have sex with men, how likely do you feel it is that you will be infected with HIV in your lifetime?" According to Weinstein (1980), a group not demonstrating optimistic bias would have an item response mean that was approximately average risk (3 = "About the same"), while a group exhibiting this bias would have an item response mean that was lower than average risk. In this group, the mean was 1.74 ($T = -8.37, p < 0.01$), indicating that the group as a whole was optimistically biased about their personal risk for HIV infection.

The group also was stratified into high- and low-risk groups for an analysis of optimistic bias. The mean lifetime perceived risk for HIV was 1.45 in the low-risk group and 2.13 in the high-risk group, a statistically-significant difference ($T = 2.12, p < 0.03$), indicating that the low-risk group had a lower average perceived risk for HIV than the high-risk group. However, the high-risk group continued to perceive themselves as having a below-average risk for HIV, indicating optimistic bias within this group as well ($T = -3.87, p < 0.01$).
Vaccine Perceptions and Understanding

Analysis of the interviews led to the development of themes about vaccine perceptions and understanding. Two primary themes emerged during analysis: intended use of an HIV vaccine and understanding of VE.

Intended Use of an HIV Vaccine

As described in the methods, interim data analysis led to the addition of a question regarding participants’ intended use of an HIV vaccine; thus some initial participants were not asked this question. Seven intended uses emerged from the remaining interviews (Table 2). A participant could report more than one intended use of an HIV vaccine. These desired uses of HIV vaccines differed between the high- and low-risk groups. These uses showed very little overlap between the risk groups. Individuals in the high-risk group cited uses that could potentially increase risks of an STD. On the other hand, men in the low-risk group provided uses that maintained a low-risk status. Within the high-risk group, the two most often cited uses were to manage one’s current high risk for HIV due to risk behaviors and to increase opportunities for unprotected or anonymous sex. Within the low-risk group, the predominant intended use was as backup for current risk-reduction practices. Each of those uses will be separated by risk group and explained in the following discussion, with examples provided from the interview text.
### Table 2. Intended uses of an HIV vaccine as a proportion of reported uses, stratified by HIV risk group

<table>
<thead>
<tr>
<th>High-Risk Group (n = 9)</th>
<th>%</th>
<th>Low-Risk Group (n = 9)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backup for current practices</td>
<td>11</td>
<td>Backup for current practices</td>
<td>66</td>
</tr>
<tr>
<td>Manage current high risk for HIV</td>
<td>33</td>
<td>Unintended lapse in current risk-reduction methods</td>
<td>22</td>
</tr>
<tr>
<td>Protect others</td>
<td>11</td>
<td>For use within a relationship</td>
<td>11</td>
</tr>
<tr>
<td>Have more opportunities for unprotected or anonymous sex</td>
<td>33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoid discussion of HIV status with sexual partner</td>
<td>11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: A single individual could report several uses for an HIV vaccine, and some individuals reported none. These percentages represent a proportion of the total number of intended uses and not the relative prevalence of intended uses within a risk group. n = the number of responses provided.*

**Intended uses for an HIV Vaccine within the low-risk group**

To have a backup for current practices. This theme involved having an HIV vaccine as an additional method for risk reduction. This appeared to be a greater concern among low-risk participants. The need for backup was articulated as protection from an unknown risk or as protection from unforeseen events that would lead to HIV exposure despite use of risk-reduction practices (e.g., condom breakage). One low-risk participant stated it as such:

“A lot of people, even if they know that they’re indulging in safe sex, they still think that ‘oh there’s still a possibility that I’m going to get the virus, because I’m having sex with a positive person’. It’s just the idea that, you know, that the person that you’re with is positive, you know. So if there’s an HIV vaccination, then somehow, you know, you’d be more comfortable, you know.”

The preceding example presented a presumption in low-risk men that appeared to be common: without proof, their sexual partners were HIV positive. Even without the possibility of being with an HIV-positive partner, low-risk men in general wanted to minimize risk as much as possible. Said one low-risk participant about HIV
vaccination:

"I’m not really one that’s highly predisposed to infection, because my sexual behaviors are minimal or not very much at risk. But I would probably do it just to be safe, you know. Just having that peace of mind."

To manage an unintended lapse in current risk-reduction methods. This use was defined as an unpredicted, unintentional lapse in what one normally does to protect oneself from HIV. This was a use cited by men in the low-risk group. One low-risk participant gave the following hypothetical situation:

"It would just be a backup to the safe sex behavior... So if I’m taking a 50 percent vaccine, and I slip twice, then I’m hoping, although you never know, that that’s going to cover those two times. Maybe it’s one of those times, so I’m still fucked. But if I have 50 percent coverage, and I slip twice in a year, I think those are pretty good numbers."

To use within a relationship. This domain was also unique to low-risk participants, who seemed to feel at higher risk for HIV with increased sexual intimacy, even in the context of a monogamous relationship. One participant stated:

"If the relationship continues to grow to a level that I cannot avoid a sexual relationship, it’s, yeah, probably it would be better to have a vaccine."

Some participants communicated that even in a monogamous relationship, HIV risk was still uncontrollable and unpredictable. One participant expressed it like this:

"And, like what I told you, I’m in a monogamous relationship for 4 years and, you know, I, myself, since the monogamous relationship, you know, most of the time we were practicing unsafe sex. And, you know, now that we’ve broken up, you know, I really don’t know when we were together if he had any, you know, like, affairs with other people."

Intended Uses for an HIV Vaccine within the High-Risk Group

To protect others. Protecting others was a use stated by one high-risk participant who reflected that his behaviors entailed risk for those with whom he came in sexual
contact. In this context, a vaccine would be useful for avoiding HIV transmission to sexual partners if one is unknowingly HIV positive. In speaking about his reasons for wanting an HIV vaccine, this participant stated:

"Well, prevention, of course, which in turn means not being able to hurt other people."

To manage current, high HIV risk. Most intended uses of an HIV vaccine by men in the high-risk group were for the purposes of minimizing risk while continuing the behaviors that currently make this group highly susceptible to HIV infection. One reason high-risk men wanted an HIV vaccine was to use a vaccine to mitigate the risk of current, unprotected sex practices. One high-risk man explained why he wanted an HIV vaccine:

"Well, survival. I mean, you know, anything that beats the odds. I'm perfectly susceptible of contacting AIDS, you know, still, although I've survived my youth and that's when I was very promiscuous."

This same man denied that a vaccine would induce him to have more sex, but that it would serve to protect him from the risk of his current sexual practices:

"No, it wouldn't change. It wouldn't change my sexual preferences. And it wouldn't make me more promiscuous either. I'm pretty much, you know, I'm old and so I can see, you know, younger people, if they get the cure then they'll go out and have more sex, but not me. I'm set in my ways."

