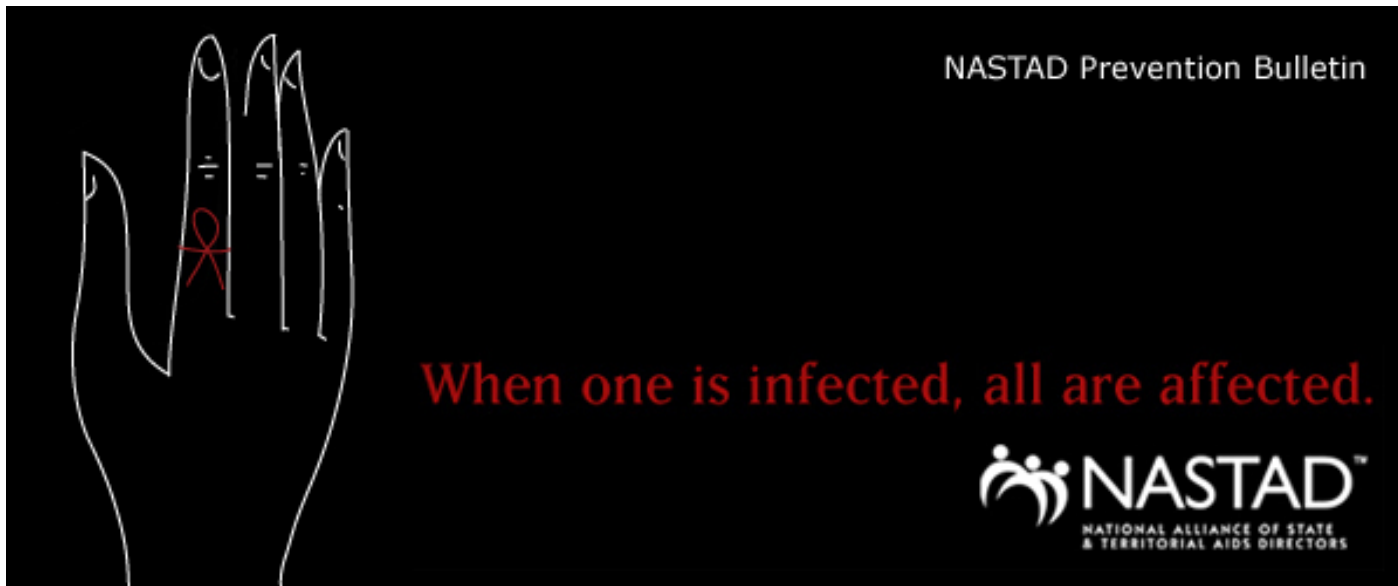


NASTAD Prevention Bulletin



March 2008

## Table of Contents: Ever Expand the HIV and Viral Hepatitis Prevention Arsenal

- [Ever Expand the Prevention Arsenal](#)
- [Non-occupational Post-exposure Prophylaxis \(nPEP\): An Already Available Tool in the Fight against HIV](#)
- [Pre-Exposure Prophylaxis \(PrEP\) for HIV Prevention: Perspectives from the Atlanta Arm of a Centers for Disease Control and Prevention \(CDC\) Study](#)
- [Male Circumcision and HIV Infection](#)
- [HIV Vaccine: NASTAD AED Vaccine Education Initiative Kickoff](#)
- [Microbicides: The Magic Bullet?](#)

### Ever Expand the Prevention Arsenal

As part of our continuing series highlighting the principles in NASTAD's [National HIV Prevention Blueprint](#) in our 2008 [Prevention Bulletin](#) series, we focus this month on strategies currently under development or review that may expand our prevention arsenal.

As we described in last month's *Bulletin*, we currently have many effective prevention services and tools that, if fully funded and implemented, could make significant progress in preventing new infections. Yet at the same time, there remains a clear need to expand the prevention options that are available. Research, translated into practice, is a critical component to ending this epidemic.

New behavioral interventions must be developed that meet the needs of specific high risk populations. These interventions must be pulled from all sources, including rigorous academic research as well as locally-developed empirical studies. Furthermore, interventions and strategies that are shown to be effective must be made widely available as quickly as possible. Those currently in the clearance pipeline must be fast-tracked to offer alternatives to our programs in the short-term as other interventions are developed.

Additionally, we must invest in operationalizing effective prevention strategies that are not yet widely practiced. For one, non-occupational post-exposure prophylaxis (nPEP) has been proven to prevent HIV infection. Still, it is not widely available in the U.S. There must also be a commitment to, and investment in, research efforts that quickly advance our understanding of the effectiveness of new and sometimes controversial approaches for preventing HIV infection. For example, building on research in the global arena, there are

- [Conclusion](#)
- [Meeting and Planning Calendar](#)

studies currently underway to determine the effectiveness and acceptability of pre-exposure prophylaxis (PrEP) and male circumcision for specific populations with HIV risk in this country. These studies will help to determine if these strategies can be effective in our communities. Finally, research into the development of not-yet-realized options like an HIV vaccine and microbicides must be scaled up. If either of these possibilities were realized, there could be a significant impact on the epidemic. Every commitment must be made to advancing these and other yet known alternatives so that they can compliment the approaches that already prevent the transmission of HIV, like condoms, clean needles and syringes and STD treatment.

