

## Beyond Condoms: HIV Prevention

In the past decade, since the advent of HIV combination therapy, we have made enormous strides in the treatment of HIV. Drug regimens have been simplified and pill burdens greatly reduced. Effective treatments for drug side effects have brought us closer to the goal of making HIV a “chronic manageable” disease. People with the virus today can expect to live longer and healthier lives than at any time since the epidemic began.

But treatment alone isn’t the answer. For one thing, the drugs used to treat HIV are wildly expensive, most notably in developed nations. In the United States, for all our wealth, the cost of providing treatment outstrips government outlays, forcing people onto waiting lists for these lifesaving drugs. Around the world, most people living with HIV go without access to effective treatment, notwithstanding well-publicized international efforts to vastly expand access.

There are other problems with a lifetime of anti-retroviral therapy: Even though the situation has

much improved, there are still many people who cannot tolerate the side effects of some or all of the available medications. Drug resistance and cross-resistance are a growing concern. And no one knows what unanticipated effects of prolonged use of these powerful drugs may yet turn up.

The fact is that we cannot treat our way out of this epidemic. Prevention is key. This issue of the *Update* deals with various issues surrounding prevention. On the medical side are articles about the search for a vaccine and effective microbicides, and the use of pre- and post-exposure prophylaxis. First-person stories examine some of the thornier issues of risk behavior, including those who seek sex without condoms.

We must not let the treatment advances of the last ten years make us complacent about HIV. Prevention, ultimately, remains the answer to eradicating this epidemic, and to ending all of the associated costs, especially the devastating human costs.

*Daniel Tietz, Editor-in-Chief*

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## What Happened to the Vaccine?

*by Richard Jefferys*

When HIV was first discovered in the early 1980s, scientists were optimistic that a vaccine to prevent infection could be developed in a matter of years. Unfortunately, that optimism was misplaced, and HIV has turned out to be a tricky foe for vaccine researchers.

### The Antibody Approach Hits a Snag

At the time of HIV’s discovery, it was thought that most vaccines worked by triggering a type of immune response called an antibody response (we now know that T cells and other parts of the immune system also play a role). Antibodies are tiny Y-shaped molecules made by a type of immune system cell called a B cell. The job of antibodies is to float around the bloodstream and glom onto pathogens, dis-

abling them and marking them for destruction. Initial experiments in the laboratory showed that HIV grown in a lab dish could be effectively blocked by antibodies that would attach to HIV’s outer protein, called the envelope protein. Scientists designed vaccines based on a molecule on HIV’s envelope called gp120 in the hopes that these vaccines would trigger the development of similar antibodies in people, thereby protecting them if they were exposed to HIV.

But before these vaccines could be tested in clinical trials, researchers realized that HIV adapts itself to life in a lab dish in a way that makes it more vulnerable to antibodies than it is in the human body. HIV taken directly from people

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Bulk copies of *ACRIA Update* are available free to agencies that provide services to people living with HIV/AIDS. For more information, call 212-924-3934 ext. 129.

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## **Transacin (NGX-4010) for Peripheral Neuropathy**

People with HIV who have peripheral neuropathy will use either Transacin (capsaicin) patches or very low-dose patches for 30 or 60 minutes a day for 3 months. Participants must be 18 or older and have had pain in both feet for at least 2 months.

## **TH9507**

People aged 18-65 who have excess abdominal fat will take either TH9507 (an investigational growth hormone releasing factor), or a placebo for 26 weeks. The two groups will then switch for 26 more weeks.

## **Lauriad for Oral Thrush**

People with oral candidiasis will take either Lauriad (miconazole) tablets once a day or clotrimazole troches 5 times a day for 2 weeks. Participants must be 18 or older and be on stable HAART for at least 2 months.

## **Crofelemer for Diarrhea**

People 18 and older who have persistent diarrhea will first take crofelemer or placebo tablets for 6 weeks. Then everyone will take crofelemer for 5 months.

## **Avandia and Serostim**

People with insulin resistance will take Avandia (rosiglitazone), or Serostim (growth hormone), or both for 6 months to see how they affect glucose, insulin levels and body shape.

## **KP-1461**

People aged 18-60 who have taken an NRTI, NNRTI and PI, and have developed resistance or stopped the drugs for other reasons, will take KP-1461 (a new type of NRTI) with no other ARVs for four months.

## **SPRING: Aptivus in Diverse Populations**

People 18 and older (half white and half non-white, half men and half women) who have taken an NRTI, NNRTI and PI (not Aptivus) and who have resistance to at least two PIs, will take a standard dose of Aptivus or receive therapeutic drug monitoring to find the best dose for them.

## **IMPACT: Reyataz Resistance**

People who have developed resistance to Reyataz will come in for one day of blood tests to study the I50L mutation.

## **TMC 125 Expanded Access**

People 18 and older who have limited treatment options and resistance to approved NNRTIs, and who have taken an NRTI, NNRTI and at least two PIs, may qualify for early access to this experimental NNRTI.

## **Maraviroc Expanded Access**

People 16 and older who have taken HAART and who have few treatment options may qualify for early access to this experimental CCR5 attachment inhibitor.

**For more information on these trials, contact Dr. Douglas Mendez at 212-924-3934 ext.126 or Dr. Yuriy Akulov at ext. 124.**

### **Editor's Note**

All material in *ACRIA Update* is presented for educational and informational purposes only, and is not intended as medical advice. All decisions regarding one's personal treatment and therapy choices should be made in consultation with a physician.

## What Happened to the Vaccine? *(continued from first page)*

could not be blocked by the anti-gp120 antibodies that worked against HIV grown in the lab. One company, VaxGen, that was developing a gp120 vaccine decided to respond to this new information essentially by behaving like a child – covering its ears and singing “la, la, la” in the hopes of not hearing bad news.

VaxGen took its vaccine, named AIDSVAX, all the way to two huge clinical trials designed to test whether it worked. One trial was conducted mainly in North America and most of the participants were gay men. The second trial took place in Thailand among people at risk for HIV infection because of intravenous drug use.

When the results finally became available in 2003, it turned out that the laboratory studies had been right. There were no differences in the number of people that became HIV infected in the trials whether they received AIDSVAX or a placebo (dummy) vaccination. Shamefully, VaxGen attempted to sift through the results of the North American study and suggest that AIDSVAX had shown some protective effect in people of color; this turned out to be a false claim based on a very small number of nonwhite individuals that had enrolled in the trial.

### **T cell Responses Take a Turn**

While this may sound disastrous, all was not lost because many other scientists continued to work on different vaccine approaches. Over the past decade or so, it has been found that there is another type of immune response against HIV that might be protective. These immune responses are called T cell responses.

T cells come in two main flavors: CD4 cells (which are monitored in people with HIV as a marker of disease progression) and CD8 cells. CD4 cells act like quarterbacks calling the plays for CD8 cells and B cells. CD8 cells have a vitally important function: They can recognize virus-infected cells in the body and zap them with destructive proteins in order to eliminate them. For this reason, they are also sometimes called cytotoxic T cells

(cyto comes from the Greek word for cell) or cytotoxic T-lymphocytes (CTL).

Several lines of evidence suggest that CD4 and CD8 cells targeting HIV can play an important role. In monkeys infected with a close relative of HIV called SIV (simian immunodeficiency virus), viral load increases dramatically if researchers artificially deplete the animals of their CD8 cells. People with HIV

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*“Because of the difficulty of blocking HIV with antibodies, a major focus of vaccine researchers has been on designing vaccines that can induce production of CD4 and CD8 cells targeting HIV.”*

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who do not develop immune deficiency – long-term nonprogressors – have been shown to have highly functional CD4 and CD8 cells that target the virus, and their CD8 cells can rapidly kill HIV-infected cells in a lab dish. People with HIV that progresses in the usual way also have CD4 and CD8 cells targeting HIV – sometimes very large numbers of them – but when looked at to see how well they work, it turns out they do a poor job of killing infected cells.

Additionally, CD4 and CD8 cells targeting HIV have been found in individuals – such as sex workers and the uninfected partners of HIV-positive people – who have been repeatedly exposed to the virus, but remain

uninfected (although it is not yet known if these T cell responses are protecting these individuals, or if they just indicate that exposure to HIV has occurred).

### **The ALVAC Vaccine**

As a result of this evidence, and because of the difficulty of blocking HIV with antibodies, a major focus of vaccine researchers has been on designing vaccines that can induce production of CD4 and CD8 cells targeting HIV. While CD4 cell responses can be triggered quite easily, it turned out to be tough to trigger the development of CD8 cell responses.