Several other men in the high-risk group also expressed that a vaccine would be important for minimizing their perceived risk:

"I haven't been the most careful person in the world. I'm concerned I could catch it, do you know what I mean? [...] my sexual practices are not exactly the safest. And um, so they're kind of concerning. Especially it's a high rate in the city. It's kind of scary to be with... certain people."
Another man expressed a similar perspective:

"Sexually? I sleep around. And not always safe. And so the concept of it is. It would make, it would make things a lot less touchy for me. You know? The concept. I mean, cuz, yeah, [HIV] still runs rampant."

**To avoid discussion of HIV status with sexual partners.** Using an HIV vaccine to avoid discussion of HIV status was cited only by high-risk participants. These participants saw an HIV vaccine as an opportunity to avoid a discussion of HIV status:

"Cause then I wouldn’t have to – well yeah I wouldn’t have to ask the person because if I’m protected from it, it wouldn’t matter if they’re positive or not and I wouldn’t have to ask them or worry about what they were or anything like that."

Another perspective was that an HIV vaccine would be one way of avoiding a potential barrier to sex:

"Cause then I wouldn’t have to – well, yeah, I wouldn’t have to ask the person, because if I’m protected from it, it wouldn’t matter if they’re positive or not, and I wouldn’t have to ask them or worry about what they were or anything like that."

**To increase opportunities for unprotected or anonymous sex.** Utilizing an HIV vaccine to increase opportunities for unprotected or anonymous sex was a domain cited exclusively by the high-risk group. Within this study group, an HIV vaccine was seen to provide many potential benefits. High-risk participants stated that a vaccine would allow them to engage in sex that was forbidden or that provided greater sensation. For example, one high-risk participant drew a comparison with the effect of HIV antiretroviral therapy (HIV cocktails) on sexual behavior:

"I wonder, it might have a large effect, I mean the, ahm, the cocktails had a large effect. Yeah. I think anything that you, that that you put out there, y’know, there’s a certain amount of the population, that’s gonna grab it. Because it’s a certain allure of, y’know, having sex bareback."
Many also thought that an HIV vaccine would increase the ability to be spontaneous with their sexual partners, something that current risk-reduction practices were seen to hinder:

“Well, it would just, you know, it would just make it more – I mean for anybody, you know, I’m sexually active, so it would just be nice to not have to worry all the time about whether or not you’re going to – or to not have to be like always stop and take precautions, you know, be more spontaneous.”

An additional perceived benefit of an HIV vaccine was that it better enabled one to engage in anonymous sex. One participant related how an HIV vaccine may facilitate anonymous sex:

“Yeah sometimes at a bar that I go to, a gay bar. And sometimes, like a park or something at night, you know, a park where guys go. So that’s very anonymous and not... you know, I don’t feel comfortable like asking a complete stranger things like that so I just do what we do without questions.”

Overall, these benefits were perceived to be available due to a reduced anxiety that accompanied unprotected sex:

“I guess was thinking, with me, I could sleep around more. It would, like, eliminate the terminal edge to unsafe sex... Yeah, in my head the vaccine creates availability of situations that aren’t available. It would be a Superman outfit.”

Understanding of Vaccine Efficacy

There were several themes that emerged about how participants understood VE. These included awareness of the VE concept; confusion about reference classes; representational-errors in heuristics used for interpreting VE; and arbitrary criteria used to evaluate VE. Confusion about VE was common. Not a single participant could correctly define VE. No differences were observed between high- and low-risk groups.
in VE understanding. In the following discussion, themes will be explained, while providing examples from the interviews.

**Awareness of vaccine efficacy concept.** Many participants had never heard of the term “vaccine efficacy” before the interview. Several were under the impression that a licensed vaccine on the market had been proven to fully protect those who had received it:

“I don’t know, ‘cause I never knew there was such a thing. I thought vaccines were—by the time they were, like, available, or they were called a vaccine, that they were a 100%.”

The novelty of the efficacy concept to these participants meant that these individuals were being asked to create an understanding of VE for the first time during the interview.

**Confusion about reference class.** The value for HIV VE refers to the relative risk of HIV infection of vaccinated individuals compared to unvaccinated individuals (Halloran et al., 1991; Orenstein et al., 1988). The reference class of VE is unvaccinated individuals. As discussed in the literature review, the reference class of VE is not explicit in its percent value. No participant correctly defined the meaning of VE and participant responses indicated that there was confusion as to what the correct reference class was.

A common belief about VE was that it referred to the proportion of immunized individuals who were protected by a given HIV vaccine:

“I think that in 97% of the subjects, perhaps that they experimented on prior to it being released on the market it was effective, and maybe 3% it isn’t. I guess there’s variation in human beings and maybe in some people for a variety of reasons it just wouldn’t work.”
Another belief was that VE referred to the proportion of HIV exposure events in which it prevented infection:

"Um... I would think maybe... 95 out of 100 that it actually protected. I don't know. Like if they take the antibodies, just by that, and put the HIV virus to it, 95% of the time the AIDS virus didn't make it through."

Of those who believed that VE referred to the proportion of protected exposure events, one participant had a deterministic variation on this concept, believing that his actions could help determine when an HIV vaccine would be protective:

**Interviewer:** So say you got this vaccine that's 50% efficacious, how do you think it would change your sex life?

**Respondent:** Have less of it.

**Interviewer:** You'd have less?

**Respondent:** Because I still wouldn't be for sure, you know, if it's not a hundred percent. If it was a 100%, you know, I'd have more. But if it's like at, you know, still like there's a possibility you could get it, I would have less, cause I want the vaccine to work.

Finally, some participants believed that the reference class of VE was the proportion of HIV that the vaccine reduced in the body. Similarly, some thought that efficacy referred to the proportion of virus prevented from entering the body. As one participant said, "It'll get 97% of the virus out of your body."

**Representational-errors in heuristics used to interpret vaccine efficacy.**

When participants were able to articulate how they chose their value for VE, they appeared to make representational errors in the heuristics used to interpret VE. Many subjects believed that an HIV vaccine with 50% or lower efficacy would provide a protection against HIV infection that was no better than chance. Respondents explained that at 50% efficacy, the chance of protection was equal to the chance of non-protection, when in reality, a 50% efficacious vaccine would reduce the infection rate
in half. This seems to indicate these participants perceived VE to be equivalent to simple probability.