The stories in this month's *Bulletin* describe the current status of new prevention tools, both those that are currently available and those that are under development, as well as strategies that health department HIV prevention programs can use to promote broad understanding of these strategies. Some of these strategies have received considerable press, so we strive in this issue to focus on what the research does and does not say about them. Because many of these strategies have not yet been fully evaluated and are under scientific review, these profiles will focus primarily on the research, rather than profiling practical applications of these strategies. However, if these potential prevention strategies have sparked discussion in your jurisdiction, we'd love to hear about it. Please contact [Dave Kern](#), NASTAD's Director of Prevention, or [Lynne Greabell](#), NASTAD's Director of Service and Support, to share these conversations.

*"What we need is more people who specialize in the impossible."*

-Theodore Roethke

### **Non-occupational Post-exposure Prophylaxis (nPEP): An Already Available Tool in the Fight against HIV**

*By Neal Carnes, Indiana State Department of Health's HIV Medical Services Program Manager*

Unofficially, yet certainly understood within HIV prevention and service programs, our estimates of HIV infection are on the rise. Microbial and immunization research has failed to produce a viable product to prevent HIV infection and existing interventions that we know work to prevent the transmission of HIV are not fully implemented and/or are sorely underfunded, or not funded at all. Now, nearly three decades into the domestic HIV/AIDS epidemic, we are watching HIV impact another generation of our brothers, sisters, mothers, fathers, friends, lovers and, yes, even ourselves. Thus, our current situation begs the question: Are there underutilized and/or underfunded options available that have strong enough evidence - both medical and psychosocial - to merit a more concerted scale up effort? This article

considers one such prevention strategy: nPEP.

nPEP builds upon the practice of post-exposure prophylaxis (PEP), which intends to prevent HIV transmission by supplying anti-retroviral medications to a person who experienced an event that placed them at risk for possible HIV exposure. PEP is a standard practice among health care and emergency response professionals, thus “occupational” in nature, who come into contact with potentially infected bodily fluids (e.g., medical and emergency response professionals who are stuck by used needles). The practice of PEP, when applied to those exposed in non-occupational settings is called nPEP. nPEP has proven profoundly effective in reducing perinatal transmission, to the point where transmission has dropped to less than two percent in the U.S.<sup>1</sup>

Applied more globally, nPEP has great potential to prevent transmission for people who are not yet infected but who engage in high risk behaviors, like unprotected receptive anal and vaginal intercourse. In fact, several nPEP programs targeting high risk populations are already operating throughout the U. S. In February, I spoke to Charge Nurse R. Kiefer St.Pierre, RN, MHA, to profile the nPEP program in Boston’s Fenway Community Health Center.

**Q: *What is the goal of Fenway’s nPEP program? How do you go about achieving that goal?***

**A:** Simply put, our goal is to prevent HIV infections. Normally, we supply a 28-day regime of Atripla to a person reporting an at-risk event within the past 72 hours. If the person calls during the Clinic’s off hours, the on-call medical provider will give them a two to three day supply to get them started and request they come in the first available day to get the rest of the necessary medications to complete the treatment. In addition, we also operate a research program in association with our nPEP program and this program is looking at the effectiveness of raltegravir (Isentress®) in combination with emtricitabine and tenofovir (Truvada®).

**Q: *How do you determine effectiveness?***

**A:** We conduct baseline CD4 and viral load tests. When the results come in we either encourage the client to complete the 28-day regimen based on their non-infection or if the results come back indicating the person is infected we call them back to inform them of the situation and determine if remaining on the regimen is in their best interest. If the person’s labs come back indicating no infection, we request that the client complete the 28-day regimen and come back in 90 days for follow-up to discern the client’s status at that point.

**Q: *Who is your nPEP program predominately serving? Who is coming in for this service?***

**A:** Given that Fenway is historically a gay, lesbian, bisexual and transgender community health clinic we predominately see men who have sex with men (MSM) in the nPEP program. We only serve people eighteen years of age or

older, yet most of our clients in this program are young adults. About 90 percent of the program's client base is white, followed by Hispanic and African-Americans. We see about 10-15 people in a given month.

**Q: *How do you get clients? Do you advertise?***

A: Referrals come mainly from outreach workers and internet ads. We do not publish print ads, like in local newspapers. We also let people know it is available when we do local events like gay pride festivals.

**Q: *Can a Bostonian access nPEP in other locations in the city or is Fenway their only option?***

A: All emergency rooms in Boston are supposed to conduct an assessment if a person comes in and indicates he or she may have been exposed. If this assessment leads the provider to believe the person has been exposed, they are supposed to provide access to nPEP.

**Q: *What is your funding source to operate the nPEP program? How long have you been running your program?***

A: If the client has insurance, as is now required of all Massachusetts residents, we bill their insurance. But if they don't have insurance, the State provides us with the medications. We've been running this program at least since 2006.

**Q: *Do you have any advice for a clinic considering an nPEP program?***

A: Make sure you operate and maintain a clear way, or entrée, into the program. There is really just a 72-hour window of opportunity, post exposure, to benefit from nPEP, so it is important that you make clear how to gain access to the regimen, who someone must see and what follow-up needs to take place.

There are several resources to consult when considering the development of an nPEP program, including the September 2005 background paper from a World Health Organization (WHO) consultation entitled, "[HIV Post-Exposure Prophylaxis Following Non-Occupational Exposures](#),"<sup>2</sup> by Michelle Roland, MD, chief of the California Office of AIDS. The paper includes an extensive examination of the empirical and theoretical foundation of nPEP. Another resource is the guidance published by CDC in its *Morbidity and Mortality Weekly Report* (MMWR) on January 21, 2005 entitled, "[Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States](#)."<sup>3</sup> Finally, *The Body* published an interview with Joshua Bamberger, MD in the summer of 2000 entitled, "[Issues in HIV Postexposure Prophylaxis](#)."<sup>4</sup>

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#### References and Notes:

1. CDC Fact Sheet, Mother-to-Child (Perinatal) HIV Prevention and Transmission, October 2007. Accessed on 2/27/08 from <http://www.cdc.gov/hiv/topics/>

[perinatal/resources/factsheets/perinatal.htm](http://perinatal/resources/factsheets/perinatal.htm).

