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A Guide to **AIDS** Research and Counseling

A Shot or a Pill: Exploring Biomedical Approaches to HIV Prevention

Jonathan Fuchs, MD, MPH, and Grant Colfax, MD

Promoting consistent use of male condoms and reducing higher risk sexual behaviors are fundamental components of any HIV prevention strategy. While counseling interventions have had some success in achieving these goals, clinical trials are testing a wide array of biomedical strategies to prevent HIV infection. Recognizing that none of these approaches will be 100 percent effective, widespread adoption of any of them will require practitioners to address clients who may abandon their condoms and safer sex approaches in hope of complete protection from a shot or a pill.

This article briefly reviews three biomedical strategies to prevent HIV: vaccines, HIV antiviral treatment (including both pre- and post-exposure prophylaxis), and treatment of sexually transmitted infections. It goes on to outline some of the key challenges in studying and implementing these strategies.

Preventive Vaccines

Many experts believe that a preventive vaccine is the best hope for stemming the global HIV pandemic. To date, however, researchers have completed only two efficacy trials of candidate vaccines, neither of which resulted in a vaccine that was able to prevent infection.

The first generation of HIV vaccines employed a strategy similar to the successful hepatitis B vaccine: they used synthetic copies of the proteins on the outer envelope of HIV in hopes of stimulating the body's production of antibodies specific to those proteins, antibodies that would then neutralize invading HIV before it entered host CD4+ cells. While antibodies produced by this approach in VaxGen's efficacy trials failed to protect against HIV, improved understanding

of the virus and how it evades antibody neutralization through its highly variable protein coat has informed the next generation of HIV vaccine candidates.

Another significant challenge in designing a vaccine involves HIV's capacity to establish itself in the host body's cellular memory. A vaccine should engage not only humoral immunity, that is, the production of antibodies, but also cellular immunity, that is, it should train the body's cytotoxic T-cells to detect and eradicate HIV-infected cells containing actively replicating virus. Because HIV can remain latent in cells for years, cytotoxic T-cells may overlook these "silently infected" cells. Thus, researchers do not expect vaccine-induced cellular responses, by themselves, to eliminate HIV infection. Cytotoxic T-cell-based vaccines may, however, reduce HIV production, which could potentially delay the progression of HIV in that person and reduce his or her infectiousness.

A significant pipeline of new vaccine candidates will enter phase I trials in 2004, although it will require at least seven years of clinical testing before one of them could be licensed for use. It is also unlikely that the first vaccine released would provide complete protection from either infection or disease progression. Recognizing this likelihood, studies employing mathematical modeling suggest that a community's adoption of a partially effective vaccine could, in fact, worsen an epidemic if individuals substantially increase their risk behaviors in response to the faulty belief that a vaccine is 100 percent effective.¹

Recent studies have assessed this potential "behavioral disinhibition" among vaccine trial volunteers. The North American/European VaxGen study randomized participants either to a vaccine plus risk reduction counseling group or a placebo shot plus risk reduction counseling group. It found, for both groups, that the prevalence of unprotected sexual practices initially declined but rose back to baseline risk levels after 36 months of follow-up.²

Editorial: Protection versus Presumption

Robert Marks, Editor

For more than two decades, the words “AIDS vaccine” have delivered the most potent dose of hope available to people working with HIV. So powerful have they been that they overshadow the magic of the words “chronic, manageable condition,” which became a popular mantra in the early days of triple combination treatment.

The idea that a shot might protect someone is not far-fetched in terms of infections like polio or measles. But despite predictions every few years that we’ll have a vaccine in two, then five, then ten years, more than 20 years have elapsed. We have something to show for it—a payoff in terms of understanding the virus far better than we did—but nothing that can be put in a syringe to save lives.

At the same time, researchers have achieved some success in implementing other “biomedical” approaches to HIV prevention. As

Jonathan Fuchs and Grant Colfax discuss in this issue of FOCUS, “PEP,” “PREP,” and STD treatment all offer the possibility of preventing infection or transmission through the use of medications. Their article outlines the state of the science and the significant challenges to implementing each of these approaches. Also in this issue Leslie Wolf and Bernard Lo discuss the role of informed consent to ensure that people understand the risks and benefits of participating in research on biomedical approaches.