The following quotation from one participant illustrates how the value 50% triggered retrieval of a heuristic that led one to conclude that a process was no better than chance:

“But if [the vaccine efficacy] was like 50%, you know, I probably wouldn’t do it. It would just be like flipping a coin and that wouldn’t be enough. It’d still be as random. Still be as random as no condom.”

Another participant reiterated that perception, saying that a vaccine of 50% efficacy would be equivalent to having unprotected sex during half of his sexual encounters:

“Well, that would mean about half the time I’m having (unprotected) sex you know... you know that half of that could be not the real thing. So to me [vaccine efficacy of] 50% would be the cutoff.”

Again, the view that a vaccine must be over 50% to provide protection was given support:

“I don’t like fifty-fifty. That’s, that’s too half-and-half. I, uh, would rather see, you know, the larger number. Aw, because that must mean it’s working. It’s doing something.”

In this study sample, there was a considerable lack of awareness of the VE concept. There are also many misconceptions about the meaning of VE that stem from ambiguity about the reference class referred to by VE as well as representational errors of VE as a simple frequency.

**Arbitrary Criteria for Vaccine Efficacy.** In these interviews participants spoke about how they would determine an acceptable VE for an HIV vaccine. Further exploration revealed that their criteria were often not based on a calculation of whether
a given efficacy would raise or lower risk. There was frequently an arbitrary nature to their criteria, in that vaccine acceptability seemed to be based on personal heuristics with limited relation for evaluating probabilistic risk. Presented below are representative responses to the question, "What is the lowest efficacy you would accept for an HIV vaccine?"

Some individuals based an acceptable VE on prior experience with what they thought was a good number, even if that comparison had no relevance to vaccines, risk assessment, or interpretation of health information. One participant, exemplifying this approach, based his criterion on what constituted a passing grade in school:

"Back to schoolboy days. 70%. C-minus. I say C-minus. That seems about right. 70% seems, I mean. I still have that sense of protection, you know, sense of security."

Still others picked levels of VE based on a feeling that they could not articulate. They had a sense of what a good number was, yet that number did not appear to be subject to intense scrutiny:

"The reason that I would say 80 is just a personal, a personal thought of my own. Would 75 change me any, well probably not, you know. I mean it’s just 5 away so it’s not like it’s a big... you know."

It was mentioned that many participants prior to this study had stated that they had not heard of the concept of efficacy. Lacking any knowledge of what VE was, these individuals had no heuristic to rely on for what they would accept. One such participant emphasized how arbitrary the criteria could be when he said that in regards to his value for acceptable VE, stating he "just picked it out of a hat."

All individuals in this study preferred a vaccine that had the highest efficacy possible. High-risk individuals, however, were more likely to accept a vaccine of lower
efficacy. High-risk participants, however, seemed to acknowledge that even partial protection from a vaccine was preferable to the high risk of exposure they currently experienced. Statements from two high-risk individuals provide examples of this sentiment:

"Of course the best protection is 95 or better but if it’s 50% the best I can get that would have to be you know."

"50 is pretty useful. You know what I mean. It's... I mean, if it's not harmful. You know, it's worth a shot whatever the percentage. My point is it would be nice to be more of a confident thing to start taking, start receiving something like that knowing that, you know, chances are higher because it would be kind of a disappoint to, you know, get your hopes up and then it not work."

On the other hand, low-risk individuals tended to see little benefit and even some risk in a low efficacy vaccine. One participant, whose lowest acceptable VE was 90%, felt that anything lower would present unacceptable risk for HIV exposure:

"You know everything – this is how life is. Everything is pretty much a risk. There’s always something that’s going to go wrong or I guess it’s just me being pessimistic."

Another low-risk participant reiterated the perception that acceptance of a low-efficacy HIV vaccine was a form of risk taking:

"Cause that tells me that it's, you know, it's not a 100% effective or it's not effective enough where it’s justified to do it; to take all the risk."

**DISCUSSION**

**Summary**

In this exploratory study, individuals of both high and low risk for HIV completed interviews on their perceptions of HIV vaccines and understanding of VE. Men in the high-risk group were found to differ from the low-risk group in terms of the
ways that HIV risk assessment and perception related to HIV vaccine perceptions. Members in the high-risk group provided intended uses for an HIV vaccine that would increase sexual risk, while those in the low-risk group cited uses that tended to decrease that risk. The two groups had almost no overlap in this regard. There also were suggestions that the high-risk group was more willing to accept an HIV vaccine of lower efficacy. Biased assessment of HIV risk and a lower perceived ability to prevent HIV infection among men of the high-risk group may explain some of these differences. Overall, no participant had a correct understanding of VE. There were several identified reasons for this, including low awareness of the VE concept, confusion about the reference class in VE, and misrepresentation of heuristics in the interpretation of VE. If corroborated by future research, these results have concerning implications for how understanding of HIV vaccines and VE may impact personal risk assessment.

Limitations

Implications of these findings can inform future work in this area of research, although as a small, qualitative study, there are several factors that affect the generalizability of the results. First, data in this study depended on self-report of participant behaviors. In dealing with sensitive issues, interviewer bias is a considerable concern in any study that asks participants to report information that may be private, uncomfortable, or stigmatized. While some discrepancies were found in a few participant interviews (e.g., variation in the number of sexual partners), all participants talked openly about sensitive aspects of their sexuality, such as potential
exposure events, sexual acts that they may have engaged in, the ways in which they have sought sexual partners, and their own perceived risk factors for HIV. It is impossible to know the veracity of participant reporting, and this may have somewhat impacted the accuracy by which participants were grouped into low- and high-risk groups (although details within the interview, and between the interview and questionnaires were largely congruent). However, based on the richness of data collected, it was felt that talking about perspectives in this context was not overly threatening.

Secondly, this was a qualitative study with a small sample size. Thus, this study group is not representative of the larger gay and bisexual community. For example, the San Francisco Bay Area is a tolerant environment for gay and bisexual men. Responses in this location may not be representative of MSM who live in less tolerant locales. Collected perspectives on HIV vaccines may be unique to San Francisco and other similar metropolitan areas where information on HIV/AIDS prevention may be more available. Though not collected from a representative sample of gay and bisexual men, the results of this exploratory study may still inform future research in this area.

In addition, efforts were made to enroll individuals of different risk levels; data collected indicate this was successful. However, participants motivated to take part in the study had a reason for their interest. Sampling bias may have resulted in a lack of representation from those uninterested in HIV vaccines; this could have biased the representativeness of the responses and decreased the generalizability. Furthermore, analysis of demographic data show that two main groups of people enrolled in the study: older, high-risk men and younger, low-risk men. This suggests that young, high-
risk men and older, low-risk men may have been missed in this investigation. While viewpoints of unsampled groups will be important in future studies, high- and low-risk groups in the study showed commonalities in their understanding of HIV vaccines. Furthermore, there are a finite number of ways in which one may intend to use an HIV vaccine. A diverse range of responses was collected in these interviews, and as more participants were enrolled, responses began to demonstrate repetition. This suggested that saturation of themes was being approached.