2. Roland, Michelle, MD, HIV Post-Exposure Prophylaxis Following Non-Occupational Exposures, A Back Ground Paper prepared for the Joint ILO/WHO Technical Meeting for the Development of Guidelines and Policies on Occupational and Non-Occupational Post-Exposure Prophylaxis (PEP), September 2005. Accessed on 2/27/08 at: <http://www.who.int/hiv/topics/arv/WHONon-OccPEP.pdf>

3. CDC, "Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States," *MMWR* 54 (RR-02) 1-20, January 21, 2005. Accessed on 2/27/08 from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>.

4. Bamberger, Joshua, MD, Issues in HIV Postexposure Prophylaxis, *In The Body*, Summer 2000. Accessed on 2/27/08 from: <http://www.thebody.com/content/prev/art2632.html>

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### **Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: Perspectives from the Atlanta Arm of a Centers for Disease Control and Prevention (CDC) Study**

Studies are currently underway to determine the safety, effectiveness and acceptability of administration of daily oral antiretroviral (ARV) therapy to prevent acquisition of HIV infection, commonly known as pre-exposure prophylaxis (PrEP). The theory behind PrEP suggests that the use of a daily oral preventive, when used with existing prevention methods, can help prevent the transmission of HIV by inhibiting infection from the immediate time the virus enters the body, akin to how the application of ARVs to women during labor and delivery and to newborns has been proven effective in preventing mother-to-child transmission.

Several clinical trials are underway worldwide, and CDC is currently supporting a PrEP trial testing the use of tenofovir (Viread®) or tenofovir in combination with emtriciabine (Truvada®) among three populations at high risk for HIV infection - heterosexuals in Botswana, people who inject drugs in Thailand and men who have sex with men (MSM) in the U.S.<sup>1</sup> Both tenofovir and Truvada® are approved, first-line ARV regimens for those infected HIV. In the U.S., three sites are conducting the MSM-focused trial: the University of California, San Francisco/San Francisco Department of Public Health; the AIDS Research Consortium of Atlanta; and Fenway Community Health in Boston. NASTAD spoke with Melanie Thompson, principle investigator for the AIDS Research Consortium of Atlanta, about the U.S. trials.

In the U.S., the trial has enrolled 400 men across all three sites to look at the safety of using tenofovir among HIV-negative men. Because of its limited size,

the trial will not be able to determine efficacy in reducing HIV transmission,<sup>2</sup> but will inform researchers about the potential side effects of the drug, in particular, its impact on kidney (renal) toxicity and bone mineral density. The San Francisco arm of the trial is looking at bone mineral density and all three sites are looking at renal toxicity. The trial has four study arms - where two arms receive either tenofovir or a placebo at the outset and the two other arms receive one or the other after nine months of enrollment. All participants receive risk reduction counseling and access to free condoms and HIV and STD testing throughout their participation.

In addition to clinical outcomes, key features of the U.S. trial include a long follow-up period (two years) for participants, follow-up with any participant who seroconverts for one year after completion of the study and monitoring of recruitment and retention issues, as well as any negative behavioral impact (called “risk compensation”) leading to abandonment of traditional preventive risk measures by those in the trial. Looking at risk compensation is the reason there are four arms of the study, with two arms delaying initiation of treatment for nine months compared with those who started at the trial outset.

In Atlanta, the trial is fully enrolled with 121 men between the ages of 18 and 64. Because of the nature of its epidemic, Atlanta has emphasized enrolling men of color in its arm of the trial. Researchers have been working with a very active advisory board, comprised of 75 percent African American men. The advisory board has advised researchers on the study design and name, marketing and messaging, informed consent and retention issues. Forty percent of the enrolled trial participants are men of color. Despite their desire for a higher percentage, Thompson says the researchers are pleased. This enrollment of men of color is very important for the Atlanta arm of the trial because it will help researchers specifically look at whether there are any differences in the safety of the drug regimen by race.

Thompson says that one of the more interesting aspects of both the Atlanta and San Francisco based trial has been the slow pace of enrollment. Previous experience with vaccine trials showed rapid enrollment, so researchers were surprised at the slow pace of enrollment for the PrEP trial. Thompson suggests several reasons that may explain the slow enrollment in Atlanta, including difficulty getting healthy individuals to take a pill everyday to prevent disease if they are not sick, with no other obvious benefits; the long length of time and commitment (two years) for the trial; and the fact that men of color are less involved in research, have less access to education about research and are less attached to health systems, often because of historically negative relationships with these systems. With only three sites for the trial, the relative mobility of the study population has also made it challenging to stay connected to participants who may leave the study area.<sup>3</sup> To compensate for these recruitment challenges, researchers have been concentrating on community education about this clinical trial.

The U.S. trial began enrolling participants in 2005. Researchers expect to have those in the trial complete their participation by June 2009. It is likely that results from the Thai study among those who inject drugs will be available before those from Botswana and the U.S., since it is already fully enrolled. However, Thompson cautions that results from all three trial studies will not be available for at least a few years and, therefore, it is premature to begin scaling up programmatic efforts until more is known about the safety and efficacy of PrEP for very specific populations at risk for HIV. While she remains enthusiastic about the prospects for PrEP as results unfold, Thompson says that it is important to continue to use “the things we know work,” such as use of condoms, other risk reduction strategies and education.