Fuchs and Colfax introduce the factor that is both the impetus for research in this area and what may turn out to be the greatest threat to its success: human behavior. Biomedical interventions are attractive because ideally, getting a shot or taking a pill would offer protection without requiring any behavioral change.

However, because of HIV’s supreme ability to adapt in response either to a vaccine or to a protective treatment, it appears that biomedical interventions are not likely to be 100 percent or even 75 percent effective. At the same time, as Fuchs and Colfax report, some research suggests that it is difficult for many of us to comprehend on an emotional as well as an intellectual level that behavioral precautions are necessary even if you get a shot. People may inadvertently place themselves at greater risk after they get a vaccine or pre-exposure prophylaxis than when they were relying on condoms or needle cleaning or their wits.

None of this means that biomedical interventions are bad: the promise of a cheap, effective vaccine or treatment is monumental. But we must continue to improve and disseminate behavioral as well biomedical approaches, and we must supplement biomedical interventions with significant education to ensure true protection, not just a false sense of security.

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Without having a comparison group, however, that underwent the same risk reduction counseling as the original trial participants but who did not receive any shots, it is difficult to know if shot recipients are altering their risk-taking behavior because they believe that the injections are protecting them from HIV. To explore this possibility, the Centers for Disease Control and Prevention (CDC) funded six VaxGen trial sites to enroll a matched control group of volunteers into a second study, called VISION.

A preliminary analysis of VISION found that among men who have sex with men, control participants—those who received counseling only—reported a more marked decline than both groups of original trial participants in the number of reported sexual partners and level of unprotected anal sex.³ One explanation for this finding is that the original trial participants were less responsive to ongoing risk reduction counseling than the control group, perhaps because they assumed that they were protected by the shot. This might have occurred despite informed consent processes emphasizing the unknown efficacy of the product being tested

and the possibility that a subject might be randomized into the placebo group. These findings suggest that innovative risk reduction counseling strategies and community education are needed to address behavioral disinhibition both during the vaccine trials and after an approved vaccine is available.

Post-Exposure Prophylaxis

Post-exposure prophylaxis (PEP) is the use of a limited course of a combination of two or three HIV antiviral drugs to prevent HIV infection immediately after a presumed exposure. The plausibility of PEP in preventing HIV infection is based on data from occupational exposures among health care workers, mother-to-child transmission studies, and animal studies, but there are no studies that actually prove its efficacy.⁴ The validity of a widely cited study suggesting that PEP decreased the risk of infection among health care workers was limited by its design.⁵

In addition to the lack of efficacy data, concerns about using PEP for sexual exposures include: potential drug side effects, adherence challenges, and potential behavioral disinhibition due to the availability of

Pre-exposure prophylaxis is the sustained use HIV antiviral drugs or “chemoprophylaxis” to prevent HIV infection in the face of ongoing exposure.

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PEP. Despite these caveats, PEP is being offered in a number of U.S. cities to people who experience “high-risk exposures,” including unprotected anal or vaginal sex with a partner who is known to be HIV-positive. With a few notable exceptions, studies evaluating PEP for non-occupational exposures have found that drug combinations have not resulted in severe adverse effects; have led to adherence rates of 75 percent to 85 percent for four-week regimens; and

when administered with substantial risk reduction counseling, have led to declines in risk behavior.⁴ In terms of efficacy, several individuals have become infected with HIV after receiving PEP regimens, but it is not clear whether seroconversion was due to PEP failure, past sexual exposure prior to PEP, or re-exposure following PEP.

The greatest challenge to PEP arises from the need to take it shortly after an isolated, high-risk exposure. Data suggest, though, that a substantial proportion of men who have sex with men, particularly those at highest risk for acquiring HIV, repeatedly engage with multiple partners in practices that may result in transmission.⁶ Therefore, interventions targeting these individuals warrant further exploration.