On the issue of the validity of findings, it was observed that many individuals had never heard of the term VE prior to participation in this study. Interviewing itself may have introduced bias. For example, before asking individuals to state their lowest acceptable VE, these men were asked to interpret the meaning of a 97% efficacious vaccine. This may have introduced anchoring bias that skewed their answer to the subsequent question (Tversky & Kahneman, 1974). Furthermore, asking these individuals to interpret the meaning of VE with no prior thought may not reflect how they would interpret this concept in the future. However, the fact that few had heard of VE prior to the study is itself a finding. The methodology of many studies on HIV vaccine acceptability queried participants to rate an acceptable efficacy (Liau et al., 1998; Liau & Zimet, 2001; Zimet et al., 1997). It can be inferred that those authors assumed the subjects understood what efficacy meant, when in fact, findings from this study indicate the opposite.

An additional limitation is that participants were asked to speculate about something that does not yet exist (an HIV vaccine) and to predict their future feelings. Studies have found that people are often inaccurate in predicting how they may act or
feel at a future time. For example, Weinstein has found that an individual’s prediction of the future tends to be optimistically unrealistic (Weinstein, 1980). Despite the possibility that study participants may have been inaccurate about their future selves, this study identified issues of concern—such as vaccine misperceptions and misinformation—that are important to HIV vaccine education. Individuals may indeed change their minds about how they may utilize an HIV vaccine, however, it is important to understand their misconceptions so that HIV vaccine education enables informed decision-making by all, especially those who are unrealistically optimistic about their risk.

**Tentative Findings**

**Vaccine use and behavioral disinhibition.** Van de Ven et al. (2002) found that one dimension of MSM’s interest in HIV vaccines was the prospect of sexual freedom. The results of this study are consistent with that finding in part. Among high-risk men in this sample, themes of HIV vaccine use—such as increased opportunities for unprotected or anonymous sex and removing the necessity of HIV status discussion with sexual partners—are examples of the desire for increased sexual freedom. However, this study also found that low-risk gay and bisexual men had different reasons for wanting an HIV vaccine. In general, low-risk men reported intending to use an HIV vaccine to reinforce their low-risk status. This included using an HIV vaccine as backup for current risk-reduction practices; for use in case of an unexpected lapse in risk-reduction practices (in contrast to the high-risk men’s anticipation of using a vaccine for a predictable, inevitable lapse in risk-reduction); and in the context of a
relationship. Strikingly, there was almost no overlap between the two groups in stated uses. In another study surveying HIV vaccine attitudes, the authors did not stratify perceptions by risk level (Van De Ven et al., 2002). The present study illuminates additional attitudes about HIV vaccines among relatively low-risk gay and bisexual men that have not been found previously. Further research in this area could explore whether behavioral disinhibition may manifest differently in high- and low-risk MSM.

The results do allow some speculation on why these differences were seen. Low-risk men’s intention to use a vaccine in the context of a relationship seemed to exemplify the high degree of risk aversion in this group. Even within a monogamous relationship with an HIV-negative partner, an increased amount of sexual intimacy signaled an increased number of potential HIV exposure events. Some of these participants reported using condoms even within monogamous relationships (with an HIV negative partner) of several years’ duration, which further suggested aversion to any HIV risk. This aspect of low-risk men’s perceptions may influence how they intend to use an HIV vaccine.

In contrast to the intended uses cited by low-risk men, those cited by high-risk men support the concerns that an HIV vaccine may lead to behavioral disinhibition, which has been discussed throughout the literature (Anderson & Hanson, 2005; Bartholow et al., 2005; Blower & McLean, 1994; Whittington et al., 2006). Excerpts from the interviews suggest some possible reasons why an HIV vaccine would lead to behavioral disinhibition. Most obviously, high-risk MSM would prefer to reduce their reliance on other risk-reduction methods for HIV. The evidence for this lies in their intended uses for an HIV vaccine such as increased opportunities for anonymous sex.
and the avoidance of HIV-status discussions. However, in order to conclude that they can use an HIV vaccine for these purposes, these high-risk men must also have reasoned that a given HIV vaccine will reduce HIV risk for those uses. A lack of awareness or misunderstanding of VE may contribute to potential behavioral disinhibition, if it affects the reasoning process that leads to disinhibition. For example, Fuzzy-Trace Theory has predicted how knowledge deficits and misrepresentational errors in gist formation may affect risk assessment (Reyna & Adam, 2003). In addition, Weinstein’s hypothesis of optimistic bias may explain how biased recall of risk information may influence the risk-decision process (Weinstein, 1989). Receiving an HIV vaccine may be a strong inducement to remember only the actions taken to decrease HIV risk, and to forget about the actions taken that increase risk.

While this study has findings that differ from Van de Ven et al. (2002) on HIV vaccine attitudes, the idea that low-risk men may experience less behavioral disinhibition must be interpreted cautiously. It has been shown that behavioral disinhibition tends to increase over time after an individual perceives that his risk for an event has lessened (Hemenway, 1993). It is possible that perceptions further in time after HIV immunization may lead to a decreased felt need for other risk-reduction methods among even low-risk MSM. For example, continued negative HIV status years after vaccination may convince an individual of a high degree of protection from an HIV vaccine. It is difficult to imagine that these particular low-risk men would experience such a profound loss of risk aversion. However, it is also difficult to predict how individuals may behave in the future, especially without a comparable analogy for HIV vaccine effects to guide those predictions.
Understanding of vaccine efficacy. Results suggest that VE is a poorly understood concept within this study sample. Many men in the sample were not aware of the concept of VE. Furthermore, not a single participant could correctly define VE. It appears that this understanding does not differ by risk-level. Reported reasons for why someone preferred an efficacy above 50% suggested it was thought of as a simple probability. Efficacy is a complex concept and others studies have shown how RRR measures are often misunderstood (Gigerenzer, 2002; Sheridan et al., 2003). As predicted by Gigerenzer about relative risk measures, there was much confusion about the reference class of VE (Gigerenzer & Edwards, 2003; Gigerenzer et al., 2005). Participants thought of VE as the proportion of people infected, the proportion of protected exposures, and less commonly, the amount of virus eliminated or prevented from entering the body.