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#### References and Notes:

1. CDC Fact Sheet: CDC Trials of Pre-Exposure Prophylaxis for HIV Prevention, April 2007, accessed on 2/18/07 at: <http://www.cdc.gov/hiv/resources/factsheets/PDF/prep.pdf>
2. A trial of MSM in Peru has a much larger sample, 3000 men, that researchers hope will be able to determine efficacy.
3. Traditionally with vaccine trials, there are multiple sites around the country that could accept study participants who may have moved from the location where they initiated their participation.

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#### Male Circumcision and HIV Prevention

One of the prevention strategies receiving the most press over the past few years has been the use of male circumcision (MC) for preventing female-to-male transmission of HIV infection. Based on observational studies and clinical trials in Africa exploring the efficacy of MC in preventing heterosexual transmission, researchers found that MC was associated with a highly significant reduction in HIV risk for heterosexual men.<sup>1,2,3</sup>

It is biologically plausible that male circumcision could protect heterosexual men from acquiring HIV. The foreskin is less keratinized (has less cytoskeletal protein) than the glans (head) of the penis and has a high density of a type of immune cells (Langerhans cells) that may provide an entry point for HIV. Thus, it is thought that the foreskin of uncircumcised men may make them susceptible to HIV infection. Because the data on the effect of MC in preventing female-to-male HIV transmission comes from Africa, the question remains about the role of MC for prevention efforts in the U.S. This becomes particularly important given that there has been significant press coverage globally, with a tendency towards sensationalism and misinformation, which may have obscured understanding the potential role of MC as a prevention strategy in the U.S.

At the 2007 National HIV Prevention Conference in Atlanta, Peter Kilmarx, MD, Chief of the Epidemiology Branch in the CDC Division of HIV/AIDS Prevention, provided an overview of research on MC and reviewed information from a CDC consultation on MC that took place in April 2007.<sup>4</sup> NASTAD spoke with Kilmarx to better understand the implications of MC for our work in the U.S.

According to Kilmarx, any decisions to implement MC programs depend on local considerations, including the cultural context for MC, as well as the resources available and nature of the epidemic. The effectiveness of MC in preventing HIV acquisition is a function of the prevalence of HIV and the predominant mode of transmission. In sub-Saharan Africa, where the HIV prevalence in the trial countries is between six and 19 percent, HIV transmission occurs primarily through heterosexual risk and MC rates are much lower than in the U.S., the rationale for a large-scale programmatic effort for MC is compelling.<sup>4,5</sup> Even so, as MC programs ramp up in sub-Saharan Africa, it is imperative that education efforts continue to stress the importance of continuing established risk reduction practices among circumcised as well as uncircumcised men (e.g., increase in condom use or decrease in the number of sex partners). While concerns exist that potential risk compensation might offset some of the benefits of MC, data from the clinical trials and other studies do not indicate that this potential risk compensation is significant.<sup>6</sup>

It is widely known that the HIV/AIDS epidemics in Africa and the U.S. are very different, particularly the populations at greatest risk for being infected. In the U.S., the predominant mode of HIV transmission is through anal-penile sex, in populations of MSM, and the overall prevalence of HIV is much lower than in Sub-Saharan Africa. In the U.S., it is not possible to make a recommendation on MC that applies uniformly to the entire male population. CDC is currently developing a *Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports* on MC and anticipates publishing it later this year after it goes through peer review and a public comment period. Kilmarx says that as this process moves forward, CDC is reviewing the input they received from the April 2007 consultation, where CDC heard that:

- For MSM, consultants felt there is not sufficient evidence to support that MC is protective against HIV. This is because the presumed protective benefit of MC is via insertive sex, and MSM risk is primarily through receptive sex. There are meta-analyses currently underway to look at this further and to determine the value of doing a clinical trial to further evaluate this risk;<sup>7</sup>
- For men at risk for HIV acquisition through heterosexual sex, consultants felt it is reasonable to generalize the findings from Africa to the U.S. However, because the prevalence of HIV is lower in the U.S. than in Sub-Saharan Africa, the relative risk of HIV is lower for U.S. heterosexual men than for their African counterparts. Thus, consultants suggested that

heterosexual men be informed of the partial protection of MC and recommended a demonstration project take place; and

- For neonatal infants, the consultants felt that there should be an effort to more clearly inform people of the valid medical benefits of MC for prevention of infant urinary tract infections, as well as HIV, other STDs and penile cancer. Complicating this suggestion is the fact that, because the American Academy of Pediatrics (AAP) in 1999 said that data at that time were insufficient to recommend neonatal MC,<sup>8</sup> many state Medicaid systems no longer pay for routine neonatal MC. (The AAP is currently reviewing their recommendations for updates in light of the clinical trial findings.)

These suggestions from the 2007 CDC consultation seem to be the likely future of MC in the U.S. Importantly, Kilmarx emphasized that in addition to these suggestions from consultants, it is clear that any consideration of MC in the U.S. should only proceed in conjunction with other proven prevention methods. CDC plans to issue a “Dear Colleague” letter on MC in the near future, and they are currently developing a plain language fact sheet (including a version in Spanish), both of which should be available in the next few months.