Pre-Exposure Prophylaxis

Both the problems and potential of PEP have recently inspired testing a new approach: pre-exposure prophylaxis (PREP). PREP is the sustained use of HIV antiviral drugs or “chemoprophylaxis” to prevent HIV infection in the face of ongoing exposure.

All currently planned PREP studies—efficacy studies in Cambodia and Africa and a safety study in San Francisco and Atlanta—use tenofovir as their PREP agent. Tenofovir is a potent, relatively safe and well-tolerated HIV antiviral agent that can be administered as a single daily oral dose. It is particularly attractive for PREP applications, because compared with other HIV medications, tenofovir infrequently leads to HIV resistance, and its “side effect profile” is similar to placebo in double-blind trials.⁷

Despite these promising factors, substantial challenges remain. Strategies that have acceptable risk-benefit ratios for treatment of an infection may be unacceptable for pre-

vention of infection, particularly in healthy, HIV-negative individuals. There are four notable challenges in studying whether PREP is even safe, much less efficacious. First, rare but serious adverse events may be associated with chronic tenofovir therapy, including metabolic complications, and renal and bone toxicities.⁷ Second, although tenofovir resistance may develop less rapidly compared to other HIV antiviral agents, if a person on PREP becomes infected—that is, if PREP does not prevent infection after exposure—he or she may have taken tenofovir monotherapy for a period of weeks or months prior to diagnosis of that infection. Such sustained monotherapy could lead to a tenofovir-resistant form of HIV, which may affect future treatment options for that individual.

Third, adherence to even once-daily PREP may prove challenging to individuals at highest risk for sexual exposure. Finally, even if PREP is shown to be effective at preventing infection, it is not known whether people will increase their risk behaviors without using any other protection, for example, condoms. As discussed above in the context of partially effective vaccines, such behavioral disinhibition may negate any protective effects PREP may have on reducing HIV transmission risks.

HIV Treatment to Prevent Further Transmission

There is increasing interest in treating HIV-positive individuals to reduce the risk of transmitting HIV to HIV-negative partners. The logic of this approach is supported by data demonstrating that among untreated populations, as viral load decreases, the odds of transmitting to partners decreases.⁸

Most notably, in a Ugandan heterosexual cohort, there were no cases of HIV transmission from people with HIV who, without treatment, had viral loads of less than 1,500. It remains unknown whether the same correlations between viral load and transmission risk hold among treated populations, that is, people receiving HIV antiviral therapy. Among untreated populations, factors that contribute to maintaining low viral loads, including a person’s immune responses and the “viral fitness” of the HIV in his or her body, may also contribute to lower transmission risk in ways that may not translate to lower rates of transmission among people who have successfully suppressed HIV through treatment. Currently, the HIV Prevention Trial Network (HPTN) is planning an international randomized controlled trial to evaluate the effectiveness of HIV antiviral therapy to prevent sexual transmission among mixed-serostatus couples. The study

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will compare two treatment strategies: early HIV antiviral treatment upon enrollment plus HIV primary care; or HIV primary care, without the initiation of HIV treatment until clinically indicated for the health of the individual. In its pilot phase, the study will determine whether it is both acceptable and feasible for HIV-positive individuals to take HIV treatment not primarily to address their own health needs, but to reduce their partner's risk of infection.

Treating Sexually Transmitted Infections

Numerous observational studies have shown that bacterial sexually transmitted infections (STIs) such as syphilis and gonorrhea can facilitate HIV transmission. There have been three large-scale, community-based randomized trials—one in Tanzania and two in Uganda—to test whether symptomatic treatment or periodic mass treatment for bacterial STIs can reduce HIV rates in a community. The Tanzanian trial, which utilized symptomatic treatment, found a 40 percent decrease in HIV incidence; the latter two failed to show an impact. These conflicting results have been ascribed to differences in population demographics, risk behaviors, prevalence of bacterial STIs, the relative maturity of the HIV epidemics in those communities, or any combination of these.⁹