For most of the 1990s, the best that researchers could do was induce CD8 cell responses targeting HIV in around 20% of HIV-negative people who received an experimental vaccine called ALVAC. ALVAC is a type of vaccine called a viral vector. It is a harmless version of a bird virus called canarypox that has been altered so that it makes several different HIV proteins when injected into people (the proteins cannot form infectious HIV).

Although most researchers think it’ll be necessary to trigger CD8 cell responses in more than 20% of recipients for a vaccine to have any chance of working, ALVAC is now being tested in a large trial in Thailand to see if it can offer any protection against HIV infection. Anyone in the trial who becomes infected will also be monitored to see if receiving the vaccine improves his or her chances of becoming a long-term nonprogressor.

### **Merck Makes a Breakthrough**

The big breakthrough for vaccines aiming to trigger CD8 cell responses came just after the turn of the millennium. Merck & Co. developed a different kind of viral vector vaccine, based on a weakened form of a virus called adenovirus (which in its natural form causes bad colds). This vaccine has been shown to trigger CD4 and CD8 cell responses targeting HIV in the majority (50-70%) of people who receive it. The HIV proteins that the vaccine makes are called *gag*, *pol*, and *nef*. Merck’s vaccine is now being tested in a

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## What's Happened to the Vaccine? *(continued from previous page)*

trial involving 3,000 HIV-negative people at risk for HIV infection. The trial got under way in January 2005, and results are expected by 2010 at the latest. As with the ALVAC trial, this study will also evaluate whether the vaccine can completely protect against infection or improve a person's chances of becoming a long-term nonprogressor.

### The VRC Weighs In

A very similar vaccine has been designed by government researchers at the Vaccine Research Center (VRC) in Bethesda, which is part of the National Institutes of Health. The VRC approach uses a two-pronged strategy called "prime-boost" vaccination. The first vaccine that is given consists of just of a piece of DNA that can make certain HIV proteins when injected into the muscle. This DNA vaccine can induce anti-HIV CD4 and CD8 cells, but only at very low levels. The VRC then uses an adenovirus-based vaccine like Merck's to boost these CD4 and CD8 cells to much higher levels.

The VRC's vaccine includes more HIV proteins: It has *gag*, *pol*, and *nef*, but also includes envelope proteins from three different HIV subtypes from different parts of the world: subtypes A, B, and C. A trial to test the effectiveness of this vaccine involving 8,500 people is just getting under way; preliminary results may be available by 2011.

### Therapeutic Vaccines

All of the T cell-based vaccines mentioned in this article (and several others) are also being studied as potential therapies. The goal of therapeutic vaccination is to improve the effectiveness of anti-HIV immune responses in people that are already infected with the virus. Studies typically vaccinate people while they are receiving antiretroviral drugs, so that anti-HIV T cell responses can develop while viral load is suppressed. ART is then interrupted to figure out if these new immune responses can control HIV better than it was being controlled before.

To date, some studies using ALVAC have shown a limited impact of therapeutic

vaccination, while others have shown no effect (or even a detrimental effect in one case). Results from studies using the Merck and VRC vaccines have not yet been presented.

### Conclusion

Results from these ongoing trials of T cell-based HIV vaccines will be critical for the future of HIV vaccine research. If some significant evidence of protection – against either infection or disease progression – is seen, researchers will be able to try to improve on those results and,

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*“Few scientists think that T cell-based vaccines will offer complete protection against HIV infection, since antibodies are thought to be necessary for this to occur.”*

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depending on the degree of success, submit the results to the FDA for approval of the vaccine.

A vaccine that reduced viral load levels could have a beneficial impact on the spread of HIV infection because people with lower viral loads are less likely to transmit the virus. It would be a challenge, however, to develop educational materials about such partially effective vaccines because recipients would need to be informed that they were not fully protected against HIV. If no hint of an effect emerges from the trials of T cell-based vaccines, vaccine researchers will have to ratchet up efforts to develop antibody-

based vaccines or alternative approaches (if any can be discovered).

There is no way of knowing what the outcome of these trials may be; most optimistically, many researchers do feel – based on results in animal models – that the vaccines may improve the chance that a vaccine recipient who becomes infected with HIV will become a long-term non-progressor. More pessimistically, few scientists think that these T cell-based vaccines will offer complete protection against HIV infection, since antibodies are thought to be necessary for this to occur.

If these scientists are correct – and current evidence strongly suggests they are – then it is extremely unlikely that a completely protective HIV vaccine will become available in our lifetime. We'll only find out for sure in a few years time, when the results of these trials are in.

For more information, visit the AIDS Vaccine Advocacy Coalition at: [avac.org](http://avac.org). Their *AIDS Vaccine Handbook: Global Perspectives (2nd edition)* contains a wealth of detail on all aspects of the search for a vaccine, from the ethics of clinical trials to the need for community activism.

*Richard Jefferys is Coordinator of the Michael Palm Basic Science, Vaccines & Prevention Project at the Treatment Action Group.*

### **ACRIA Drop-In Support Groups**

The popular groups formerly offered by Body Positive have found a new home. These peer-led drop-in support groups are held every Thursday and Friday from 6:30 to 8:00 p.m. at the LGBT Community Center, 208 West 13th St., NYC.

For more information, call Gustavo Otto at 212-924-3934 x129.

# Microbicides: Where Are They Now?

One of the drawbacks of the condom is that its use may be controlled by the insertive partner – so it can sometimes be difficult for the receptive partner to make sure that one is used. Even the female condom requires a partner’s cooperation for proper use. Add to this the fact that many men don’t like the feel of male condoms and that they can sometimes make it difficult to maintain an erection, and you can see why microbicides are being studied, especially when the aim is to provide women with a prevention tool they can control.

This article (adapted from information available at the Global Campaign for Microbicides) answers some of the basic questions people have about microbicides, and provides updates on the candidates that are furthest along in testing.

## What is a Microbicide?

A microbicide is a substance that can reduce transmission of sexually transmitted infections (STIs), including HIV, when applied in either the vagina or rectum. A microbicide could be produced in many forms: gels, creams, suppositories, films, lubricants, or sponges or vaginal rings that slowly releases the active ingredient.

A microbicide could prevent HIV and STIs by:

- killing or otherwise immobilizing pathogens;
- blocking infection by creating a barrier between the pathogen and the cells of the vagina or rectum; or
- preventing the infection from taking hold after it has entered the body.

Ideally, a microbicide would combine some or all of these mechanisms for extra effectiveness.

When used consistently and correctly, condoms are likely to provide better protection against HIV and STIs than microbicides, so they will still be the preferred option. But for people who cannot or will not use condoms, and particularly for women whose partners refuse condoms, microbicides could save lives and have a substantial impact on the spread of HIV. In fact, one mathematical model showed that if even a small proportion of women in lower income countries used a microbicide that was 60% effective in half the sexual encounters where condoms are not used, 2.5 million HIV infections could be avoided in just three years.

## HIV, STIs, and Pregnancy

Since STIs are caused by different pathogens (some viral, some

bacterial), a microbicide that works against one STI might not protect against another. Reducing HIV risk is the primary goal of microbicide research, but some of the microbicides currently being tested appear to have some efficacy against at least one other STI in addition to HIV. Eventually, a combination product that works in multiple ways could offer protection from a wide range of STIs, including HIV.

Some microbicides being studied prevent pregnancy and some do not. It’s important to have both non-contraceptive microbicides and “dual-action” microbicides that prevent pregnancy and infection, so that women and couples can protect their health and still have children. This is not possible with condoms.

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*“Pharmaceutical companies have not invested significantly, because microbicides are a classic ‘public health good’ that would yield tremendous benefits to society but for which the profit incentive is low.”*

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## Trial Safety and Ethics

Any new product must go through rigorous safety testing before becoming available to consumers. Women’s health activists and researchers are working closely together to ensure that the clinical testing of microbicides is thorough and ethical. Fortunately, some of the substances and mechanisms of action under investigation are already in use on other products – so some safety data about them are available already (although their possible efficacy as microbicides is not yet proven).

Current clinical trials are studying whether microbicides could protect HIV-negative women from infection, but there is hope that some products may eventually be shown to protect men if their female partner is HIV positive. Evaluating whether a microbicide protects male partners, however, will require separate clinical trials.

Virtually all microbicide research to date has been conducted by not-for-profit and academic institutions or small biotech companies. Studies are funded by charitable foundations and government grants. These funds also support basic science, social and behavioral research, and clinical trial infrastructure that contribute to microbicide research and development. Large pharmaceutical companies have not invested significantly in this field, primarily because microbicides are a classic “public health good” that would yield tremendous benefits to society but for which the profit incentive to private investment is low.