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1. As reported by Peter H. Kilmarx, MD, Chief of the Epidemiology Branch at the CDC, NCHHSTP Division of HIV/AIDS Prevention, at the 2007 National HIV Prevention Conference, “*Male Circumcision and HIV*,” Presentation available at: <http://www.cdcnpin-ta.org/Public/ViewDocument.aspx?DocumentID=55b89429-453f-4e08-b175-b342d2f536c4>.
2. CDC HIV/AIDS Science Facts - Male Circumcision and Risk for HIV Transmission: Implications for the United States, Updated February 2008. Accessed on 2/20/08 at: <http://www.cdc.gov/hiv/resources/factsheets/PDF/circumcision.pdf>.
3. For male to female transmission, the latest study result reported at CROI 2008 revealed no significant reduction in male-to-female HIV transmission when HIV-infected men were circumcised and there was a trend towards increased transmission when couples resumed sex before the man had healed completely. Wawer M, Kigozi G, Serwadda D, et al. “*Trial of Male Circumcision in HIV+ Men, Rakai, Uganda: Effects in HIV+ Men and in Women Partners*.” Oral presentation, Conference on Retroviruses and Opportunistic Infections (CROI), Boston, MA, February 2008.
4. Kilmarx, 2007
5. Ibid
6. For example, Kalichman, Seth, Lisa Eaton, and Steven Pinkerton, “Circumcision for HIV Prevention: Failure to Fully Account for Behavioral Risk Compensation.” In *PLoS Medicine*, March 2007, vol. 4, Issue 3, pp. 0597,

downloaded on 2/20/08 at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1831748>. And a response from Sullivan PS, Kilmarx PH, Peterman TA, Taylor AW, Nakashima AK, et al. (2007) "Male Circumcision for Prevention of HIV Transmission: What the New Data Mean for HIV Prevention in the United States." *PLoS Med* 4(7): e223 doi:10.1371/journal.pmed.0040223.

7. See also, Millett, Gregorio A., "Circumcision Status and HIV Infection Among Black and Latino MSM," presentation downloaded on 2/20/08 from: <http://www.cdcnpin-ta.org/Public/ViewDocument.aspx?DocumentID=88ad1a33-289e-4faa-a3b1-b052589375a0>

8. American Academy of Pediatrics, "Circumcision Policy Statement," *Pediatrics*, Vol. 103 No. 3, March 1999, pp. 686-693 Accessed on 2/27/08 at: <http://pediatrics.aappublications.org/cgi/content/abstract/103/3/686>.

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### HIV Vaccine: NASTAD's Vaccine Education Initiative Kickoff

Consistent with NASTAD's *Prevention Blueprint*, development of an effective HIV vaccine would be a major accomplishment that would contribute to the arsenal of prevention tools to stop the spread of HIV/AIDS. But building support for vaccine research is a challenge for all vaccine development efforts; especially so for HIV vaccine research.

Recent events, including the termination of the STEP trial of the Merck AIDS vaccine candidate, MRK-Ad5 due to lack of vaccine efficacy as well as the question of potentially increased HIV susceptibility among trial volunteers, could set back support for future HIV vaccine trials (data released at last month's Conference on Retroviruses and Opportunistic Infections (CROI) suggests that male circumcision status played a role in the increased susceptibility among trial participants<sup>1</sup>). The National Institutes of Health (NIH), National Institute of Allergy and Infectious Disease (NIAID), has developed an explanatory slide set which provides clear summaries of the analysis of data from the STEP trial as well as answers to a handful of frequently asked questions related to STEP. The [slides](#) explain the rationale behind the multivariate analyses as well as a breakdown of the findings related to Ad5 serostatus and circumcision status among male volunteers. The slide set is best understood in conjunction with Susan Buchbinder's presentation from CROI, which can be viewed [online](#).

Long-term ongoing efforts to inform the general public of the ethics, safety and status of HIV vaccine clinical research are therefore essential to the success of vaccine research and the participation of volunteers in clinical trials.

Clinical trials are a major component of HIV vaccine development. Since NIH support for HIV vaccine clinical trials began in 1987, more than 26,000 participants have enrolled in over 100 NIH-sponsored trials testing nearly 60

potential HIV vaccines. Analysis of U.S. enrollment in Phase I and II HIV vaccine trials funded by NIAID between 2004 and 2006 showed that racial and ethnic minorities represented 40 percent of trial enrollees; whereas in 2005, the CDC estimated that racial and ethnic populations comprised 70 percent of people living with HIV/AIDS in the U.S.

One important component necessary in order to ensure that results of clinical trials are generalizable to all segments of the population is to recruit and retain sufficient numbers of the most highly affected populations into HIV vaccine trials. It is also important to create a climate in which HIV vaccine research is understood, accepted and supported.

Research does reveal, however, that public awareness and understanding of HIV vaccine research is low, with a lower level of understanding among certain populations considered most at risk. Allen, Liang, and LaSalvia (2005) found in a study of over 3,500 individuals that over 47 percent of African-American participants believed that a preventive HIV vaccine already exists, while 27 percent of Latinos thought the same.<sup>2</sup> A recent study by the MAC AIDS Fund surveyed over 4,000 individuals in the U.S. and abroad and found that large numbers of respondents believed that there is a cure for AIDS. In the U.S., the majority of respondents who believed there was a cure and that AIDS was not fatal were African American.<sup>3</sup> A third study by Jonathan Fuchs and colleagues discussed what the researchers termed negative social impacts (NSIs) from those participating in the world's first large-scale phase III vaccine trial.<sup>4</sup> The most common NSI was negative reactions from friends, family and partners, reported by 14 percent (785) of the study participants. These reactions primarily stemmed from two misunderstandings. First, others often believed the participant was at risk for being infected by the vaccine or that the vaccine was unsafe. Second, others sometimes believed that they themselves were at risk for infection if they were exposed to vaccinated participants. These studies and others indicate there is public confusion that requires a continued need for educating communities about HIV vaccine research.