All cited definitions of VE by study participants involved determinations of protection at the individual level. It is not unexpected that most individuals would have been inclined to interpret VE in this manner, because it is the most concrete way of assessing one’s own risk. However, VE is a population-level statistic. It refers to the reduction of HIV incidence in the vaccinated group compared to the unvaccinated group (Halloran et al., 1999). The statistic alone says nothing about the mechanism that effected the reduction in HIV incidence. The percentage in which VE is expressed does not reveal whether HIV incidence was reduced by the proportion of people protected, the proportion of exposures protected, or the magnitude of effect on the virus. Yet these participants attempted to use VE in that manner.

A correct understanding of VE would be informative for determining whether a
vaccine will be suitable for one’s needs for HIV prevention. If an individual’s need is to reduce his risk-reduction practices, and he concludes—through an incorrect understanding of efficacy—that a given vaccine will satisfy those needs, his mistaken risk-assessment will place him at higher risk for HIV. Gigerenzer suggested that expressing RRR measures as ARR may be easier for individuals to interpret because of the similarity of the latter to natural frequencies (Gigerenzer & Edwards, 2003), although other studies dispute that ARR is more easily understood (Sheridan et al., 2003). Additional work that tests how ARR and other measures affect the understanding of HIV vaccines may lead to a useful tool for risk information communication.

The misunderstandings of VE that were found could affect risk decision-making neutrally, positively, or negatively. Based on results from this study, VE misunderstanding within this group could influence decision-making in a protective manner. Because of the belief that efficacy was a simple probability, most participants thought that an HIV vaccine of 50% efficacy would provide protection that was no better than chance alone. They were more likely to reject this vaccine. In reality, this vaccine would result in a 50% reduction in HIV incidence. A high-risk MSM who correctly understood VE may be more likely to accept a 50% efficacious vaccine and conclude that it satisfies his needs for a vaccine. Based on these study subjects, the result would likely include an increase in risk behaviors. Thus, a correct understanding of efficacy could possibly lead to more behavioral disinhibition compared to an incorrect understanding.

Nonetheless, many men in this group had never heard of the term VE and were
surprised that any vaccine on the market could provide anything less than complete protection from a disease. If this lack of awareness of VE is common with a partially efficacious HIV vaccine, this category of HIV vaccine misunderstanding could be a source of increased risk for HIV.

**Risk decision-making with vaccine efficacy.** As discussed in the literature review, correct reasoning requires both the ability to reason correctly and the motivation do so (Kunda, 1990). As Reyna posited in her Fuzzy-Trace Theory, reasoning utilizes both precise and gist representations, of which gist representations are more enduring and more often used (Reyna, 2004). People who would attempt to use VE to make a risk assessment may do so with a gist representation rather than a precise one, whether or not the gist is correct. For example, it is probably easier to recall that efficacy percentage indicates "the level of protection against infection" than "the percent reduction in infection incidence in the vaccinated group compared to the placebo arm." This would be an example of a representational error in gist formation (Reyna, 2004). Encoding the former representation of efficacy into memory would lead to errors in decision-making based on VE every time it was retrieved.

On the other hand, it was also observed that many participants had no prior experience with the efficacy concept. Being asked during the interview to define efficacy and to make a decision of lowest acceptable VE may have led them to retrieve the gist representations they may have thought were equivalent to efficacy (e.g., proportion of people protected, proportion of exposures protected, comparison to school grades, etc.). This could be an example of a representational bias (Reyna, 2004). This bias may have become even more pronounced with decreasing familiarity with
mathematical concepts and may have explained the *seemingly* arbitrary nature for how individuals chose their lowest acceptable VE.

Yet, the ability for correct reasoning is not the only factor in decision-making with HIV vaccines. A person must also be motivated to expend the effort to reason correctly. That process involves the decision to come to an accurate conclusion or to a desired (directional) conclusion, while also adapting to changing levels of arousal or emotional states. While Kunda (1990) hypothesizes that increased arousal may motivate reasoning to arrive at a directional conclusion, an individual cannot reach desired conclusions when faced with a preponderance of evidence contradicting that position. Accepting a directional conclusion requires at least the semblance of accuracy (Kunda, 1990). Optimistic bias can provide an appearance of accuracy that becomes a mechanism by which individuals make unrealistic appraisals of their risk (Weinstein, 1989). While this study did not test whether participants were attempting to come to accurate conclusions, results did suggest that high-risk participants as a group made unrealistically optimistic assessments of their risk for HIV.

There are alternate possible explanations for this finding of optimistic bias. Some men may have interpreted the question, “Using the following scale, compared to other men who have sex with men, how likely do you feel it is that you will be infected with HIV in your *lifetime*?” as including HIV positive men in the comparison. If that was the case, then HIV-negative high-risk men in the study may have accurately rated their lifetime risk as below average compared to *all* other HIV-positive and HIV-negative MSM. However, the result of optimistic bias appears to be congruent with those results found by Weinstein (1989) and Bauman & Siegel (1987). Seeing that these participants
were subject to optimistic bias in their own HIV risk assessment indicates that this bias may allow these high-risk individuals to overestimate their risk reduction from an HIV vaccine. Consequently, optimistic bias could lead some high-risk men to conclude that a partially efficacious HIV vaccine would be protective despite the risk behaviors they plan to engage in. As discussed earlier, individuals tend to remember risk-decreasing actions and not risk-increasing actions (Weinstein, 1982, 1989). Receiving an HIV vaccine is a concrete action that may be a powerful instance for risk-decreasing actions taken, and may exacerbate one’s optimistic bias.

Between high- and low-risk groups, a difference in qualitative preference for lowest acceptability VE was observed. One possible explanation is that while all men in this study would benefit from a highly efficacious vaccine, high-risk men would benefit more from a partially efficacious vaccine than low-risk men. Different conclusions drawn during risk-benefit analysis may account for some of the differences between high- and low-risk men. However, as was seen by the arbitrary criteria used for lowest acceptable VE, men in the sample had difficulty explaining how they arrived at their value for VE. Unconscious processes, such as the role of arousal, may also have played a role in reasoning with VE.