## A Failed Candidate

Until recently, two organizations were conducting separate trials of cellulose sulfate (CS), also known as Ushercell. CONRAD, a

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## Microbicides: Where Are They Now? *(continued from previous page)*

reproductive health research organization, was conducting a trial among women in Benin, India, South Africa, and Uganda, while Family Health International (FHI) was conducting a trial in two sites in Nigeria. Both sponsors are not-for profit research groups dedicated to advancing health in developing countries.

CONRAD halted its trial after early results suggested that CS might be contributing to an increased risk of HIV infection among women in the study. Even though the FHI trial did not find the same increased risk, it decided to stop its trial, choosing to err on the side of caution. There were no differences in the rates of STIs other than HIV between the two groups.

Before the CONRAD trial was stopped, 35 women had seroconverted (in both the experimental and the control groups – we do not know yet how many were in each group). The analysis was based on small numbers and may change as more data are studied – more women may be found to be HIV positive once all women return to the site and are tested, or it may be learned that some women received false negative HIV test results at the time of their enrollment.

Eleven safety trials on CS were conducted prior to the initiation of these Phase III trials and no differences were observed between women using the CS gel and women using placebo gel. All participants in both trials received monthly HIV prevention counseling, free condoms, and prompt diagnosis and treatment for any curable sexually transmitted infections. Extensive measures were taken at all trial sites to help women understand that they should not rely on the test product to protect them from HIV, and that half were receiving a placebo gel (known to be ineffective).

Scientists are trying hard not to speculate until more is known. It is likely to be several months before the data analysis will be completed and publicly available. In the meantime, studies of other candidates continue.

### The Candidates

#### ***Carraguard***

Carraguard is an attachment inhibitor that provides a physical barrier between pathogens and vulnerable cells in the cell wall (epithelium) of the vagina or rectum. It is not expected to be contraceptive, and may provide some protection against HIV, HSV,

HPV, and gonorrhea. The active pharmaceutical ingredient in Carraguard is carrageenan, a substance derived from seaweed. Carrageenan is used as a thickener in foods and as an emulsifier in topical creams and lotions such as those used in the cosmetics industry.

A large trial of Carraguard, conducted by the Population Council, was completed in March of 2007, with results expected by the end of 2007 or early 2008. Carraguard is the first new microbicide to have reached completion of its Phase 3 trial.

#### ***BufferGel***

BufferGel is an acid buffer that keeps the vagina acidic even in the presence of semen. It also creates a physical barrier that stops or slows down the passage of pathogens into the vaginal and cervical walls. It is hoped it will also work to prevent pregnancy, at the same time helping to protect against HIV, HPV, HSV, chlamydia, and gonorrhea. Buffer Gel is being studied along with PRO 2000 (below) in a large trial (HPTN 035) of 3,100 women at seven sites in Malawi, South Africa, Zambia, Zimbabwe, and Philadelphia.

In this trial, women are placing a single dose of BufferGel, PRO 2000 gel, or placebo gel into the vagina up to 60 minutes before vaginal intercourse, using single-use, pre-filled applicators. The trial also includes a “condoms only” arm in which women apply no gel at all. Everyone receives ongoing HIV risk reduction counseling, condoms, and diagnosis and treatment of sexually trans-

mitted diseases. Results are expected in 2009.

#### ***PRO 2000***

PRO 2000 (naphthalene sulphonate) is an entry and fusion inhibitor that binds to viruses and bacteria to prevent them from infecting healthy cells. Its ability to prevent pregnancy may depend on the dose used. It may help protect against HIV, gonorrhea and HSV. See above for info on current trials.

#### ***Tenofovir Gel***

Tenofovir is an HIV drug contained in Viread, Truvada, and Atripla. It was chosen to test as a microbicide gel because it is active in many of the cells that HIV targets for infection, such as dendritic cells, macrophages, and CD4 cells. These cells are abundant in the vagina. Animal studies found that tenofovir gel

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prevented infection in monkeys when given before or after infusions of SIV (a virus similar to HIV).

It is being studied in HPTN 059, a six-month trial of two methods of use: either daily or only before sex. Women in the study will use either tenofovir or placebo gel, and half the women will have colposcopies (an examination of the cervix). All participants will be provided with condoms and counseled to use them. The trial is being conducted in Birmingham, Alabama; the Bronx, New York; and India. Another trial is being done in the Dominican Republic.

### ***Other Candidates***

Several other microbicides are in early development, including dapivirine (TMC120), an HIV drug that is being studied as both a gel and a vaginal ring; lauryl sulfate (“the invisible condom”), which is liquid at room temperature but changes to a gel when applied to the body; UC-781, a drug in the same class as Sustiva that is being studied in gel form; and SPL7013 (VivaGel), which uses synthetic molecules called dendrimers to encapsulate and disable HIV. VivaGel is the only microbicide being studied for use both in the vagina and on the penis.

### **Rectal Microbicides**

The few international studies available show that anal intercourse occurs all over the world – and not only in men who have sex with men. Heterosexual couples also engage in anal sex in many cultures. In U.S. surveys, 35% of heterosexual women reported having had anal intercourse at some time in their lives and 6.7% of heterosexual couples practice anal intercourse at least once a month.

Receptive sex partners (whether women or men) are at 10 to 100 times higher risk of HIV infection than insertive partners during unprotected anal intercourse. But both partners can be exposed to other STIs, including anal warts, hepatitis B, syphilis, and gonorrhea. For those unable or unwilling to use condoms, rectal microbicides could be a safe and effective alternative means of reducing risk, especially if they were unobtrusive or enhanced sexual pleasure enough to motivate consistent use.

Although a number of microbicides are being studied for vaginal use, it’s not clear yet which of them would also be suitable for rectal use. The rectum and the vagina differ significantly in many ways. The vagina, for example, is virtually a closed pouch while the rectum is part of an open-ended cavity. A greater quantity of the microbicidal product will probably be needed for adequate rectal coverage than for vaginal use. The rectal lining is more fragile than most of the tissue lining the vagina, and the rectum is also richer in the CD4 cells that are particularly vulnerable to HIV infection. Some of these factors further enhance rectal vulnerability to irritation, tearing, and infection during sex.

Some researchers have been looking at the “over-the-counter” lubricants available in pharmacies and sex shops to see if they might work as microbicides. Three of these commercial products have been shown to kill HIV in the test tube. However,

commercial lubricants often contain preservatives, perfumes and other ingredients that could cause irritation if applied internally on a regular basis and/or in large quantities. Preliminary research already suggests that some lubricants are significantly more likely to cause rectal irritation than others. More research and advocacy regarding lubricant safety is urgently needed.

As we learned with nonoxynol-9 (which, after years of being recommended as possibly helpful in protecting against HIV, was found actually to increase the risk of HIV infection, and to be especially damaging to the rectum), it is dangerous to make assumptions about a product’s safety or effectiveness before the research on it is complete. There is no proof that any of the available over-the-counter lubricants are either safe or effective as microbicides – and there is evidence suggesting that some may be more irritating to rectal tissue than others.

### **Conclusion**

No one strategy or technology will “solve” the AIDS pandemic. We must use all existing prevention strategies: behavior change, voluntary counseling and testing, STI diagnosis and treatment, broad access to male and female condoms, and access to sterile syringes and HIV treatment, while we work to develop new tools and technologies. Microbicides will likely be available and accessible sooner than an HIV vaccine. Even after a safe and effective vaccine is discovered, however, vaccines and microbicides will have different, complementary roles to play in a global HIV prevention strategy.

And once we find effective microbicides, it’s essential that they get into the hands of women and men who need them at a price they can afford. In the past, new health technologies have rarely become widely available in developing countries until more than a decade after their approval in the U.S. and Europe, an unacceptable delay for life-saving products developed primarily with public funds. Advocates are working with researchers and policy makers now to emphasize the need to address issues of access and affordability up front, in order to be prepared to deliver a microbicide rapidly as soon as one is proven safe and effective.

For more information on microbicides, and information on how to get involved to advocate for more research, visit these sites:

### **The Global Campaign for Microbicides**

[www.global-campaign.org](http://www.global-campaign.org)

### **The Alliance for Microbicide Development**

[www.microbicide.org](http://www.microbicide.org)

### **International Rectal Microbicide Working Group**

[www.irmwg.org](http://www.irmwg.org)

### **The Microbicide Trials Network**

[www.mtnstopshiv.org](http://www.mtnstopshiv.org)

# Before and After: PrEP and PEP

by Luis Scaccabarozzi and Mark Milano

One of the more surprising discoveries of the last decade was that HIV meds could not only treat HIV infection, but also prevent it. Using these drugs soon *after* exposure to HIV has become an accepted practice, but using them *before* exposure remains controversial. Here's what we know about both of these approaches.