Long-term ongoing efforts to inform the general public of the ethics, safety and status of HIV vaccine clinical research are essential to the success of HIV vaccine clinical trials research and the participation of volunteers. In order to accomplish this, the Division of AIDS (DAIDS) within NIAID/NIH began the HIV Vaccine Communications Campaign (HVCC) in 2000 to expand awareness and support for HIV vaccine research among U.S. populations most affected by HIV.

NIAID's HIV Vaccine Research Education Initiative (NHVREI) continues and expands upon the HVCC. The NHVREI partnership program aims to build strong partnerships between NIAID, key influencers, national HIV prevention leaders and the community to foster an environment that supports HIV vaccine research and to increase individuals' willingness and intent to participate in HIV vaccine clinical trials. By engaging national and local organizations, tapping into their

extensive networks and reaching into communities most affected by HIV/AIDS, support for HIV vaccine research and HIV vaccine clinical trial participants will increase.

The NHVREI partnership program has two approaches working simultaneously together: the Local Partnership Program (LPP) and the NHVREI National Partners. The LPP seeks to create a supportive local environment for HIV vaccine research by educating key communities about this research in localities where HIV vaccine clinical trials are ongoing or planned. Local Partners have been selected and are in Atlanta, Birmingham, Boston, Chicago, Nashville, New York City, Philadelphia, Rochester, San Francisco, Seattle and the District of Columbia. Other domestic areas that have clinical trial units but don't currently have local partners include Raleigh, North Carolina and Puerto Rico. The LPP is focused on: (1) educating HIV-affected communities; (2) building longer-term relationships with key opinion leaders and gatekeepers; (3) creating supportive environments in cities with active trial sites; and (4) building capacity within information gate-keeping organizations and among key opinion leaders to inform their communities about HIV vaccine research.

The NHVREI National Partners program will provide a broader outreach mechanism to improve public awareness across the United States and its territories. The two partnership programs together will support the NHVREI goal of increasing knowledge about and support for HIV vaccine research by concurrently working at the local and national level. For more information, visit the [NHVREI website](#).

NASTAD was recently selected by the Academy for Educational Development (AED - contractor for NHVREI) to serve as one of the NHVREI National Partners. NASTAD's goal for the two-year project will be to assist NIAID and AED in broadening the dissemination of accurate and important information about HIV vaccine research. NASTAD will accomplish this through a series of activities, including information dissemination, outreach and training and technical assistance. Specific components of the project include:

1. Publish specific articles regarding HIV vaccine research and clinical trials in NASTAD's *Prevention Bulletins*.
2. Conduct sessions at NASTAD's Annual Meetings in 2008 and 2009 focusing on HIV vaccine research and clinical trials. It will be the goal of these sessions to provide accurate scientific information regarding the recent STEP trials and future vaccine efforts.
3. Highlight HIV Vaccine Awareness Day activities in NASTAD newsletters and other materials in May 2008 and conduct a webinar for health department staff on or around HIV Vaccine Awareness Day in 2009. HIV Vaccine Awareness Day is May 18.

4. Conduct breakout sessions focused on HIV vaccine awareness during NASTAD's ADAP and viral hepatitis technical assistance meetings in 2008 and 2009.
5. Work with NASTAD's African American Advisory Committee's Research Subcommittee and Latino Advisory Committee to increase awareness of HIV vaccine education and awareness within health departments.
6. Conduct two national technical assistance conference calls for health department staff (in Fall 2008 and 2009) to increase awareness of HIV vaccine research and participation in clinical trials.
7. Develop a fact sheet for health departments designed to increase awareness of HIV vaccine research and clinical trials. The fact sheet will include best practices that health departments are utilizing to increase awareness of vaccine research and clinical trials as well as strategies to consider for doing the same.
8. Routinely distribute information regarding HIV vaccine research and clinical trials in existing NASTAD publications, where appropriate.
9. Participate in at least two conferences to highlight health department efforts to increase awareness of HIV vaccine research and clinical trial participation.

*For more information regarding NASTAD's "Increasing Awareness of HIV Vaccine Research and Participation in HIV Vaccine Clinical Trials through Education and Coalition Building with State and Local Health Departments" project, please contact [Joy Mbajah](#) or [Murray Penner](#).*

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1. Conference on Retroviruses and Opportunistic Infections. Robertson M, et al "Efficacy results from the STEP study (Merck V520 protocol 023/HVTN 502): a phase II test-of-concept trial of the MRKAd5 HIV-1 Gag/Pol/Nef trivalent vaccine" CROI 2008; Abstract 88LB
2. Allen MA, Liang TS, LaSalvia T. Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. *Journal of Acquired Immune Deficiency Syndrome* 2005
3. MAC AIDS Fund. "New Global Study from M•A•C AIDS Fund Uncovers Surprising Reality That Disease Is Still Underestimated as a Global Killer." Press Release 2007.
4. Fuchs, J. et. al. Negative Social Consequences Follow HIV Vaccine Trial Participation *Acquired Immune Deficiency Syndrome* 2007;46:362-368.

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## Microbicides: The Magic Bullet?

