



# Is HIV Treatment HIV Prevention?

Reilly O'Neal

*"All of us need to get over this distinction between prevention and treatment—that somehow there are two different agendas that compete here. It could not be clearer that prevention of HIV transmission is the foundation for HIV treatment sustainability."*

*—Robert Grant, MD*

As antiretroviral drugs have become increasingly effective (and tolerable), more people are living longer with HIV and research is suggesting that the drugs used to treat HIV disease may also contribute to HIV prevention. The "treatment as prevention" strategies currently under study fall into two categories: treatment-based prevention to help HIV positive people avoid transmitting HIV, and pre-exposure prophylaxis, or "PrEP," to help HIV negative people stay negative.

Both potential strategies are founded on extensive research and trials. For example, a study published in the March 30, 2000, issue of the *New England Journal of Medicine* reported that "the risk of transmission increased substantially with increasing viral loads" in a sample of 415 serodiscordant couples (in which one partner has HIV and the other does not). Subsequent studies, including two reported at the 2009 Conference on Retroviruses and Opportunistic Infections, have found that the risk of HIV transmission is significantly reduced in serodiscordant couples when the HIV positive partner is on antiretroviral treatment that

suppresses viral replication.

Recent studies in animals and humans provide evidence that some antiretroviral drugs may also prevent HIV *acquisition*—that is, antiretroviral drugs taken orally or used topically by HIV *negative* people as PrEP may help prevent HIV from establishing infection in their bodies. Human clinical trials of this strategy are based on evidence that monkeys given oral or topical tenofovir (Viread), emtricitabine (Emtriva), or both before exposure to a monkey form of HIV were significantly less likely to become infected than were monkeys who received only placebo. PrEP studies with human volunteers are now underway around the world.

### QUESTIONS, CONTROVERSIES, AND CAUSE FOR HOPE

“Treatment as prevention” appears to offer promising new options for protecting the health of individuals and communities and for curbing the spread of HIV around the globe. However, the approach is not without its share of controversies, and many questions remain to be answered by clinical trials and through conversations with the people and communities most likely to use these new strategies if they are shown to be effective for HIV prevention.

To address the complex issues surrounding treatment-based HIV prevention and PrEP, the San Francisco AIDS Foundation recently convened a panel of local and nationally known experts in various HIV-related fields—as well as community members, who are the experts in their own lives and know best their own health and prevention priorities and needs—for a frank discussion of the potential benefits and challenges of using HIV treatment as HIV prevention.

The panel included Lisa Capalini, MD, Assistant Clinical Professor of Medicine at the University of California, San Francisco (UCSF) and a San Francisco-based clinician since 1989; Moupali Das-Douglas, MD, Director of the Research Unit of the HIV Prevention Section at the San Francisco Depart-

### PREP AND PEP

While the terms are similar enough to cause confusion, “PrEP” and “PEP” are different HIV prevention strategies.

Pre-exposure prophylaxis, or PrEP, is an experimental strategy in which HIV negative people would take antiretroviral drugs before possible exposure to the virus (for example, before having unprotected sex) in an attempt to avoid HIV infection. As mentioned throughout this article, PrEP is currently being studied to determine whether it is a viable new approach to HIV prevention—in short, does it work, and how well?

Post-exposure prophylaxis, or PEP, involves starting a course of antiretroviral drugs within 72 hours after a known or suspected exposure to the virus (for example, following a needle-stick injury in a medical setting or after unprotected sex with a partner who is or may be living with HIV) to help prevent the virus from establishing itself in the body. PEP has been in use since 1996 and has been proven effective in many studies.

ment of Public Health and Assistant Clinical Professor of Medicine in the Division of HIV/AIDS and Infectious Diseases at UCSF; Robert Grant, MD, Betty Jean and Hiro Ogawa Endowed Investigator at the Gladstone Institute of Virology and Immunology and Associate Professor of Medicine at UCSF; and Dana Van Gorder, Executive Director of Project Inform, a San Francisco-based nonprofit HIV/AIDS advocacy organization. The forum was moderated by Judith Auerbach, PhD, Vice President of Science and Public Policy at the San Francisco AIDS Foundation.