## PEP

PEP, short for *post-exposure prophylaxis*, was first shown to be effective in preventing occupational exposure to HIV (needlesticks and blood splashes, etc.). This led researchers to study whether giving HIV meds shortly after sexual exposure might also work. But since the drugs used are all FDA-approved and available by prescription, it was not considered ethical to conduct controlled studies (in which half the participants get drug and half get a placebo, or dummy pill). So the only studies done have given meds to everyone in the study – a useful source of data, but not a method that can conclusively prove whether this approach works. Still, results have been impressive: of 401 people treated in a PEP study in San Francisco in the late '90s, none seroconverted.

## How Does It Work?

Timing is critical when it comes to PEP. HIV meds must be started as soon as possible (recommendations vary from 36 to 72 hours after exposure), and continued for 28 days. The effectiveness decreases the longer treatment is delayed, so starting quickly is important. In many states, every organization working with people with HIV is required to have a policy in place to deal with occupational exposures so that employees don't have to scramble to find out what to do after an exposure occurs. People should know where to go for care before an exposure happens. If you're exposed in the middle of the night, don't wait until morning to call your doctor – go to the nearest ER as soon as possible and take that first dose!

Before starting PEP, a provider must determine that:

- The exposure occurred within the preceding 72 hours (NYS DOH recommends 36 hours).
- The patient is HIV negative (a new HIV antibody test is recommended before starting PEP).
- It is known, or there is a good chance, that the source individual has HIV.
- There was a significant risk of exposure (PEP is usually used only for occupational exposures or for vaginal or anal intercourse without a condom, but each case is considered individually).

If it's possible to interview the source individual, a regimen will be chosen based on that person's treatment history and any known drug resistance. For women, interactions with birth control meds and the possibility of pregnancy will be taken into account. Generally, triple combination therapy (the same kind used to treat HIV infection) is used.

## Sticking To It

PEP is not a picnic. Side effects to HIV meds are often strongest in the first few weeks, and for PEP to be effective, it must be taken for at least 28 days. Choosing a regimen that will lead to the fewest missed doses and preparing for side effects (including what to do if they occur) is important. It's also necessary to check for any interactions with other drugs, including over-the-counter and street drugs.

The final step is to follow up with another HIV antibody test in four to six weeks. If that's negative, another test should be taken three months after the exposure to confirm that infection did not occur.

## PrEP

PrEP is intended for rare, one-time exposures – not for repeated use. For people who are exposed to HIV on a regular basis, a more controversial approach is being studied: the use of HIV meds to

prevent infection *before* exposure. Called PrEP, for *pre-exposure prophylaxis*, it is based on the common practice of using antiretrovirals to prevent HIV transmission in pregnancy.

Current PrEP studies are using either Viread (tenofovir) or Truvada (tenofovir plus emtricitabine). These products were chosen because they are taken once daily, can be taken without food, and have strong safety records, limited side effects, and favorable resistance profiles. In addition, animal studies have shown that Viread and Truvada can reduce the risk of transmission of simian immunodeficiency virus (SIV) in monkeys. SIV is a virus commonly used in animal research in the hopes that it mirrors HIV infection in humans. But results have been mixed: some studies have found that PrEP in monkeys prevented transmission of SIV, while others found that PrEP only delayed transmission. And, of course, humans may not respond in the same way.

A study presented last month at the 16th International HIV Drug Resistance Workshop found that infusions of Truvada given 2 hours before and 24 hours after exposure prevented SIV infection in all of the six monkeys tested. Once again, we don't know if this will translate to HIV exposure in humans. (All PrEP trials to date have studied the drugs taken as pills once a day, not as infusions just before and after exposure.)

## False Starts

Four PrEP trials have been stopped before completion for very different reasons. Studies in Cambodia and Cameroon were stopped when activists protested that adequate safer sex counseling was not being provided and that little or no planning was in place to provide healthcare for those who seroconverted during the trial. The Malawi Ministry of Health ended a trial because of concerns that widespread use of tenofovir could complicate its use as an HIV treatment, and a trial in Nigeria was shut down due to questions about trial sites' capacity to conduct the study.

Questions have also been raised about the populations being studied. We know from experience in countries like Thailand that government enforcement of condom use in brothels can dramatically lower HIV infection rates. So is it ethical to conduct studies in sex workers when we already have a method proven to work? In particular, is it ethical to conduct studies in injection drug users in countries where clean needles are not provided by the government? These concerns and others have been the subject of heated debate.

### First Results

After years of waiting, the first results of a PrEP study were presented at the International AIDS Conference in Toronto in 2006. A study in Ghana enrolled 936 HIV-negative women, half of whom took Viread and half placebo. The results showed that two of the women taking Viread and six of the women taking placebo seroconverted. But these results were not statistically significant because the rigorous safer sex education done by the trial sites led to a decrease in the number of new partners and an impressive increase in self-reported condom use during the last reported sexual encounter – from 52% to 94%! It may be that trials that are conducted ethically (that is, with proper counseling) will lead to too few seroconversions to yield useful results.

### Ongoing Trials

In Thailand, the CDC is conducting a study of once-daily Viread in 2,000 HIV-negative injection drug users. The trial is being conducted in collaboration with the Thailand Ministry of Public Health at 17 drug-treatment clinics in Bangkok. But the Thai government, like that in the U.S., does not provide clean needles for drug users, and concerns have been raised about the ethics of testing an unproven prevention method when a proven intervention is not also made available.

The CDC is also conducting a trial with the Botswana Ministry of Health of once-daily Truvada. 1,200 HIV-negative heterosexual men and women aged 18 to 29 are being recruited at HIV counseling and

testing centers, sexually transmitted disease and family planning clinics, youth organizations, and community events. The trial had originally been planned to study Viread alone, and had already enrolled 71 people before there was evidence to support trials of Truvada. Researchers therefore will continue to follow those participants to obtain data on the safety of Viread alone.

In the U.S., the CDC is studying once-daily Viread in collaboration with the San

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*“The rigorous safer sex education done by the trial sites led to a decrease in the number of new partners and an impressive increase in self-reported condom use during the last reported sexual encounter – from 52% to 94%!”*

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Francisco Department of Public Health, the AIDS Research Consortium of Atlanta, and Fenway Community Health in Boston. A variety of recruitment techniques, including outreach and referrals through clinicians and community-based service organizations, are being used to enroll 400 HIV-negative men who have sex with men (MSM) who have had anal intercourse during the past year. To reflect the demographics of the U.S. HIV epidemic, a substantial number of the par-

ticipants will be MSM of color.

Two groups in the U.S. study will take either Viread or placebo, and two other groups will do the same but after waiting nine months after enrollment. This design will allow researchers to compare risk behaviors among persons who are taking a daily pill and those who are not. This analysis will be critical to understanding the potential impact of a daily drug regimen on HIV risk behavior. Because the number of people in the trial is comparatively small, it will study only the safety of this approach, not its effectiveness.

The National Institutes of Health is preparing a safety and efficacy trial of Truvada PrEP in 1,400 MSM in Peru and Ecuador, and the CDC is in the planning stages for a U.S. study of the safety of Truvada PrEP. (For details on current PrEP studies, visit [prepwatch.org](http://prepwatch.org).)

### Other Issues

There have been concerns that people may use PrEP before studies are complete, thinking they are protecting themselves from HIV. Rumors abound that some gay men are already using PrEP, including a “new cocktail” at sex parties called “MTV” (Meth, Tenofovir, and Viagra). But a CDC survey given at gay pride events in 2005 showed that out of 397 HIV-negative gay men, only one person had used PrEP, while five had used PEP. Almost 19% said they had heard of PrEP, indicating that though the concept is somewhat known, its use is not widespread.

If PrEP is proven effective, understanding its impact on HIV risk behaviors will be critical. One of the greatest risks is that people will reduce their use of proven prevention strategies. Because no single strategy will likely be 100% effective, reducing transmission will require integrating all available methods – both biomedical and behavioral. During trials, all participants must receive state-of-the-art HIV risk-reduction counseling and other proven HIV prevention interventions.

Even if these trials demonstrate that PrEP can reduce HIV transmission, it is equally important to understand whether per-

*(continued on page 19)*

## Personal Perspective: HIV- UB2?

by Mark Milano

“Are you clean?” I looked down at the guy who was asking me this. As opposed to what, I wondered. Dirty? Well, I did take a shower before I left the house. So, yeah, I was clean.