Are microbicides the magic bullet HIV prevention advocates have long awaited? “No. Absolutely not. Even those of us who are passionate about this issue recognize that HIV prevention is about options, options, options,” responded Jim Pickett, chair of International Rectal Microbicide Advocates (IRMA) and Director of Advocacy at the AIDS Foundation of Chicago. NASTAD spoke with Pickett to learn more about microbicide development and the role that health departments can play in advancing this important prevention strategy of the future.

According to the [Alliance for Microbicide Development](#), microbicides are technologies that can be applied to the vagina or rectum to help prevent the transmission of sexually transmitted diseases including HIV and, in some cases, pregnancy. Microbicides take several forms, including gels, creams, tablets and rings. Microbicides currently in development work to prevent infection through various means including providing a physical barrier that keeps pathogens, like HIV, from reach target cells; enhancing existing bodily defense mechanisms; and disabling or preventing replication of pathogens.<sup>1</sup>

There are currently 13 microbicide candidates in clinical trials globally, according to an [Alliance for Microbicide Development summary](#). Unfortunately, the most far along in the clinical trials process, Carraguard® gel, a microbicide candidate derived from seaweed, did not demonstrate effectiveness in preventing male-to-female HIV transmission according to a February 18, 2008 [press release](#) from the Population Council, the candidate’s sponsor. Carraguard®, like a majority of microbicide candidates, focuses on developing a product for vaginal use.

Rectal microbicides, also an important tool for the future HIV prevention arsenal, have received much less attention. According to a new report released last month by IRMA, [Less Silence, More Science](#), there were no coordinated efforts to develop a rectal microbicide until 2004. Currently, only one rectal microbicide candidate is in Phase I clinical trials, with two others planned for 2008.

When asked why it is important to develop a microbicide for both vaginal and rectal use, Pickett said, “The vagina and the rectum are very different environments. First, the vagina is thicker—up to 40 cell layers—while the rectum is only one cell layer thick, so it’s very delicate, fragile, and more susceptible to trauma like microscopic tearing. The rectum also has CD4 receptors right under the one layer, so it’s like a welcome wagon for HIV. Second, the vagina and rectum have different pH, so it’s very likely that a

product developed for one environment won't work in the other. Third, the vagina is an enclosed pouch with a known amount of area while the rectum is a long tube. After anal sex, semen can travel up to two feet, so this begs the question: where does infection occur? Close to the end of the rectum or two feet up?" Pickett went on to point out that knowing where rectal HIV infection actually occurs is very important when trying to develop a product to protect from it since the product will likely need to stay ahead of HIV-infected semen as it travels.

When asked about other challenges in microbicide development, Pickett commented, "Where we run into challenges is our human nature. [An effective microbicide] is the light at the end of a very long tunnel. There are so many things that need to be done, requiring our attention and time now. This is a long term commitment. Consider drug development: hundreds of agents start in development and maybe only one is ever ready for licensure. It's a long, hard road, fraught with failure, but that's the only way you learn."

Given that health departments face many immediate competing priorities in their HIV prevention work, NASTAD asked Pickett what health departments can do to support longer range efforts like microbicide development. "We have so few things at our disposal now. Condoms, we all know, are the best option and should always be encouraged, but if people don't use them, it doesn't matter. There's not even enough attention paid or resources for options that we already have, like nPEP. We have this option now, so why aren't we starting pilot programs for it? At the same time, we need other tools that focus on not interrupting sex as it happens, like PrEP. We have to start talking now about how the prevention landscape will change in the future."

Pickett went on to suggest that health departments identify low threshold options for advancing microbicide development and other yet-to-be realized prevention strategies. He suggests that health departments educate their staff and their community planning groups about these topics. "They can just dip their toe in the water by getting people engaged. CPGs and HIV care planning councils must start talking and learning about new technologies. This is an easy thing. They may not be able to prioritize these strategies in their next planning cycle, but availability may not be that far off. Like PrEP, there are large scale clinical trials for microbicides. If this works, these could be part of the arsenals very near down the road. We need to start planning. Groups like [IRMA](#) and the [Global Campaign](#) have presentations that can be downloaded off their websites.

"Health department staff should be educated too. Anyone can sign up for listservs and be on calls. Raising general awareness costs no pennies and little time. Health department experts should also be helping shape research and science because they understand what works in the real world. 'Safe' and 'effective' doesn't mean acceptable—think about the female condom. Health departments should be sharing their expertise so that clinical trials are designed

well and move forward. Also, health departments can endorse the microbicide development by saying ‘We’re committed to research and development of safe and effective products. We support good research and science.’ It’s not hard advocacy, which many health departments are unable to do.”

Pickett also stated that health departments can help correct misperceptions about sexual behaviors. “There this silence around anal intercourse among heterosexuals and there is a faulty assumption that heterosexual sex is vaginal sex. We need to start asking people what their actual behaviors are. We need to collect more specific and detailed data about how transmission is occurring. We need better data on the behaviors that happen around a sexual act, like douching before or after sex, because microbicides, ultimately, wouldn’t change a person’s routine. Knowing how people have sex will help us understand how to better intervene to reduce risk and, at the same time, not compromise a person’s style. We have to systemically ask about it on questionnaires and intake forms. Hello PEMS! We’re already asking a lot of questions.”

Pickett acknowledged that many health departments are not clear about how they can be involved because of all the issues they have to address on a daily basis. “The case just hasn’t been made clearly. It’s no one’s fault that health departments haven’t been more engaged. It’s a big a shift in our mindset about prevention.” Pickett sees education about new strategies as important steps that must be taken, even if the long range benefits are far off. “While the availability of microbicides won’t cure sexism or ensure equal rights for those who lack power, particularly women, it is necessary step in the right direction.”