Following are excerpts from the panel and audience discussion highlighting important questions and issues around treatment as prevention and goals for future research and advocacy to ensure that these strategies—if proven effective—can be made available to the people who need them most.

### TREATMENT AS PREVENTION: AN OVERVIEW

As Robert Grant explained in an introductory presentation, the strategy of diagnosing infectious diseases and using treatment to prevent their spread is not new; for example, diagnosing and treating tuberculosis is the mainstay of preventing its spread. Rather, Grant said, “The question that’s really emerged is, ‘Can this standard approach also work for HIV?’”

Grant outlined what is known—

and what is not known—about treatment-based HIV prevention, citing studies showing that the risk of HIV transmission in serodiscordant couples is strongly correlated with the HIV positive partner’s viral load: a higher viral load means a higher risk of HIV transmission, whereas a lower viral load accomplished through antiretroviral therapy means a lower risk of transmission. What is not yet known, Grant cautioned, is exactly how much virus must be present in bodily fluids to allow transmission to occur; without this crucial data, it is unclear how much antiretroviral treatment actually reduces transmission risk.

Shifting to the topic of PrEP—in which antiretroviral drugs are taken by HIV-negative people to help them remain negative—Grant cited early studies showing the plausibility of this approach. For example, a trial conducted between 2004 and 2006 in West Africa found daily oral PrEP with tenofovir to be safe and well tolerated and saw lower rates of HIV infection among participants taking daily PrEP than in the placebo group (two and six new infections, respectively), although the difference was not statistically significant.

Studies to determine whether tenofovir and emtricitabine (which together make up the popular antiretroviral combination pill Truvada) used as PrEP can help prevent HIV acquisition are underway at research

sites around the world, Grant noted, with a combined total of nearly 20,000 participants, including gay men and other men who have sex with men (MSM), intravenous drug users, and commercial sex workers. Data from these studies are expected to become available starting this year.

### WHY DO WE NEED NEW HIV- PREVENTION STRATEGIES?

*“What we’re doing isn’t working. Whether this approach is the correct approach is open to question, but do we need better, more successful approaches? Undoubtedly.”*

—Lisa Capaldini

The panelists agreed that, although the money available to promote HIV prevention is limited, it is necessary to devote time and funds to finding new HIV prevention tools because currently available options (including condoms and behavior-change strategies), while clearly beneficial in lowering HIV infection rates, are simply not enough to dramatically reduce HIV incidence today.

Moupali Das-Douglas and Robert Grant also noted that not all prevention tools work for all people; tools like condoms work for some but not all couples and communities, and PrEP could complement existing strategies. As Grant put it, “There’s a diversity of people who are getting HIV around the world, and I think we need a diversity of different approaches for them.”

Das-Douglas framed this need in terms of social justice, noting that we need new prevention approaches to help address health disparities: “In resource-rich settings, marginalized communities are more disproportionately affected, and the prevention strategies are disproportionately not working in those marginalized communities. I think that we need to do better to serve people in all communities.”

Dana Van Gorder agreed, but stressed the need for adequate research before launching any PrEP program or treatment-based approach to prevention. Van Gorder also pointed

out that the current discussion about treatment-based prevention provides an excellent opportunity to educate people about the benefits of knowing their HIV status and getting the treatment and care they need.

### THE CONTROVERSIAL “SWISS STATEMENT”: IS ANTIRETROVIRAL THERAPY AS PROTECTIVE AS CONDOMS?

*“We need to accept that there’s a variety of harm reduction strategies out there, and they all have risks, they all have benefits. I think in this case the benefits are clear—viral load decreases dramatically on successful therapy, and that almost certainly reduces risk.”*

—Robert Grant

In 2008, the Swiss Federal AIDS Commission published a paper stating that HIV positive individuals may be considered “sexually non-infectious” if they:

- have perfect adherence to their antiretroviral regimen,
- have had an undetectable viral load for at least six months,
- get their viral load checked regularly,
- do not have concurrent sexual partnerships, and
- have no other sexually transmitted infections (STIs), and neither do their (monogamous) sex partners.