You see, I had been talking to this guy on a phone sex line (this was before internet hookups) for almost an hour when he invited me out to his house in Brooklyn - at two in the morning. All he wanted was to have oral sex, he said. The subway ride took about an hour, with a ten-block walk to his house. And after all that, just before we were ready to start, he decides to try to find out my HIV status.

It wasn't the first time I'd experienced this. And, of course, guys never ask, “Do you have HIV?” It's always a dodge: “Are you safe?” “Are you healthy?” And the most insulting, the one this guy used: “Are you clean?”

Just what exactly do these guys think they're doing? Protecting themselves? Gimme a break. I think the response of many guys with HIV is, “Which answer gets me a blow job?” Do people actually think the information they get from a stranger is in any way useful? Especially when that guy wants sex right now?

That's why I've been upset by recent efforts to encourage “serosorting” (having sex only with people of the same HIV status). Serosorting works fine if you are HIV positive. Many people with HIV choose to have sex only with other people with HIV. It eliminates the “disclosure moment” and also the need for condoms, if you aren't concerned about superinfection with a second strain of HIV (most documented cases of which have occurred within two years of a person's initial HIV infection).

Serosorting for people in long-term relationships is another matter (I'll get to that later), but encouraging HIV-negative gay men to ask strangers their HIV status is not only useless, it's dangerous. Here's why.

First, the information is arguably worthless. Someone you

barely know has little motivation to be honest, since no personal or emotional bond exists. And even if someone thinks he's negative, he could be wrong. He may have been tested two years ago, or he may have been infected last week (in which case he would have an incredibly high viral load, increasing the risk of infection). Relying on the self-reporting of someone you barely know when making a decision about safer sex is foolish at best. Recent studies have shown that a significant number of new infections are occurring during the “window” period - the time when someone who is newly infected still tests HIV negative (up to three months).

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**“Guys never ask, ‘Do you have HIV?’ It's always a dodge: ‘Are you safe?’ ‘Are you healthy?’ And the most insulting, the one this guy used: ‘Are you clean?’ ”**

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Second, it's dangerous. If the guy claims to be negative, do you then do things you wouldn't do with someone who is positive? For many, the answer is yes. Guys who avoid even low-risk behavior - like oral sex without ejaculation - will do that with someone who claims to be negative. But believing a stranger is negative can remove a lot of inhibitions, leading to really unsafe behavior, like anal sex without a condom. So, in the end, asking HIV status and making decisions about what you will do based on the answer can actually lead to higher-risk behavior than not asking.

Third, if you reject people who admit to being positive, you may encourage them to lie the next time. And some guys can be brutal, as anyone who is positive knows. I've been with guys who were clearly ready to have anal sex without a condom.

But when I ask, “Are you positive?” and they say no, the sex is over once I say that I am. And I mean over - no touching, no kissing, nothing. Yet the guy who is too scared even to kiss a guy with HIV had been eager to have anal sex without a condom before I spoke up.

As someone with HIV I believe I have an obligation to behave responsibly and not infect others. I've had a number of negative boyfriends, and they are all still negative. In fact, only one guy I dated had a bad reaction when I disclosed my status. My current boyfriend and I have had great sex for five years, and he remains negative. (This isn't rocket science, folks - we just use a

condom!) I wouldn't agree to oral sex without a condom until he was fully informed about the (low) risk and had made a sober decision to do it, a decision not made in the heat of passion.

But it can be difficult to feel compassion for strangers who will often be cruel once we disclose our status. And guys who ask "the HIV question" can be surprisingly thoughtless. I've had guys come up to me in a bar and within two minutes pop the "Are you healthy?" question. Now, wait a minute! I may not even be interested in this guy, but I'm supposed to start disclosing my medical history to him? The sense that something as personal as your HIV status is public information never ceases to amaze me.

With the rise of the internet, attempted serosorting seems to have really taken off. Many online ads post cold warnings: "Disease-free only" or "HIV- UB2." And most gay male hookup sites require you to post something about your HIV status. I put up an ad at one site and was required to choose "Negative, Positive, Unknown, or No Answer" for my HIV status. I chose "No Answer" and got very few come-ons. So, as an experiment, I changed my status to "Negative."

Sure enough, I suddenly began getting a bunch of hits. And when I spoke to them on the phone, it was clear many of them were looking for bareback sex (anal sex without a condom). In spite of the overhyped stories about barebackers looking to get infected, I've found that the vast majority of HIV-negative gay men – including those who bareback intentionally – are quite concerned about avoiding HIV, and people with it.

It's good that negative men want to stay negative – we need to help them find ways to do that. But trying to screen out all people with HIV via interrogation is nothing more than a fantasy. I actually had one guy say he could tell if someone was lying about their status by looking into their eyes when he asked. Hello?

And this is not only about sex with strangers. Many gay

men take off the condoms just a few weeks into a relationship, with little or no discussion of the risk. I knew a 22-year-old who had fallen in love with his dream boyfriend. He asked him if he was negative, and was assured that he was. They took off the condoms, and now he's positive. So if you can't trust even the information you get from someone you're in love with, how can you trust information from someone you meet on the internet?

There are recommendations for couples who want to take off the rubbers, and I agree with them: get tested together, and if you're both negative, work out an agreement on either being monogamous or being safe with outside partners. And most especially, be able to be honest with each other if one of you slips and has unsafe sex with a stranger. You each must explicitly agree that if one of you admits to being with someone else, you will engage in a frank and honest conversation, and not just start screaming and end the relationship. Of course, this approach involves accepting a certain level of risk, and in a way puts your life and health in the hands of your partner. And that takes a lot of talking, a lot of trust, and a lot of caring – something you're not going to find in someone you meet at a bar or online.

If you choose to have casual sex, you must decide what you are comfortable doing with someone who is positive and then do that with everyone. If you won't have sex with someone who is positive, don't do it with a stranger just because he assures you he's "really" negative.

It's unfortunately true that more gay men are choosing to be unsafe, but letting them think they can screen out HIV-positive partners or suggesting "harm reduction" for barebacking (see p. 12) is not the answer. Maybe letting them know that people with HIV are not lepers and that safer sex is doable is one approach. It's certainly better than letting the fantasy of serosorting lead to seroconversion.

*Mark Milano, who always showers before sex, is an HIV treatment educator and editor of ACRIA Update.*

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***"I actually had one guy say he could tell if someone was lying about their HIV status by looking into their eyes when he asked. Hello?"***

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# Harm Reduction for Barebacking?

by Rafael Madrid, PhD

I came to New York City, like many other gay men, looking for a place where I could be myself and escape the repressive, conservative, and homophobic society of my native Chile, where you can't talk about sex, period. What I actually found — in the city where the Stonewall Riots happened and the gay rights movement began — was an only slightly less homophobic society. I found a city facing the same problems as other societies that preach abstinence or perfect behavior as the only way to deal with the complicated issue of human sexuality.

After living here awhile and working in the HIV and LGBT fields, I began to hear people talking about “condom fatigue” and the rise of “barebacking” among gay men, including the use of websites as a way to practice it. I learned about concepts like “PNP” (Party and Play – mixing recreational drugs and sex) and the reality of burnout and the tiredness of old prevention campaigns.

## What is barebacking?

Barebacking is gay slang for intentional unprotected anal intercourse. Different from just skipping the condom in the heat of passion, barebacking means making a deliberate decision before sex to not use one. (The term “barebacking” may not be acknowledged by all men who practice this behavior – some men use the terms “raw” or “natural” instead. Health professionals who are tailoring programs toward barebackers must recognize this in order to design effective prevention services.)

Internalized homophobia can be an important stressor that contributes to barebacking. According to Michael Shernoff, it creates an “an unconscious sense that a gay man is unimportant and undervalued, thus increasing his sense that he is expendable, and so too are the men with whom he has sex and from whom he seeks love and validation.”

Research conducted in New York has shown that use of crystal meth correlates directly with barebacking among white, black, and Latino (but not Asian) gay men. A study of gay meth users in New

York City suggested that men with certain psychological profiles are attracted to methamphetamine, use it in environments and contexts that are sexually charged, and as a result are more likely to engage in barebacking. Whether men use the drug intentionally as a way to facilitate barebacking or whether barebacking is a byproduct of methamphetamine use – or some combination of the two — are issues that need further exploration.

## Barebacking and the Internet

Men looking for sex partners have found the internet very useful for connecting with other men, and it's used by gay men of all races, ethnicities, educational backgrounds, and ages. The increasing use of websites for hookups correlates with the increasing number of HIV infections, and with the rising use of crystal meth. In fact, there are websites that cater specifically to barebackers, and many of them purposely avoid information about the risks of barebacking or ways to prevent HIV. Any mention of barebacking risks is often met with harsh criticism on these sites.