Since viral, although not bacterial, STIs are being recognized as the most common cause of genital ulcer disease worldwide, greater attention has been drawn to the association between genital herpes, caused by herpes simplex virus-2 (HSV-2), and HIV transmission. A recent meta-analysis reported that the risk of acquiring HIV was doubled in those with prior HSV-2 infection.¹⁰ This observation is biologically plausible: HSV-2 can create micro-ulcerations in the genital tract that act as portals for HIV entry. In addition, since these ulcerations are caused by infection, activated lymphocytes migrate to them, and these are the very cells HIV targets for infection. Considering the prevalence of HSV-2 and these

associations with HIV transmission, the number of new HIV infections attributable to HSV-2 is likely to be substantial.

With the availability of safe, effective, and inexpensive HSV-2 suppressive therapy, two large, international, randomized placebo controlled trials will look at whether daily acyclovir can reduce HIV incidence. The first study is evaluating whether treating HIV-negative, HSV-2-positive men and women with acyclovir will decrease HIV acquisition rates. The second study will evaluate whether HSV-2 suppressive therapy in herpes-infected, HIV-positive individuals will reduce the chance of transmitting HIV to their partners.

Again, all participants in both HIV prevention studies will receive state of the art HIV risk reduction counseling and condoms. They will also receive acyclovir for HSV-2 outbreaks. If shown effective in preventing HIV, acyclovir taken twice daily at less than \$75.00 a year will create an affordable HIV prevention option. Its broad use in places such as sub-Saharan Africa where HSV-2 may account for up to 45 percent of new HIV infections could have a significant impact on the global pandemic.

Conclusion

To prevent behavioral disinhibition during the clinical testing and potential deployment of these biomedical approaches, the prevention community must be steadfast in offering innovative risk reduction counseling and promoting male condom use. Even though mounting observational data suggest that HIV antiviral treatment and some sexually transmitted infection treatments may be helpful in preventing HIV transmission, they should not be used until proven safe and effective in well-designed randomized-controlled trials. Finally, policymakers, working closely with communities and scientists, must identify mechanisms to finance the manufacturing, purchase, and distribution of these potentially costly biomedical options to ensure that available technologies are also accessible to people at highest risk.

Clearinghouse: Biomedical HIV Prevention

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Little K, Surjadi M. A scientific overview

Informed Consent in HIV Research

Leslie E. Wolf, JD, MPH and Bernard Lo, MD

A person does not lack capacity to give consent simply because he or she makes what researchers view as “bad” decisions.

Informed consent is the cornerstone of research ethics. Informed consent is a process—not just a signed form—that seeks to ensure that a research participant’s choice to participate is voluntary and based on an understanding of the potential risks and benefits of a research project, the project’s purpose, and alternatives to participation.

Informed consent requires that a research participant be a competent adult, that researchers disclose all information pertinent to the decision to participate, and that consent is free from coercion or undue influence.¹ HIV biomedical treatment and prevention research presents special challenges to this process, because participants may have multiple vulnerabilities, people with mental illness may not be capable of giving informed consent, research may be considered a benefit, and research participation may present psychosocial

harms. In addition, study personnel need to remind potential participants that research is not the same as health or behavioral health care and need to help ensure that all participants have access to appropriate care independent of the research setting.

Decision-Making Capacity

Vulnerable participants. Some research participants may be considered vulnerable because of personal characteristics or circumstances that may affect their ability to freely consent.² For example, a person who is contacted shortly after learning of his or her HIV infection may find it difficult in the midst of shock, fear, or other emotional

responses to weigh the risks and benefits of enrolling in an early treatment study. Men who have sex with men, injection drug users, people of color, and women, who, for various reasons, may be at higher risk of HIV infection, are more likely to be socially and economically vulnerable because of historical attitudes and discrimination.

Investigators conducting HIV-related research must, therefore, pay attention to vulnerabilities of potential participants and how these vulnerabilities might affect the consent process. For example, investigators working in immigrant communities should consider consulting with community members to develop a consent process that is culturally appropriate.