The paper suggested that the HIV risk of unprotected sex with an individual meeting those criteria is roughly equal to the risk of using condoms during sex with an individual who does not meet those criteria.

Some advocates heralded this statement as a blessing for HIV positive people, noting that it may help to destigmatize HIV and decriminalize sexual activity with undisclosed HIV positive partners in some countries. However, others in the HIV research, advocacy, and medical communities

argued that the criteria described in the “Swiss statement” are unrealistic, and that the statement sends a potentially dangerous message.

The panelists’ perspectives on the Swiss statement varied. “I think of it as a bit of a thought experiment,” said Lisa Capaldini. “Certainly, in the abstract it might be quite applicable, but when you get into the real world of people’s lives, all the criteria [form] a pretty daunting list.”

Capaldini observed that, in addition to the concern about breakthrough viral replication (viral load “blips”), which may increase the risk of HIV transmission even by people on successful treatment, the set of criteria “does not seem to fit the behavior profile of the majority of HIV infected people I work with.” For example, the monogamy criterion relies on both honest communication between partners and the desire to have only one sex partner at a time. Based on what she has observed in her own practice, “many couples plan to be monogamous and simply aren’t.”

Das-Douglas brought up another important point: The Swiss statement builds on data from studies of heterosexual couples, which may render it less applicable to epidemics in some regions. In addition, she noted, the prevalence of STIs (which can make it easier to pass on or get HIV) varies by region and population and may therefore make the criteria outlined in the Swiss statement less broadly applicable. Lastly, Das-Douglas stressed that underlying the criteria regarding regular viral load monitoring is the larger issue of access to adequate medical care, which is not a given for all people living with HIV. “Somebody who had a totally suppressed viral load in May may not in September,” she said. “If they’re going on their data from May, they may not know...the risk of possibly transmitting to their partner.”

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Van Gorder offered a different take. “I think we want to be encouraging HIV positive people to engage in treatment and not discouraging them with too many caveats,” he said, and noted that adhering to the criteria outlined in the Swiss statement need not be seen as an alternative to using condoms. Although further data are needed regarding the potential effect of such a strategy on HIV infection rates in the United States (particularly among gay men and other MSM), “nevertheless,” said Van Gorder, the Swiss statement “has the potential, for HIV positive people, to be an additional way of supporting us in our effort to prevent transmitting HIV to others, and I think we should welcome it with open arms, recognizing all the potential limitations.”

Grant agreed, emphasizing that the Swiss statement’s criteria essentially represent a “harm reduction” strategy: the statement’s authors recognized that people do have sex without condoms, and tried to reduce the possible harm of condomless sex by promoting optimal medical care along with behaviors shown to reduce the likelihood of transmitting HIV. The Swiss Commission presented evidence that treatment, in combination with partner reduction and the absence of other STIs, offers another harm reduction approach with a demonstrated potential benefit. Said Grant, “Acknowledging that clear benefit is better than ignoring it, which is what we were doing before the Swiss statement.”

### **THE TEST-AND-TREAT APPROACH: PUBLIC HEALTH VS INDIVIDUAL HEALTH, OR GOOD FOR BOTH?**

*“I think that this question is often posed in a way that implies cross-purposes between individual benefit and the benefit to society, and it’s a false dichotomy to separate individual benefit from the benefit to society... with respect to [HIV] transmission.”*

—Moupali Das-Douglas

Recently published mathematical models suggest that expanded HIV

testing and treatment can virtually halt the spread of HIV in some regions. For example, a model published in the January 3, 2009, issue of *The Lancet* by Reuben Granich and colleagues from the World Health Organization suggests that South Africa—one of the hardest-hit parts of the world—could see the number of people with HIV drop to less than 1% of the population in the next 50 years if the country implemented voluntary HIV testing for everyone and immediate antiretroviral treatment for those found to be HIV positive, regardless of their CD4 cell count (a measure of immune health used to guide treatment initiation; also called “T cell” count).