Kunda (1990) hypothesized that accepting the reality of an undesired event leads to arousal, which a person seeks to reduce if (s)he feels responsibility for that event. That person then seeks to reduce that arousal by changing his or her actions appropriately. One study observation was that high-risk men tended to view sexual impulses (and therefore HIV risk) as uncontrollable, while low-risk men identified an internal locus of control for sexual impulses (and HIV risk). This observation could be
explained by cognitive dissonance theory, where dissonance arising from perceived HIV risk could have led to those men changing the perceptions of their high-risk behaviors (i.e., being beyond personal control), rather than changing their high-risk behaviors (Festinger, 1957). Furthermore, asking a participant to consider the lowest acceptable efficacy would have forced that individual to reconsider his HIV risk, potentially inducing arousal from perceiving oneself at risk for HIV. With an external locus of control (i.e., unprotected sex is uncontrollable), high-risk men may have felt less responsibility—and less arousal—to change their behaviors than low-risk men, who viewed HIV risk as under their control. The way for low-risk men to reduce their arousal may have been to accept only high levels of VE, which demonstrated they took responsibility for their own HIV risk, by taking the highest level of control of the situation. In comparison, high-risk men may have experienced less of the arousal that motivated low-risk men to seek the higher VE.

Implications for HIV risk due to a partially efficacious vaccine. These results suggest serious implications for HIV risk due to a partially efficacious vaccine. High-risk gay and bisexual men in this study wanted an HIV vaccine to help manage their current high risk for HIV, or to increase opportunities for unprotected sex. This suggests that an HIV vaccine could indeed lead to behavioral disinhibition should these exploratory results be corroborated in a larger population of gay and bisexual men.

Furthermore, health policy makers have worried that a partially efficacious HIV vaccine could have low uptake by populations at risk (Esparza et al., 2003; IAVI, 2005). However, this study found suggestions that high-risk men were more likely to accept a vaccine of lower efficacy than low-risk men. This finding suggests that
attitudes about VE are more nuanced than other studies have reported. Other studies, not stratifying vaccine acceptability by risk level, found that high VE was most important in the acceptance of an HIV vaccine (Liau et al., 1998; Liau & Zimet, 2001; Newman et al., 2006; Webb et al., 1999; Zimet et al., 2000). Many of these studies used a factorial design to present different HIV vaccines with different combinations of characteristics, including specific, varied levels of efficacy (Liau et al., 1998; Liau & Zimet, 2001; Newman et al., 2006; Webb et al., 1999; Zimet et al., 2000;). Presentation of specific efficacy levels in those studies may have framed the choices of participants and may account for the differences seen in this study, which used an open-ended approach. If indeed applicable to the larger MSM population, it is concerning that those at highest risk for HIV are more willing to accept a vaccine of lower efficacy. Increased risk behaviors along with a partially efficacious vaccine are the worst-case scenario for exacerbation of the HIV epidemic, consistent with what previous models have shown (Anderson & Hanson, 2005; McLean & Blower, 1993).

Conclusion

This was an exploratory study, the goal of which was to generate hypotheses about how MSM think about HIV vaccines. Analysis of these data have led to the following preliminary hypotheses:

**Hypothesis 1: High-risk MSM would like an HIV vaccine to enable high-risk activities.** Most HIV vaccine studies that suggest behavioral disinhibition have not looked at differences between high- and low-risk groups. Whereas other studies have treated MSM as a
homogenous community in terms of HIV vaccine attitudes, results from this study finding strikingly different intended uses of an HIV vaccine between risk groups. This suggests that risk groups should be studied separately in future investigations. This hypothesis would predict that behavioral disinhibition may be influenced by risk level, where high-risk MSM use an HIV vaccine to limit their risk-reduction measures, and engage in risk-increasing activities. Should this hypothesis be confirmed by additional data, it suggests that HIV vaccine risk communication would need to be targeted for specific groups.

**Hypothesis 2: Heuristics used to evaluate vaccine efficacy are arbitrary and fallible.** Participants, when asked to explain how they chose their lowest acceptable vaccine efficacy, seemed to provide reasons unrelated to how efficacy would affect risk. This may be due to unfamiliarity with the concept of VE, along with biased representation and/or retrieval of heuristics used to evaluate VE. The reasons why efficacy was evaluated in this manner need to be elaborated. However, the results from this group of gay and bisexual men may not be true for the larger MSM population and remain to be replicated in a larger study.

**Hypothesis 3: Behavioral disinhibition may be influenced by a lack of understanding of HIV vaccines and vaccine efficacy.** It was found that no participant in this study could correctly define vaccine efficacy.
If true in a larger population, this suggests that most people would have difficulty making accurate risk assessments about an HIV vaccine due to a lack of understanding of HIV vaccine efficacy. In addition, the high-risk group in this study provided intended uses for an HIV vaccine that would increase risky behaviors, suggesting that a vaccine would lead to behavioral disinhibition. It would be important to know whether the potential for behavioral disinhibition is related to a lack of understanding of vaccine efficacy, or to other factors that make MSM at high-risk for HIV. The former could be remedied by well-implemented health education, while the latter would need a different behavioral approach. Elaboration of how individuals understand vaccine efficacy and how this may be related to their intended uses for an HIV vaccine may be an important topic for future research.

**Hypothesis 4: Higher risk MSM may tolerate a lower vaccine efficacy than lower risk MSM.** The finding that high- and low-risk gay and bisexual men have different acceptable vaccine efficacy levels is new and has not been reported before in the literature. Given the exploratory nature of this study, this finding needs to be replicated in a larger sample. The role of VE in prior vaccine acceptability studies is not clear given the high likelihood that individuals studied did not understand what was being asked, and the fact that vaccine efficacy in those studies was not well-defined. Future studies exploring this
hypothesis must be explicit about the definitions of VE provided to participants in order to understand why this difference between low- and high-risk MSM may exist.

While this was a small sample that was not representative of the larger MSM population, the results do suggest that misunderstanding of HIV vaccines and of VE may be common. While this study has focused on understanding of VE, it is not crucial that the average person fully understand this complex concept. Instead, the burden lies on public health institutions to develop clear risk communication messages for populations that would be targeted for a future HIV vaccine. With the possibility of a partially efficacious first generation HIV vaccine, it is especially crucial that the public understands the benefits and risks from accepting such an immunization. This study suggests that unexplained information about vaccine efficacy is not sufficient for evaluating how an HIV vaccine may impact personal risk. Results from this study provide a direction for future research that finds ways to facilitate risk calculation among populations targeted for an HIV vaccine. It is incumbent on public health officials to ensure that those who would receive an HIV vaccine be able to make accurate judgments about their own risk, using an HIV vaccine to decrease their risk and not increase it.
Appendices
APPENDIX A: STUDY ADVERTISEMENT

University of California, San Francisco

UCSF sponsored study is looking for gay & bisexual men who are HIV negative and at least 18 years old to interview about HIV Vaccines.

Participation will take about 1 hour for an interview and questionnaire. Participants will receive $25.