Incapacitated participants. People who lack decision-making capacity cannot consent to research participation. Since mental illness and substance use may compromise this capacity, researchers must evaluate participants’ capacities to make informed decisions. One method of testing both capacity and comprehension is for investigators to ask participants to explain in their own words what will happen if they participate in the study, in terms of the study procedures and benefits and risks. For example, in a vaccine trial, participants should be able to explain that they will receive vaccine or placebo, the choice will be made randomly—not by study personnel—and that they should continue to use prevention measures to protect themselves from HIV infection.

It is ethically problematic to conduct research with people who cannot give informed consent if the research could otherwise be conducted with competent persons. However, it may be ethically permissible to enroll people who lack decision-making capacity—with a surrogate’s consent—for research on cognitive impairment, for example, HIV-related dementia, or serious diseases affecting the participants. It is important to note that a person should not be judged as lacking capacity because he or she makes what researchers view as “bad”

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See also references cited in articles in this issue.

decisions. For example, surrogate consent could not be used to enroll a person who persistently engages in activities that place him or her at risk of HIV infection in trials of post-exposure or pre-exposure prophylaxis.³

Disclosure of Risks

Psychosocial risks. Psychosocial risks may be prominent in HIV research, because HIV research often collects detailed information about participants' sexual behaviors and use of legal and illegal drugs—all of which may be stigmatized by society and disclosure of which may lead to physical harm, discrimination, or legal action. Researchers need to discuss these risks carefully during the consent process. For example, HIV-positive participants who disclose to researchers that they have had unprotected sexual intercourse with HIV-negative partners may be at risk of criminal or civil liability in some states for knowingly exposing others to HIV if the research records were disclosed.⁴ Potential participants need to know what steps researchers are taking to keep records confidential and thereby reduce this risk.

Researchers should also address the ways in which trial participation may lead to alienation from family or friends. For example, if a participant tells friends or family about the study, listeners may conclude that the participant is HIV-positive or is engaging in specific stigmatized activities, even when he or she is not. Further, participants in vaccine trials may test HIV-positive even if their seroconversion represents only that the person has received the trial vaccine and is not actually HIV-infected. This may lead to limits on international travel and on eligibility for certain governmental jobs, for example, in the U.S. Peace Corps, foreign service, and military.⁵

Psychosocial risks may not be as apparent as physical risks. Therefore, researchers must take special care to ensure that potential participants appreciate these risks and understand the steps that researchers will take to minimize these risks. For example, investigators should also tell participants who on the team will have access to the data that is collected, whether the data will be coded to obscure identity, and what other steps—for example, obtaining a federal Certificate of Confidentiality to protect identifiable research data from subpoena—researchers will take to protect participant confidentiality.

Assumption of efficacy. A serious concern for investigators researching biomedical prevention interventions such as vaccines, post-exposure prophylaxis (PEP), and the

experimental pre-exposure prophylaxis (PREP) is that trial participation may actually result in an increase in risky behaviors. In these situations, participants may mistakenly believe or may want to believe that the study intervention is 100 percent effective and will protect them from infection.⁶ Researchers must clearly address these concerns during the consent process by emphasizing that the intervention may not be effective and that participants need to avoid behaviors that may expose them to HIV. This information should be highlighted in the consent document, even using bold print or all capitals letters, and raised with participants throughout the study.

Therapeutic misconception. Research differs from clinical care in that its goal is to test a hypothesis and develop generalizable knowledge in order to benefit society in the long-term and not necessarily to benefit individuals in the short-term.⁷ Moreover, innovative drugs offered in clinical trials often are shown to be ineffective. Many research participants do not understand this distinction. Early in the antiviral era, HIV advocates were among the first to view research as a benefit—as access to better care—and demanded right of entry to it. However, researchers need to help participants understand that while they may hope that clinical trial participation will provide them direct clinical benefits, the research is being conducted because no one knows whether the experimental intervention is safe and effective compared to the control intervention.