A recent survey of 1,178 men who have sex with men (MSM) in Los Angeles and New York City found that barebackers spent significantly more time on the internet looking for sex than non-barebackers, and HIV-positive barebackers specifically spent the most time online looking for dates.

## The Culture of Barebacking

Some perceive barebacking as a lifestyle, in the belief that it is a matter of personal choice. These men may have problems fitting into the “safer-sex world” and feel that society or the government cannot tell them how to live their lives.

Some men take on the identity of the barebacker in an attempt to remain “sexual outlaws.” Others choose to bareback on the basis of a committed monogamous relationship, believing that bonds of trust keep them safe and strengthen the ties between them. In addition, the exchange of semen is perceived by some men as an important and emotionally binding choice. Trust and the decision to have unprotected sex often go together, as seen in the

worldwide epidemic of infected married women who felt safe in what they thought were monogamous relationships. This is not to say that people, gay or straight, in committed relationships cannot ever take off the condoms. The motivations for having unprotected sex within committed relationships may vary but whatever the reason, there needs to be a frank and open discussion about what that means . . . and what happens if one partner does have sex outside the relationship.

## Harm Reduction?

Harm Reduction is a public health philosophy intended as an alternative to the outright prohibition of certain potentially dangerous lifestyle choices. The idea is that some people will always engage in risky behaviors like casual sex or drug use, so the objective of harm reduction is to mitigate the potential dangers and health risks. These strategies meet individuals “where they are.”

A harm reduction approach includes sex education that emphasizes tools like condoms and clean needles to protect against disease transmission and pregnancy. This runs contrary to the ideology behind abstinence-only sex education, which holds that telling young people about sex can encourage them to engage in it. Supporters of harm reduction cite statistics showing it to be significantly more effective at preventing teenage pregnancy and STDs than abstinence-only programs. Critics maintain that harm reduction makes dangerous behavior seem safer, leading to an increase in that behavior. But most research has overwhelmingly shown the latter to be untrue.

Some have suggested that a harm reduction approach could be applied to barebacking, as follows:

- Reducing the number of partners
- Serosorting: Choosing partners only of the same HIV status
- Strategic positioning: An HIV-positive man taking the receptive (bottom) role during barebacking with an HIV-negative man

- Withdrawal: Pulling the penis out before ejaculation
- Negotiated safety: An agreement between two partners in a committed relationship to go through a process that will eventually lead to removing condoms during sex

In the end, this debate comes down to the definition of harm reduction. Yes, decreasing the number of your partners from ten a night to one a night will lower your risk – but the chance of infection is still high. Traditional harm-reduction approaches, like clean needles and condoms, can dramatically reduce the risk of HIV infection, but only abstinence eliminates it. That’s why we talk about “safer” rather than “safe” sex. Applying the term “harm reduction” to actions that reduce risk only slightly sends a confusing message at best.

The other approaches suggested are equally questionable. “Serosorting” out all people with HIV is simply a fantasy (see page 10), as is early withdrawal (ask any woman who got pregnant from pre-cum). And while studies have shown that the insertive partner is at less risk than the receptive partner, the risk for both partners is still significant. The only way that barebacking can be called an HIV prevention strategy is when two HIV-positive people have sex, since no new HIV infection is possible. However, this does not apply to STDs or different strains of HIV.

The fact is that recently infected individuals have very high viral loads for up to three months before an HIV antibody test will show a positive result. A research letter published recently in *AIDS* argues against serosorting: “Our conservative calculations show that serosorting based on disclosure is not likely to be an effective prevention strategy when the prevalence of recently infected ‘HIV-negative’ disclosers comprises approximately 4% of the potential sex partner population... By ignoring the increased potential for HIV transmission by recently infected individuals, serosorting may paradoxically increase the number of new HIV infections in certain populations.”

“Negotiated safety” within a relationship is possible only after HIV testing and open, honest discussion. A study of 500 HIV-negative and -positive MSM in the Multicenter AIDS Cohort Study found that about 15–20% of those who said they had arrangements that precluded outside sexual partners actually had multiple partners despite their negotiated arrangements. So even this type of “negotiated safety” is not foolproof.

Nevertheless, MSM are using these strategies, regardless of how effective they may or may not be. A study of 1,168 MSM in New York and San Francisco found evidence of attempts at serosorting, strategic positioning, and early withdrawal in both cities.

### Breaking the Myth

The CDC reports that HIV infections are on the rise among MSM (from 56,680 in 2001 to 60,259 in 2005), and barebacking is most likely playing a part. People may think, “Now that I have HIV, I can bareback – what could be worse?” or, “My friend with HIV takes only one pill once a day – no big deal,” or, “HIV isn’t a death sentence anymore,” and of course, “My partner told me he’s negative; I saw his HIV test results from yesterday.”

But the fact is that getting HIV today is not the same thing as being infected in the ’80s. Up to 30% of new infections are of strains of the virus resistant to HIV meds. Also, there have been cases of HIV-2 in New York – a type of HIV that used to be found only in parts of Western Africa. Some HIV meds don’t work against HIV-2.

Making decisions based on HIV test results is risky. A partner’s negative HIV test today means only that he was negative three months ago. The immune system needs time to create the antibodies that the HIV test looks for. In fact, many new infections are occurring during the “window period” (the time between infection and when an HIV antibody test will return a positive result), since people in the window period have a very high amount of HIV in their body.

A 2005 CDC survey found that of 450 MSM who tested HIV positive, 48% were unaware they were infected. And HIV-positive men seem to be learning that disclosing their HIV status will lessen their chances of finding a partner. A study published in the *American Journal of Public Health* in 2003 found that 42% of HIV-positive men who reported any sexual activity (protected or unprotected) had not disclosed their HIV status to their partners. And a California study of 250 Latino men (200 negative and 50 positive) who used the internet to seek sex partners found that about 41% of the HIV-positive men misrepresented their status to prospective partners.

### Conclusion

Many theories have been presented to explain the increase in barebacking behavior: a lack of social support within the gay community, “condom fatigue,” a desire to regain a sense of belonging by joining the “community” of barebackers, and of course, the added sense of intimacy that unprotected sex may provide. We need to find innovative prevention approaches that address these problems, rather than offering false hopes that could lead to more people with HIV.

Going from 100% risky behavior to 0% risky behavior overnight isn’t realistic. New approaches to counseling gay men who either choose to bareback or who do it without thinking – including approaches that address the way the internet can facilitate multiple partners – must be created.

Risk reduction does have tangible benefits: If you are driving at 70 mph and you slow down to 55, your risk of being in an accident and of sustaining a serious injury drops. But can this be applied to barebacking? Unfortunately, the “harm reduction” methods being proposed don’t go nearly far enough. There is no such thing as being only partly HIV positive. In the end, most suggestions for lowering the risk of HIV from barebacking sound less like harm reduction and more like tap dancing in a mine field.

*Rafael Madrid is an HIV Health Educator at ACRIA.*

# New York State Department of Health/AIDS Institute

## HIV/AIDS Regional Training Center Course Descriptions

### Building Bridges to Cultural Competency

Friday, October 5, 9am-5pm, Manhattan

This one day training explores the broad definition of culture and its relationship to competent and effective healthcare and human service delivery. Using didactic presentations, case studies and skills building exercises participants will:

- Discuss invisible privilege and its affect on both receiving and providing services;
- Be encouraged to self reflect and explore potential obstacles;
- Learn how these obstacles are created when diverse cultures, Western medicine and human service deliveries collide.

**Prerequisite:** None

**Audience:** All Health and Human Service Providers.

### Basic Information about Domestic Violence

Friday, September 21, 9am-5pm, Manhattan

This one-day training gives overview of the interrelationships between adult domestic violence and HIV/AIDS.

The goals of this training are to assist health and human services providers to:

- Understand the nature and dynamics of domestic violence;
- Conduct assessments and discussing domestic violence with clients living with HIV/AIDS;
- Create emergency safety plans with victims of domestic violence;
- Make appropriate referrals in situations involving domestic violence.