While highlighting the dramatic potential benefit of a “test-and-treat” approach to HIV prevention, this particular model has proven controversial. Das-Douglas warned that it contains a number of assumptions that undermine its accuracy and its applicability to other settings. For example, the model assumes a high level of adherence to highly effective treatment regimens, which may not be the case in all (or most) regions or communities. In addition, as pointed out in a recent letter to *The Lancet*, the model does not take into account that sexual concurrency—having more than one sex partner at a given time—is common in many regions and may help drive high infection rates. Nor does the model address the potential impact of acute infection. This initial stage of HIV disease is missed by standard HIV antibody tests, yet rapid viral replication during this months-long period may render newly infected individuals up to 43 times more “infectious”—and therefore significantly more likely to transmit HIV—than during later stages of HIV disease. Re-evaluation of this model, Das-Douglas said, is underway to assess the potential effect of universal testing and immediate treatment in different contexts with different epidemic dynamics.

Regarding treatment initiation at high CD4 counts, Das-Douglas cited

research linking HIV replication with neurocognitive impairment and cardiovascular, kidney, and liver disease. There is “an accumulating mountain of evidence that the virus itself is bad for your body,” she explained. These data, Das-Douglas noted, in combination with evidence that starting treatment at a CD4 cell count as high as 500 (rather than at the 350-cell level recommended in the current U.S. Department of Health and Human Services guidelines) may confer substantial health benefits, suggest that starting treatment at HIV diagnosis and suppressing viral replication as quickly as possible may be good for both the individual’s health and public health.

Capaldini’s opinion differed: “I’m very concerned that we’re having this pendulum swing in the HIV treatment world towards earlier treatment in a way that is very well intentioned and based on use of science [but that goes] beyond the point where we really know actual results.” For example, eligibility criteria for clinical trials of early treatment may exclude individuals who have mental health issues and comorbid conditions; “the folks who are reluctant to start, for whatever reasons, might reflect a very different population,” said Capaldini.

In her own medical practice, she observed, the patients who want to begin treatment (which may involve taking multiple pills throughout the day and dealing with drug side effects) at higher CD4 cell counts are those who are already able to manage their own health, while patients who are struggling—and are perhaps unable to consistently meet their health, housing, and nutritional needs—say, “I’m not starting these meds; I can barely keep my act together!” For these patients, starting lifelong antiretroviral treatment before it is medically necessary may simply introduce an additional burden and ultimately prove unmanageable.

Capaldini also observed that studies linking HIV replication with disease and other problems throughout the body are not definitive. For example,

she noted, some researchers suggest that minor cognitive dysfunction may stem not from ongoing viral replication but from damage caused when the virus entered the brain shortly after infection; the timing of treatment initiation will have little effect on this type of neurological damage. “I think scientifically the jury still is very, very out on the benefits of earlier treatment,” Capaldini said. “My hunch is what we’re going to see, when we really study this in a controlled fashion, is that it probably doesn’t matter whether you start at 350 or 500, or 300 or 500, or maybe even 250 or 500 [CD4 cells]—what matters is that you get tested, you have access to care, and once you have access to care you *continue* to have access to care.”

This discussion of public and individual health led to a description of Das-Douglas’s work on a new marker of population-level HIV health, called “community viral load.” As she explained, just as a thermometer measures temperature, “community viral load measures the level of infectiousness or the viral burden in a community.” Using HIV testing and viral load data from the city’s HIV/AIDS surveillance registry to calculate the average viral load in various neighborhoods and communities, Das-Douglas and others at the San Francisco Department of Public Health found that the four San Francisco neighborhoods with the highest community viral loads (the Tenderloin, South of Market, Bayview, and Visitacion Valley) are those with the lowest median household incomes.