For additional low threshold ideas for supporting microbicide development, please read the one-page “Rectal Microbicides Advocacy Includes You” at the end of IRMA’s *Less Silence, More Science*. For more information about microbicides and International Rectal Microbicide Advocates, please contact [Jim Pickett](#) (312) 334-0920.

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#### References and Notes:

1. <http://www.who.int/hiv/topics/microbicides/microbicides/en/>

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#### Conclusion

This review of potential new prevention strategies makes clear that our prevention toolbox will be expanding in the years to come. But these stories also point out that it is imperative we scale up interventions and strategies that already work to prevention infections as well as invest in the development of new non-biomedical interventions. New targeted interventions are needed to

address gay men of all races and ethnicities. And in order to provide more options for highly impacted communities of color, there must be more concerted and intentional efforts to bring them into research and clinical trials. As two of the chief agencies conducting and supporting HIV prevention research, the National Institutes of Health (NIH) and CDC must work together to develop a coordinated research action plan to increase the number of behavioral interventions in the prevention arsenal.

At the same time, the profiles in this *Bulletin* also point out that a critical aspect of our prevention research agenda is to pay careful attention to the rigor of the science and to clearly and accurately communicate the findings. Many of these potential new prevention strategies are extremely complex. Therefore, the programmatic implications and applications of these strategies are not simple questions. Yet, because the epidemic continues to ravage many communities, and because of our frustration at not seeing the expected reductions in new infections over the past decade, it is tempting to latch on to any new thing we feel could stem the tide. But, as our [March 2007 Prevention Bulletin](#) on “Prevention du Jour” pointed out, we must not expect or search for the “magic bullet.” As we look to the future, we *will* utilize the substantial and ever-growing science base which provides us incredible resources to drive program planning, funding, implementation and evaluation. But in our movement forward, we must remain vigilant about the intended and unintended consequences of any new HIV prevention strategy in public health policy and practice.

### Meeting and Planning Calendar

Capacity Building Opportunities: For a searchable database of CDC-supported capacity building trainings and events, please visit the [Capacity Building Branch's Group Events Management System site](#).

March 10, 2008

National Women and Girls AIDS Awareness Day. For more information, visit the [event website](#).

March 3-7, 2007

National Housing and HIV/AIDS Research Summit III: Examining the Evidence: The Impact of Housing on HIV Prevention and Care. Sponsored by the National AIDS Housing Coalition (NAHC). For more information, visit the [conference website](#).

March 20, 2008

National Native HIV/AIDS Awareness Day. For more information, visit the [event website](#).

March 28-29, 2008

17th Annual HIV Conference, Orlando, FL. Sponsored by the Florida/Caribbean AETC. For more information, visit the [conference website](#).

May 18, 2008

HIV Vaccine Awareness Day. For more information, visit the [website](#).

May 19, 2008

World Hepatitis Day. For more information, [link](#) to the newsletter.

May 19, 2008

National Asian and Pacific Islander AIDS Awareness Day. For more information, visit the [event website](#).

May 22-25, 2008

20th Annual National Conference on Social Work and HIV/AIDS, Washington, D. C. For more information, visit the [conference website](#).

June 11-14, 2008

HIV Prevention Leadership Summit (HPLS), Detroit, MI. For more information, visit the [conference website](#).

June 27, 2008

National HIV Testing Day. Sponsored by NAPWA. For more information, visit [www.NAPWA.org](http://www.NAPWA.org)

July 28-29, 2008

2008 National Conference on Latinos and HIV/AIDS, Miami, FL. For more information, visit the [conference website](#).

August 3-8, 2008

XVIII International AIDS Conference, Mexico City, Mexico. For more information, visit the [conference website](#).

August 25-28, 2008

Ryan White HIV/AIDS Program Training and Technical Assistance Grantees Meeting and 11th Annual Clinical Update, Washington, D.C. Convened by HRSA.

September 15-16, 2008

1st Global Conference on Methamphetamine: Science, Strategy, and Response, Prague, intended to bring together scientists, world leaders and professionals to discuss the intersection between methamphetamine use, public health, law enforcement and civil society. For more information, visit: [www.globalmethconference.com](http://www.globalmethconference.com).

September 18-21, 2008

United States Conference On AIDS (USCA), Miami Beach, FL. For more information, visit the [conference website](#).

November 13-16, 2008

Toward A National Policy: The 7th National Harm Reduction Conference, Miami, FL. For more information, visit <http://www.harmreduction.org/article.php?list=type&type=60>

December 11-12, 2008

"Connecting the Dots: Economic Development and Rural Minority & Multicultural Health," National Rural Health Association's 14th Annual Rural Minority and Multicultural Health Conference, Albuquerque, NM. For more information and a Call for Abstracts (due May 30, 2008), visit <http://www.ruralhealthweb.org/conferences/sub/MMConf.html>.

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### Credits, Feedback and Input

The *NASTAD Prevention Bulletin* is edited by NASTAD staff and is written by staff and prevention experts from around the country. NASTAD's production of the *Bulletin* is made possible through funding provided by CDC's Division of HIV/AIDS Prevention (DHAP) in the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention.

If you have an idea or program that you would like to include in the *Bulletin*, please contact Dave Kern or Lynne Greabell (202/434-8090). NASTAD welcomes feedback to issues presented in *Bulletin*. To submit commentary, please e-mail us at [NASTAD@NASTAD.org](mailto:NASTAD@NASTAD.org).

Electronic versions of the *Bulletin* are available on our webpage.

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