**Prerequisite:** None

**Audience:** All Health and Human Service Providers including: Case Managers, HIV/STD Counselors, Substance Use Counselors, Nurses, Mid-level Practitioners, HIV Educators/Outreach Workers

### HIV/AIDS Treatment Update

Friday, Sept. 7, 1-5pm, Bronx / Friday, Nov. 30, 1-5 pm, Queens

This half-day training will provide updated information for non-clinical providers about advances in HIV/AIDS treatment. Programs are updated regularly to address emerging issues and will cover various topics ranging from:

- New developments in Highly Active Antiretroviral Therapy (HAART)
- Newly approved (or soon to come) medications;
- Vaccine research;
- Drug resistance and resistance testing
- Drug/drug interactions;
- Updates to treatment guidelines; and
- The role of the non-clinical provider in supporting decisions around treatment

**Prerequisite:** Prior attendance at a basic training, such as "Overview of HIV Infection and AIDS", is required.

**Audience:** All Health and Human Service Providers who work with people with HIV/AIDS.

### HIV/AIDS Confidentiality Law

Friday, Oct. 15, 1-5pm, Bronx / Friday, Oct. 29, 1-5pm, Queens

This half-day training provides information about New York State's HIV Confidentiality Law (Public Health Law Article 27-F). This training is designed to meet provider requirements for initial and annual confidentiality training.

Topics to be covered:

- Basic components and intent of the law;
- Rules concerning confidentiality;
- Disclosure and signed releases;
- Penalties and sanctions for violation of the law;
- Documentation and record keeping;
- Workplace policy and procedure requirements; and
- Information about regulations regarding HIV case reporting and partner notification as it relates to confidentiality issues.

**Prerequisite:** None

**Audience:** All Health and Human Service Providers

### Introduction to Case Management

Friday, November 2, 9am-5pm, Manhattan

This one-day training will provide participants from COBRA and AIDS Institute grant-funded programs with the basic understanding of the case management process.

Topics to be covered include:

- History and evolution of case management;
- Review and comparison of case management models;
- Distinction between case management and other forms of client interventions;
- Nature and importance of goal-planning;
- Components and relationship between steps of the case management process;
- Case coordination with other service providers; and
- Reasons and process for closure.

**Prerequisite:** Although there is no prerequisite for this course, it is *strongly* suggested that participants have previous training in HIV confidentiality and basic HIV/AIDS medical information.

**Audience:** New Case Management staff and Health and Human Service Providers including: Direct-service staff, Supervisors, Program Directors

### Enhancing the Partnership

Friday, October 19, 9am-5pm, Manhattan

This one-day training will provide participants with skills to establish effective partnerships with their clients. This training will focus on what both the case manager and client bring to the case management process. The training will also explore how to address sensitive issues with clients, develop positive confrontation skills and strategies to work with client resistance.

Topics to be covered include:

- Engaging and maintaining clients in the case management process;
- Clarifying roles and responsibilities of clients and Case Managers;
- Recognizing and following through on client's subtle hints, cues and inconsistencies regarding sensitive issues;
- Using a strength-based approach in dealing with resistance;
- Confronting clients in a respectful and effective manner; and
- Developing a variety of strategies to address clients' resistance.

**Prerequisite:** Although there is no prerequisite for this course, it is *strongly* suggested that participants have previous training in HIV Confidentiality, Basic Domestic Violence, Basic HIV/AIDS medical information and have taken "Introduction to Case Management."

**Audience:** Case Management staff and Health and Human Service Providers including: Direct-service staff, Supervisors, Program Directors

*(continued on page 17)*





(continued from page 12)

## HIV Treatment Education Integration

Tuesday-Friday, October 9-12, 9am-5pm, Manhattan

This four-day training will build participants' knowledge and skills to effectively communicate with people living with HIV/AIDS about HIV treatment.

Topics include:

- The Immune System and the Life Cycle of HIV
- Antiretroviral Therapy Including Resistance, Cross-Resistance and Side Effects
- Strategies to Promote Adherence
- HIV Treatment Guidelines
- Role of the Non-Medical Provider in Treatment Education
- Integrating Treatment Education into Existing Services to Clients

**Prerequisite:** None

**Audience:** Health and human service providers with agency support to integrate HIV treatment education in their work with clients

## HIV Testing in NYS: 2005 Guidance

Thursday, November 15, 1-5pm, Manhattan

This half-day training will provide information regarding the 2005 Department of Health (DOH) guidance on HIV counseling and testing. As a result of this training, participants will be able to:

- List the core elements of the 2005 DOH guidance;
- Describe streamlined options for preparing clients for testing;
- Determine when a patient would benefit from face to face pre-test counseling;
- Be familiar with revised "Informed Consent to Perform HIV Testing" and "Authorization for Release of Medical Information and Confidential HIV Related Information" forms;
- List the elements of effective post-test counseling with an emphasis on: Strategies for effectively linking HIV positive patients to care; Working in partnership with HIV positive patients to promote notification of sexual and needle sharing partners and; Referring high risk patients who test negative to prevention services.

**Prerequisite:** Although there is no prerequisite for this training, it is *strongly* recommended that participants have previous training in basic HIV/AIDS.

**Additional Training:** Participants who would like an opportunity to practice the skills associated with offering HIV testing services may choose to attend "HIV Testing: Skills Practice Session".

**Audience:** Experienced and new health or human service providers who offer HIV testing as a part of their job responsibilities. Staff performing or offering testing in community based organizations may attend this training or "Offering Rapid HIV Testing in CBOs Serving High Risk Communities".

## Domestic Violence in the LGBT Community

Friday, September 28, 9am-5pm, Manhattan

This one-day training was developed by the New York State Office for prevention of Domestic Violence and the New York State Department of Health AIDS Institute.

This one-day training program will assist participants to:

- Examining the beliefs, values and attitudes that can impact their ability to respond to Lesbian, Gay, Transgender, Bisexual (LGTB) victims of domestic violence; and
- Increase knowledge and skills to sensitively and effectively address LGTB domestic violence.

**Prerequisite:** Although there is no prerequisite for this course, it is *strongly* suggested that participants have previous training on domestic violence, and basic HIV/AIDS information. Participants are strongly encouraged to attend the "Basic Information about Domestic Violence" prior to attending this training.

**Audience:** All Health and Human Service Providers including: Domestic Violence Service Providers

## HIV Testing Skills: Practice Session

Friday, November 16, 9am-5pm, Manhattan

This one-day training will provide participants with an opportunity to practice key skills related to offering HIV testing services. As a result of this training, participants will be able to:

- Assess when a client requires face to face pre-test counseling;
- Conduct streamlined pre-test counseling;
- Deliver preliminary positive and confirmed positive HIV test result;
- Link newly diagnosed HIV positive patients to health care and support services;
- Work in partnership with HIV positive patients to promote notification of sexual and needle sharing partners, and;
- Conduct the NYS domestic violence screening protocol.

**Prerequisite:** Knowledge of basic HIV/AIDS information and attendance at "HIV Testing in NYS: 2005 Guidance " or an equivalent training.

**Audience:** Any health or human service provider who offers HIV testing as part of their job responsibilities.

## Promoting Adherence to HIV Treatment

Monday, Oct. 22, 1-5pm, Bronx / Friday, Oct. 26, 1-5pm, Queens

This half-day training will assist participants to identify and take advantage of multiple opportunities to support treatment adherence in the course of their work.

Participants will increase their knowledge and practice skills in which to:

- Provide support at the initiation of therapy;
- Discuss side effects and their impact on adherence;
- Support clients in taking advantage of various adherence tools;
- Identify the importance of peer support; and
- Monitor adherence throughout the course of care.

**Prerequisite:** It is *strongly* recommended that participants have previous knowledge or training on basic HIV/AIDS information.

**Audience:** All non-physician Health and Human Service Providers

## Overview of HIV Infection and AIDS

Monday, Nov. 5, 1-5pm, Bronx / Monday, Nov. 12, 1-5pm, Queens

This half-day training is designed to give the participant a basic understanding of HIV infection and AIDS.

Topics to be covered:

- HIV transmission;
- HIV prevention strategies;
- Course of HIV infection and AIDS;
- Importance of early detection;
- Treatment to slow down HIV; and
- Treatment to prevent opportunistic infection.

**Prerequisite:** None

**Audience:** All Health and Human Service Providers.

For an on-line application please visit our website at [www.acria.org](http://www.acria.org) or call 212-924-3934 x129 for more info.

*This listing only includes AIDS Institute/Regional Training Center trainings offered by ACRIA.*

*For information on trainings provided by other Regional Training Centers or Centers of Excellence please visit the following websites:*

**AIDS Institute:** [www.health.state.ny.us/diseases/aids/training](http://www.health.state.ny.us/diseases/aids/training) **Cicatelli Associates Incorporated:** [www.cicatelli.org/calendar](http://www.cicatelli.org/calendar)

**National Development and Research Institutes:** [www.training.ndri.org](http://www.training.ndri.org)

## **\$1M for Older Adults HIV Program**

Since last summer, when ACRIA released the findings of its comprehensive Research on Older Adults (ROAH), “ACRIA News” has been reporting on the reaction to this groundbreaking study in the AIDS service community and the New York City government. Finally, in June, the City Council approved a budget for the 2008 fiscal year that included a \$1 million appropriation to fund the first-ever comprehensive citywide HIV prevention and health literacy program focused specifically on older adults.