Community viral load also corresponds with other known socioeconomic contributors to health disparities. For example, the community viral loads among San Francisco’s African Americans and among homeless and marginally housed individuals are twice the city’s mean. Injection drug users also have a higher community viral load. By contrast, among people who have private health insurance and excellent access to medical care, the community viral load is significantly lower than the

overall San Francisco mean. A study in Vancouver has shown similar results: Community viral load among injecting drug users predicted HIV incidence independent of reported unprotected sex and needle sharing. Community viral load is, said Das-Douglas, “a nice way to marry prevention and treatment, because the burden of virus and the magnitude of virus in a particular group or community can be related to how much *transmission* is happening in that community.”

### PREP: WHAT DO WE DO IF IT WORKS?

*“Because we could begin to see data within a year that could point to at least some degree of efficacy, I think there is a sense of importance among advocacy groups about beginning to understand exactly how it is that we might implement [PrEP].”*

—Dana Van Gorder

Van Gorder and Grant both described the groups most likely to want and to benefit from PrEP if it is proven to be a worthwhile strategy. In the U.S., “we will want to target it to the people who are at highest risk for HIV,” said Van Gorder, “which would principally be people of color, lower-income folks, MSM of color, and women.” Grant observed that the people most interested in participating in PrEP trials are gay men and other MSM and serodiscordant couples. Das-Douglas agreed: “The only instances where I’ve ever discussed PrEP have been [with] discordant couples desiring pregnancy or discordant couples where condom use is not happening.”

Is there anyone who should *not* use PrEP? The most obvious group, as Grant pointed out, is people who are already HIV positive but don’t know it, as intermittent use of PrEP—just like inadequate adherence to antiretroviral therapy—may allow an individual’s virus to become drug resistant, putting their health in jeopardy. “It’s conceivable that PrEP will have to be started only after an RNA test [which detects HIV earlier than standard antibody

tests] is negative, and that HIV testing during PrEP [use] will be important so that the drugs can be stopped if there’s any sign of infection,” said Grant.

In addition, while the two antiretroviral drugs currently under study for oral and topical PrEP are not known to cause dangerous drug-drug interactions when taken with recreational drugs or methadone, both tenofovir and emtricitabine are active against the hepatitis B virus (HBV) and could cause drug resistance if taken intermittently by people living with HBV. Das-Douglas also noted that HBV “flare-ups”—sudden replication of the hepatitis B virus—can occur when individuals halt a treatment regimen containing tenofovir and emtricitabine. This concern applies to the intermittent use of these drugs as PrEP and will be particularly significant, Das-Douglas explained, “in parts of the world where hepatitis B infection is more prevalent, like in Asia and Africa.”

Capaldini focused on another potential concern: “Earlier on, the point was made that PrEP is going to complement condom use rather than replace it, but I certainly don’t have the impression that that’s how people see it.” Treating PrEP drugs as a new tool to use along with condoms may seem counterintuitive to many potential PrEP users. As Capaldini put it, “If they’re going to continue to use condoms, why would they take the meds? And if they’re taking the meds and the meds work, why should they continue to use barrier methods?”

Grant acknowledged this challenge. “How do we counsel people who are looking for ways to use condoms less often? And to what extent will we be able to suggest that PrEP is an alternative? And would we ever *do* that in practice?” he asked. The answers revolve around planning ahead for PrEP implementation. “I think that we have to work with community groups [and] counseling organizations to design appropriate research and consultative processes to come up with the right way to talk about PrEP,” Grant said.