Conclusions

The special characteristics of HIV, HIV research, and the populations most affected by the epidemic create special challenges to informed consent. Investigators should pay particular attention to these issues when conducting HIV research, which must ultimately protect participants as well as further HIV-related prevention and care.

Comments and Submissions

We invite readers to send letters responding to articles published in *FOCUS* or dealing with current AIDS research and counseling issues. We also encourage readers to submit article proposals. Send correspondence to rmarks@itsa.ucsf.edu or to Editor, *FOCUS*, UCSF AIDS Health Project, Box 0884, San Francisco, CA 94143-0884.

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Recent Reports

Willingness to Volunteer for Vaccine Trials

Strauss RP, Sengupta S, Kegeles S, et al. Willingness to volunteer in future preventive HIV vaccine trials: Issues and perspectives from three U.S. communities. *Journal of Acquired Immune Deficiency Syndrome*. 2001; 26(1): 63–71. (University of North Carolina, Chapel Hill; and University of California, San Francisco.)

A three-city study that was able to survey three different subpopulations found that almost half of research subjects would willingly participate in a hypothetical future HIV vaccine trial.

Researchers recruited 87 participants, ranging from 20 years old to 72 years old for this qualitative study. The study targeted gay and bisexual men in San Francisco, injection drug users in Philadelphia, and African Americans in Durham, North Carolina.

Participants filled out sociodemographic questionnaires and engaged in semi-structured, open-ended interviews. In order to reveal the breadth of possible responses, interviewers used a technique called “freelisting” to encourage participants to brainstorm all possible feelings in response to specific questions. Interviewers asked four questions: would a participant volunteer for a vaccine trial; what participants perceived as potential benefits of volunteering; what participants perceived as the risks of volunteering; and what information participants would want to have about the trial prior to volunteering.

Forty-six percent of all participants said they would volunteer for a vaccine trial, 41 percent said they would not volunteer, and 12 percent were unsure and said they needed more information before making a decision. There were no statistically significant differences among participants from all three populations in terms of willingness to volunteer.

Seven themes emerged among the perceived benefits cited by participants. The three most common themes were “altruism,” “a desire to help stop the spread of AIDS,” and “self-benefit,” a category that included both financial or practical compensation and potential improvement in health. Other benefits included increased social networks, minimal side effects, the

development of an effective vaccine, and reduced economic costs.

The most commonly cited risk focused on the negative side effects of the trial vaccine, including reactions that may result but are unknown at the time of recruitment. Participants, particularly those in San Francisco, were also concerned about the social consequences of volunteering, for example, stigmatization. Other risks included contracting the virus from the vaccine, having an unpleasant experience, testing HIV-positive, experiencing inconveniences or limitations to daily life, and risking the chance that the vaccine would not be effective. Participants, again particularly

in San Francisco, also stated that overly optimistic perceptions of the vaccine’s effectiveness might lead to an increase in high-risk behavior.

Most subjects (72 percent) stated that prior to volunteering, the information they would most want to know would be about the potential side effects of the trial vaccine. Other desired information related to

methodology, trust and confidentiality, incentives, assistance with potential complications, effectiveness of the vaccine, future availability of the vaccine, and risk of contracting HIV.

Notably, participants in San Francisco had more responses to each question, which may be related to greater exposure to HIV education through local media.

Nevirapine as Pre-Exposure Prophylaxis

Jackson JB, Barnett S, Piwowar-Manning E, et al. A phase I/II study of nevirapine for pre-exposure prophylaxis of HIV-1 transmission in uninfected subjects at high risk. *AIDS*. 2003; 17(4): 547–553. (Johns Hopkins University.)

A small exploratory phase I/II trial found that low-dose nevirapine may be worthy of further study as HIV pre-exposure prophylaxis. Taken at any of three tested dosing increments, the HIV antiviral drug was well tolerated, resulted in minimal or no blood or liver toxicity, and achieved target nevirapine levels in most subjects.

Researchers recruited 33 men and women over the age of 18, selecting subjects who engage in behaviors that put them at high risk for HIV. Of the 33 subjects, 10

Half of subjects in a three-city, three-population study said they would willingly participate in a hypothetical future HIV vaccine trial.