For more information contact: myAIDSvaccine@gmail.com or (415) 774-6345.
APPENDIX B: STUDY SCREENING FORM

Telephone Study Screening Form

[Staff prompt in quotations. Mark responses as appropriate. Pause between paragraphs and ask individual if he has any questions.] “Thank you for your interest in the study. This research will look at gay/bisexual men’s perceptions of HIV vaccines. The study will also ask about sensitive topics such as sexual behavior. If you agree to take part in the study, your participation would consist of one visit that would last a total of about an hour and a half. During this visit, you will be interviewed about HIV vaccines and given a short questionnaire.

All steps will be taken to protect your identity. Some identifying information will only be collected for the purposes of communicating with you. We will collect the minimum amount of information necessary to maintain communication. Furthermore, this information will be destroyed at the conclusion of the study. You can choose an interview venue that is most comfortable and convenient for you, as long as it is not your home. An example is a comfortable café in your neighborhood. If you desire more privacy, we can set up a private meeting space at a location like the San Francisco Department of Public Health.

Interviews will be kept anonymous: your interview responses will be kept completely separate and unlinked from any identifying information that we collect. An audio recording of the interview will be made. Afterwards, a written transcript of the recording will be made. At the conclusion of the study, we will destroy your voice recording. Interview transcripts will not contain your name. Following the interview, there will be a brief, written questionnaire that will ask information such as your age, race, education level, income, as well as some questions about your sexual history.

“If you decide to participate, you will be given $25 in appreciation of your time.”

“How did you hear about this study?”

☐ YES ☐ NO

☐ Were you approached at a café, bar, or club?
☐ Did you see a flyer at a café, bar, or club?
☐ Did you see the ad on Craig’s List?
☐ Were you approached on the street?
☐ Did you see a flyer at a clinic?
☐ Did you see a flyer at a sex club or bathhouse?
☐ Did you hear about it from a friend?

“Are you interested in participating?” (circle) ☐ YES ☐ NO

………..If so: “May I ask why you are not interested?” Record reason below. “Thank you for your time.”

End screening for refusing

REASON FOR DECLINE:

………..If yes: “Great! I will ask you a few questions to see if you qualify to participate. These questions will ask about for information like your sexual orientation and HIV status. Is this something that you feel comfortable discussing now?” If individual does not feel comfortable, offer to schedule another time for screening.

(Continued on other side)

Instructions for staff: Ask ALL of the following questions. DO NOT write responses to screening questions!
"Please answer 'yes' or 'no' to the following questions.
1. "Are you at least 18 years of age?"
2. "Do you identify as gay or bisexual?"
3. "Do you believe yourself to be HIV negative?"
4. "Are you able to read and understand English?"
5. "Have you ever participated in a study that tested an experimental HIV vaccine?"

.............If responses to questions (1-4) are "yes": "You qualify to participate in this study."
.............If question 5 response is "yes" individual qualifies if fewer than three participants have been enrolled in that category.

"By what name you like to be called?"

"Where and when would be a good time for you to meet? Please consider a place that you are comfortable meeting at and would be conducive to a conversation. There is also the option of arranging a private meeting space at the San Francisco Department of Public Health (SFDPH)."

Place: __________________________ Date: __________________________

Time: __________________________

.............If at least one "no" to question numbers 1-3; or if question 4 response is "yes" and three or more vaccine trial participants have already enrolled in this study: "I'm sorry, but you do not qualify to participate in this study. If you are interested in participating in other research, SFDPH HIV research section is doing many studies on HIV that might interest you. If you like, I can give you contact information for them."
.............If the individual expresses interest in SFDPH studies: "For more information, you can visit the website www.helplighthiv.org for more information. For more information, you can also call SFDPH at (415) 554-9068. All studies at the SFDPH HIV Research Section have been approved by the UCSF Committee on Human Research." [End screening for non-qualifying individuals]

"In case there is a problem with scheduling, what is the best way for me to contact you?"

Phone (_____ ___) Leave Message? □ Yes □ No
□ Best time(s) to contact? __________________________

Alternate (_____ ___) Leave Message? □ Yes □ No
□ Pager (_____ ___)

□ E-mail __________________________

[If OK to leave message] "If I need to contact you and have to leave a message, to protect your privacy, I will identify myself, but not the study.

"If you have any further questions, please feel free to contact me by phone at (415) 774-6345 or, if you'd like, by e-mail at myAIDSvaccine@gmail.com. Also, feel free to think more about participating. If after thinking about the study, you decide you would no longer like to participate, just let me know by phone or email. If any problems arise and you can't make our scheduled time, or if you would like to reschedule, you can also reach me by email or phone. Thank you."
APPENDIX C: INTERVIEW GUIDE

Interview Guide
<Prompt> This interview is designed for people who have many different lifestyles. So, some questions will fit you better than others. Please remember that for all the questions, there are no “right” or “wrong” answers—we are just interested in getting your perspective and experiences.

Vaccine Knowledge and Interest
<This part of the interview is designed to be very open-ended to allow for rapport building and participant relaxation. Ask sub-questions if not mentioned in participant response, especially with quieter individuals>
1. What do vaccines do? What are some examples of vaccines you have received in the past?
2. What do you know about HIV vaccines?
   <If not included in HIV vaccine knowledge response (#2)>
   (a) Is there an HIV vaccine?
   (b) How close are we to having one?
   (c) Where have you gotten information about HIV vaccines in the past? What type of information was it? What did you think of the quality of the information?
3. How interested are you in getting an HIV vaccine? Why? <If not included in previous response. Probe for completeness> What characteristics would an HIV vaccine need for you to get it?

Awareness & Interpretation of Vaccine Efficacy
4. How can you tell if a vaccine works or not? How can you find out?
5. You might have heard the term “vaccine efficacy” before. It is often used in speaking about how well a vaccine works. Vaccine efficacy is stated as a percentage. For example, a vaccine may be 97% efficacious. Please put into words what a “97% efficacious vaccine” means.
6. Where do you think the vaccine efficacy number comes from?
7. What are your impressions of that number’s accuracy? Why?
8. What are your impressions of a vaccine that has 100% vaccine efficacy?
9. What are your impressions of a vaccine that has less than 100% efficacy?
10. What is the lowest level of vaccine efficacy you would consider an HIV vaccine to be useful at?
11. Why did you pick that number?
12. <Use participant’s numerical response from question 10> Imagine that the U.S. government approved the vaccine you mentioned, a vaccine of X% efficacy. You get this vaccine. How do you think this HIV vaccine would change your sex life? <If unmentioned, identify any methods or strategies used to avoid HIV, which might be changed post-vaccination, and why vaccine would effect this change>
13. How would you figure out what your chances for HIV are after getting the vaccine?
14. How do you think this HIV vaccine would change the sex lives of gay/bisexual men who get it? <If not mentioned> What about the vaccine would make them change their sex lives?
15. How do you think this HIV vaccine would change the chances of HIV infection for most gay/bisexual men who get it?