Moderator Judith Auerbach also

noted that we do not yet know how well PrEP may work: “Like other HIV prevention strategies that have been tested or are being tested—microbicides, vaccines—it’s not assumed that these approaches will be 100% or even 98% effective in preventing transmission.” As Capaldini observed, trials assessing the efficacy of new prevention tools, including PrEP, must explain to trial participants that the intervention under study may not actually prevent HIV infection; it is being tested to find out whether or not it works, so participants should continue to protect themselves by using condoms. Yet it is not always clear how many trial participants actually heed this advice. (For more on this and other limitations of prevention trials, see “Confronting the Evidence in Evidence-Based Prevention: Current Scientific and Political Challenges” in the Summer 2008 issue of *BETA*.)

Further complicating PrEP roll-out is its likely high cost. As Van Gorder explained, PrEP implementation will require broader HIV testing to determine who is eligible to use it, delivery of PrEP drugs by health care providers or other sources, and regular medical monitoring and continued HIV testing to minimize side effects and avoid the development of drug-resistant virus. Such intensive implementation will be costly, and “we simply aren’t going to be able to pay for it for everyone,” said Van Gorder. He also noted that Medicaid, Medicare, and private insurance companies are unlikely to cover the costs of PrEP drugs; rather, Van Gorder foresees the necessity of asking Congress and state governments to fund programs dedicated to PrEP delivery.

Van Gorder noted that a group of San Francisco HIV advocates is currently planning how to craft a demonstration project in the city in preparation for PrEP implementation if the strategy is found to be efficacious, as implementation will require educating the community and health care providers about the benefits and risks of PrEP, as well as decisions about how (and to whom)

PrEP drugs are made available and who will pay for them. “We’re definitely trying to gear up the effort to actually figure out how this would be delivered and financed,” he said.

### A QUESTION OF JUSTICE

*“We can’t even study PrEP unless we can become convincingly linked to social justice agendas.”*

—Robert Grant

The discussion concluded with an open conversation between the audience and the panelists, during which audience members asked insightful questions about how health disparities and stigma around HIV may interact with implementation of PrEP and treatment-based HIV prevention. Grant outlined a view of PrEP delivery and treatment that brought the conversation back to social justice. “It’s not fair to recruit young gay men in Peru into a study unless you can advocate for being gay in Peru,” he said. “You can’t recruit commercial sex workers... unless you’re willing to advocate for them. And so from start to finish, I think that prevention needs to become about social justice.”

Grant also stated that PrEP could help get HIV treatment to more people who need it by mitigating some of the stigma around visiting an HIV clinic; if positive and negative people alike are leaving HIV clinics with the same pills, some of that stigma may dissipate. Furthermore, said Grant, PrEP may help to remove stigma by showing that people take these drugs to fight a virus, plain and simple. A virus—not sex or drug use, nor any kind of “moral failure”—causes AIDS, and, as Grant put it, “If we can use a drug that does nothing other than target that virus to prevent that infection, I think it would make it clear to us, maybe for the first time, that [HIV is] not a moral plague.”

### CONCLUSION

Using antiretroviral drugs to prevent HIV infection—either through expanded treatment and viral load

suppression for HIV positive people or through pre-exposure prophylaxis for HIV negative people—is a strategy both highly promising and extremely complicated. The recent panel and audience discussion showed that there is much work to be done before PrEP and treatment-based prevention can be promoted, but also indicated a clear path for HIV prevention and treatment advocates: We need new prevention approaches to curb the spread of HIV, and we need to prepare *now* so that if these two approaches work, they can be made available as quickly as possible to the people who need them most.

No HIV prevention tool will be effective if people cannot or will not use it correctly and consistently. (We know this from years of promoting condoms for HIV prevention—condoms can’t prevent HIV infection if people can’t get them, don’t know how to use them properly so they don’t break or slip off, or are unable to use them consistently.) Bridging the prevention-treatment divide and bringing community members, advocates, researchers, and health care providers together to plan for the implementation of new tools like PrEP and treatment-based prevention is our best hope for safeguarding the health and interests of all communities affected by HIV.

**Reilly O’Neal** is the editor of *BETA*.

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