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engaged in non-monogamous unprotected sex, eight had HIV-infected sex partners, eight were men who have sex with men, and seven injected drugs, had sex with injection drug users, or both.

Researchers divided subjects into three groups: 12 subjects were in Cohort A, which had a weekly regimen of nevirapine; 12 subjects were in Cohort B, which had a twice-weekly regimen; and nine subjects were in Cohort C, which took the pills every other day. Each dosage was 200 milligrams, and the duration of the study was 12 weeks.

Subjects reported a total of 30 adverse events during the study. Of these, 25 were ranked as mild and five were considered moderate. None was described as severe.

The most common adverse events were respiratory problems, nausea, and headaches. The Centers for Disease Control and Prevention has not included nevirapine on the expanded list of antiviral drugs recommended for post-exposure prophylaxis due to reports of serious life-threatening liver toxicity and rashes. However, study participants did not report these conditions, possibly due to the significantly lower dosages of nevirapine used in this study, the small number of subjects, or the careful selection criteria for participation. One subject did experience a rash, but he or she had eczema before and during this study.

Nine participants dropped out of the study, seven of whom ceased contact with researchers following their departure. The percentage of subjects who dropped out of the study increased with increasing dose. This could suggest a possible toxicity problem. However, the higher dose frequencies may have served as a deterrent to continued participation based on greater daily commitments to the study.

Participant Attitudes in Thai Vaccine Studies

Maek-A-Nantawat W, Pitisuttithum P, Phonrat B, et al. Evaluation of attitude, risk behavior and expectations among Thai participants in phase I/II HIV/AIDS vaccine trials. *Journal of the Medical Association of Thailand*. 2003; 86(4): 299–307. (Mahidol University, Bangkok.)

A Thai study found that participants in an HIV vaccine trial responded positively to the incorporation of participant education, risk reduction counseling, and verification of participant comprehension of trial procedures into the recruitment and trial process. The study also resulted in decreases in high-risk sexual behavior among participants.

Researchers conducted this study as part of two Phase I/II vaccine trials. The first took place in 1997–1998, and the second took place in 2000–2001. Researchers conducted educational sessions, performed risk reduc-

tion counseling at each visit, and administered questionnaires on behaviors, knowledge, attitudes, expectations, and social influences at the beginning of the study, after four months, and after 12 months.

In the first questionnaire, 62 percent of subjects reported being sexually active, 42 percent of whom had had sex with commercial sex workers. After participation in the study for one year, only 35 percent reported being sexually active, only 1 percent of whom had sex, which was protected, with a commercial sex worker.

None of the subjects experienced rejection from friends or lovers due to their study participation. One subject in the 1997 study, however, did have an application for insurance rejected by an insurance company.

One year after the beginning of each study, 61 percent of participants in the earlier study and 85 percent of participants in the later one reported having positive attitudes toward their involvement in the studies. The remainder in each study expressed neutral feelings.

After four months, 98 percent and 100 percent, respectively, reported experiencing benefits from their participation, and after one year both these figures rose to 100 percent. Benefits included periodic medical check-ups, education, and a sense of social contribution. Finally, after one year, 93 percent and 98 percent, respectively, reported that they would consider volunteering in a future trial, demonstrating high satisfaction rates.

Next Issue

Professional counseling makes little room for unverifiable phenomena such as religious or spiritual belief. The result is that many highly competent professionals are ill-equipped to accommodate religious language, spiritual exploration, and the host of issues at the intersection of religion and society. In the May issue of *FOCUS*, **Robert Hopcke, MFT**, a therapist in private practice in Berkeley, California and the former Coordinator of the AIDS Prevention Program for Operation Concern in San Francisco, examines the role of spiritual development and the stages of faith in HIV-related counseling.

Also in the May issue, **Martin Milton, PsychD**, Course Director of Psychotherapeutic and Counselling Psychology at the University of Surrey in the United Kingdom, describes existential-phenomenological therapy and its application to HIV.

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