Under the plan approved by the City Council, the funding will be used to develop, among other initiatives, a curriculum tailored to older adults; provide training at senior centers and other senior services sites; and create prevention and HIV education publications targeted to older adults.

This ambitious program will be managed by ACRIA, and specific services will be developed and provided by a coalition of partners that designed the original initiative. Besides ACRIA, the coalition includes the Council of Senior Centers and Services (CSCS), Gay Men’s Health Crisis (GMHC), the Jamaica Service Program for Older Adults (JSPOA), and Services & Advocacy for GLBT Elders (SAGE).

The program will be conducted in neighborhoods where the incidence of HIV is high, and services will be provided in dozens of senior centers and other sites that serve older adults throughout the five boroughs and in each of the 51 City Council districts. In addition to those who worked on designing the original initiative, other organizations will be recruited to participate in the development and implementation of the program. An independent research group will be hired to evaluate the program, assessing what is working and what isn’t, so that needed improvements and modifications can be made.

New York City is the epicenter of the HIV epidemic in North America, and has frequently pioneered HIV prevention and service programs later introduced across the country and abroad. The generous funding set aside by the City Council, along with the expertise contributed by a broad range of organizations, should enable us to develop services and approaches that can be adapted to serve the growing numbers of older adults in areas beyond the city limits.

People over 50 now represent the fastest growing group with HIV. In New York City, the HIV/AIDS epicenter in the U.S., 32% of the almost 100,000 people living with the disease are over age 50. Within a decade, it is anticipated that people over 50 will constitute more than half of the city’s HIV-positive population.

Yet, as ROAH clearly demonstrated, the disheartening fact is that this population has been and continues to be largely ignored and marginalized.

The funding, which consists of \$640,000 of City funds matched with a \$360,000 grant from New York State, was spearheaded by Councilmember Maria del Carmen Arroyo (D-Bronx) and members of the Council Committees on the Aging and on Health. The initiative is the product of a workgroup convened by Councilmember Arroyo and others, largely in response to the findings of ROAH and the testimony of ACRIA’s Executive Director Daniel Tietz and others at a joint hearing of the Council’s Aging and Health Committees.

“Our research paints a stark picture of an aging population that lacks the social support most of us take for granted, and has continuing and chronic age-related illnesses compounded by HIV/AIDS,” said Tietz. “The \$1 million grant will go a long way in working to rectify this situation.”

Tietz thanked Councilmember Arroyo for her commitment to securing the funds.

“This funding would not be possible without the foresight, vision and energy of several people. Councilmember Arroyo has championed this cause from the start and ensured the City Council \$1 million budget allocation for the initiative. We at ACRIA and our coalition partners are most grateful for that support.”

The coalition is made up of a broad range of groups serving older New Yorkers and people with HIV. In addition to ACRIA, CSCS, GMHC, JSPOA, and SAGE, the members include Aging in America, Callen-Lorde Community Health Center, Federation of Protestant Welfare Agencies (FPWA), Griot Circle, Jewish Board of Family and Children’s Services (JBFCS), Metropolitan Council on Jewish Poverty (MCJP), Momentum AIDS Project, and the New York Association on HIV Over Fifty (NYAHOF).

“Many still picture the face of AIDS as belonging to a white, homosexual male – the media archetype of the 1980s,” said Dr. Stephen Karpiak, ACRIA’s Associate Director for Research. “But for people living with the disease in New York City and around the country, the face of HIV/AIDS is much more that of a heterosexual over the age of 50 who is a person of color and probably female.”

He explained that stigma and assumptions regarding the elderly, sex, and substance use, as well as confusion about HIV symptoms and age-related illness, are factors contributing to a steady increase in new HIV diagnoses among people age 50 or above in the past five years. Moreover, as advanced medical treatments and medication allow people to live longer and healthier lives, their numbers will continue to grow. Mainstreaming the needs of the older adult population, regardless of their HIV status, is the first step toward focused primary and secondary HIV prevention.

“It is vital that the healthcare system, elected officials, policy makers, and

everyone in a position to confront the HIV/AIDS pandemic understand the changing population and the complicated health needs that make up the new face of AIDS,” said Tietz.

### **ACRIA Welcomes New Staff . . .**

*Liza Kelly-Rossini, MSN, MPA, ANP*, has joined ACRIA as our new Clinical Trials Manager. Ms. Kelly-Rossini has an extensive medical background, having worked as a nurse practitioner and research nurse practitioner at Columbia University Medical Center, Weill Medical College of Cornell University, Rockefeller University, the Polari Group, and the Southern Westchester Infectious Disease Group. She also served as AIDS team nurse liaison and nurse practitioner at Beth Israel Medical Center, and has held a variety of nursing and related posts over the past thirty years.

*Esteban Perla*, our new Regulatory Affairs Coordinator, comes to ACRIA

from Philadelphia’s AIDS Services in Asian Communities, where he was an HIV case manager. His other experience includes teaching high school biology, serving as a teaching assistant in the General Biology Lab at Bucknell University, and working as a National Park Ranger at the Wolf Trap National Park for the Performing Arts. A native of the Philippines, Mr. Perla has also lived in Indonesia and Egypt.

*Gustavo Otto* brings a diverse background and valuable skills to his new job as Administrative Coordinator in ACRIA’s HIV Health Literacy Program. He is a proficient English/Spanish translator with special training and expertise in medical and related translation, and has held administrative positions in private industry and has organized and operated his own business. Mr. Otto’s background also includes visual merchandising, interior design for commercial spaces, and work as a licensed massage therapist.

### **. . . and Board Members**

*Leslie R Klotz* is Vice President of Business Development for Art + Commerce, a leading agency representing and promoting artists and image makers. She has also held top management positions at Banana Republic and Polo Ralph Lauren in New York and Creative Artists Agency in Los Angeles. Besides ACRIA, Ms. Klotz also sits on the boards of Literacy Partners and the Hamptons Film Festival.

*Judith Godwin Rabkin, PhD, MPH*, is a renowned HIV/AIDS researcher with a resume too extensive to briefly summarize. Currently with the New York State Psychiatric Institute, Dr. Rabkin is a Fellow of the American Psychopathological Association and the Society for Clinical Psychosocial Research, and a member of the Council of Research Scientists of the New York State Department of Mental Health and the International AIDS Society

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## **Before and After: PrEP and PEP** *(continued from page 9)*

sons at risk will be willing and able to maintain consistent use of a daily drug. These trials will therefore closely examine participants’ adherence to, and acceptance of, daily drug use.

Drug resistance will also need to be addressed during trials. Unlike PEP, which has been so effective that developing resistance has not appeared to be a problem, it is unclear how often resistance will develop if PrEP fails and a person becomes infected while taking Viread alone. Similarly, while the risk of drug-resistant virus will likely be lower in trials of Truvada, which contains two drugs, it will be important to assess any resistance that emerges to either drug.

Several study procedures have been designed to minimize the risk of resistance among any individuals who become infected despite receiving PrEP. It is hoped that regular HIV testing with a

rapid HIV test and immediate discontinuation of study pills if participants become infected will lower any risk of a resistant virus emerging. In addition, HIV resistance testing will be provided to all persons infected during the trial. These data will provide important information on the degree to which resistance occurs and will help guide treatment decisions as infected persons are referred to treatment and care.

### **Community Response**

Community activists are balancing two contradictory needs. Advocacy is needed to ensure these new prevention ideas are funded appropriately and tested ethically. But it’s important not to raise expectations for interventions that may not work, that may prove no more popular than condoms, or that may do harm if used inappropriately.

And PrEP raises some particularly challenging issues of access. Health care

providers will need to ensure that PrEP is used before exposure, not after infection, or it could lead to drug-resistant HIV. And exactly who would be prescribed PrEP? Would people be required to prove they’re “high risk,” and will that lead to their being stigmatized? Will it be available through questionable websites, like Viagra? If it is found to be effective, will ineffective quick fixes like “MTV” become rampant?

It’s important to remember that if PrEP is found to be effective, it will need to be a part of a comprehensive HIV prevention program that includes education, empowerment, and proven risk-reduction behaviors. At the same time, after 25 years of HIV, many people are clearly hoping for something other than a lifetime of rubber-insulated sex.

*Luis Scaccabarozzi and Mark Milano are editors of ACRIA Update.*

# generous contributions

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## AIDS COMMUNITY RESEARCH INITIATIVE OF AMERICA



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