16. How completely or incompletely would an HIV vaccine protect those exposed to different strains or types of HIV?

17. Please discuss your impressions of the following statement: "An HIV vaccine would protect all people equally."
   
   (a) *If participant believes there are differences amongst group in terms of protection* What does vaccine efficacy say about how well an HIV vaccine protects different groups?

18. For how long would an HIV vaccine protect an individual?

**HIV Vaccine Function (CMI vaccines)**

We talked about HIV vaccines that work by keeping you from getting infected with HIV. But many scientists think that our first HIV vaccines may allow people to get infected (catch the virus), but not get sick (*i.e.*, get AIDS) or may delay the time until someone gets AIDS. These vaccines may also decrease the amount of virus in your blood, protecting others who come in contact with you.

19. What are your impressions of a vaccine that allows you to get infected with HIV, but not get AIDS?
   
   *If not already stated* Is this a useful vaccine? Why?

20. Please put into words what you think "vaccine efficacy" means for this type of vaccine.

21. What is the *lowest* level of vaccine efficacy you would consider this HIV vaccine to be useful at? Why?

22. Imagine that you got this vaccine. How do you think this HIV vaccine would change your sex life?

23. Imagine a vaccine that would allow you to get infected with HIV, and eventually AIDS, but would protect you from getting AIDS for longer than with drugs alone? *Show participant diagram of AIDS time course with/without vaccine to clarify concept. Refer to diagram for question: 23-26*

24. Please put into words what you think "vaccine efficacy" means for this type of vaccine.

25. What is the *lowest* level of vaccine efficacy you would consider this HIV vaccine to be useful at? Why?

26. Imagine that you got this vaccine. How do you think this HIV vaccine would change your sex life?

27. What are your impressions of an HIV vaccine that allows you to get infected with HIV and can still get AIDS, but it decreases the chance that you’ll give it to someone else? That is, this vaccine only protects your sexual partners.

28. Please put into words what you think "vaccine efficacy" means for this type of vaccine.

29. What is the *lowest* level of vaccine efficacy you would consider this HIV vaccine to be useful at? Why?

[END OF INTERVIEW]
Diagram for Interview Questions #23-38

No HIV Vaccine

HIV Vaccine

TIME

Gets HIV Infection

Gets HIV Infection

Vaccine Benefit

X years

Gets sick with AIDS

Gets sick with AIDS
APPENDIX D: DEMOGRAPHIC & RISK PERCEPTION QUESTIONNAIRE

Questionnaire

1. What is your Age? 

2. What is your Racial/Ethnic Background?  
   (Mark one)  
   ☐ African/Black  
   ☐ Asian/Pacific Islander  
   ☐ European/White  
   ☐ Hispanic/Latino  
   ☐ Native American  
   ☐ South Asian  
   ☐ Other (specify):________________________

3. What is your County/State of Residence?  
   ________________________________________  
   COUNTY STATE

4. What is the Highest Level of School you completed?  
   ☐ Less than high school  
   ☐ High school  
   ☐ High school equivalency (GED)  
   ☐ Some college or two-year college degree  
   (Associate's degree)  
   ☐ Bachelor's degree  
   ☐ Post-graduate education

5. What is your Annual Income before taxes?  
   ☐ Less than $23,750  
   ☐ $23,750 to $39,599  
   ☐ $39,600 to $63,349  
   ☐ $63,350 to $79,799  
   ☐ $79,800 to $99,750  
   ☐ Greater than $99,750

6. What is your primary occupation?

7. What is your sexual orientation? (Mark one)  
   ☐ Gay  
   ☐ Bisexual  
   ☐ Heterosexual  
   ☐ Other (specify):________________________

8. How many men have you had sex with in the last year? (includes oral sex, fucking, etc.)

9. How many women have you had sex with in the last year? (includes oral sex, fucking, etc.)

10. Do you have a primary partner?  
    ☐ Yes -  
    ☐ No (Skip to Question #11)

    ☐ If yes, how long? ☐ Years ☐ Months

    ☐ HIV status of this person? (Mark X)  
    ☐ Positive (+)  
    ☐ Negative (-)  
    ☐ Unknown

11. Have you ever participated in an HIV/AIDS vaccine trial?  
    ☐ Yes  
    ☐ No (Skip to Question #14)

12. Briefly describe your (most recent) study:

   ________________________________________

13. What year was the study? ☐ ☐ ☐

   For the Questions 14 - 25, mark (X) the box that most closely indicates your agreement with the following statements

14. HIV is the cause of AIDS.  
    ☐ STRONGLY DISAGREE  
    ☐ SOMewhat DISAGREE  
    ☐ SOMewhat AGREE  
    ☐ STRONGLY AGREE

15. Having HIV is like having diabetes or high blood pressure; it is a long-term (chronic), but treatable condition.  
    ☐ STRONGLY DISAGREE  
    ☐ SOMewhat DISAGREE  
    ☐ SOMewhat AGREE  
    ☐ STRONGLY AGREE

16. For people with HIV, most currently available therapies will eventually stop working and they'll run out of effective treatments.  
    ☐ STRONGLY DISAGREE  
    ☐ SOMewhat DISAGREE  
    ☐ SOMewhat AGREE  
    ☐ STRONGLY AGREE

17. My sexual behavior is risky in terms of HIV.  
    ☐ STRONGLY DISAGREE  
    ☐ SOMewhat DISAGREE  
    ☐ SOMewhat AGREE  
    ☐ STRONGLY AGREE

More questions on back

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18. I do things that could cause me to become infected with HIV.

20. I am less concerned about becoming infected with HIV because getting infected is less serious than it used to be.

21. There is little chance that I could become infected from HIV, or infect others, from what I do sexually.

22. Knowing that fewer people are getting AIDS has caused me to have more unprotected sex.

23. I am more likely to die in a car accident than to die of AIDS.

24. The people I have sex with are not the kind of people who could ever get HIV.

25. Knowing about improved treatments has caused me to have more unprotected sex.

26. How many times, if ever, have you taken post-exposure prophylaxis (PEP) after a sexual encounter to avoid catching HIV? Examples include antiretroviral drugs such as tenofovir (Viread) or zidovudine (Retrovir/AZT)?

27. When was your last HIV test?

28. About how many times per year do you get tested for HIV?

29. Using the following scale, compared to other men who have sex with men, how likely do you feel it is that you will be infected with HIV in your lifetime?

That is the end of the questions.
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