Rudy Owens
April 21, 2011
Case 15, Day 1

LO: Investigate arguments for test and treat and prevention strategies for HIV and STIs.

A test and treat strategy to curb the spread of HIV shifts the public health response from behavioral interventions and faces criticism from skeptics

Abstract: *A U.S. Government-funded initiative to reduce the spread of HIV has been launched in U.S. cities in conjunction with the Obama's administration's National HIV/AIDS Strategy that calls for more HIV testing.[1] The approach, called test and treat, calls for voluntary, routine HIV testing of all adults in a community and then treating them with highly active antiretroviral therapy (HAART, also called ART) if they are found infected. Though this is still a preliminary initiative that has been rolled out in New York City and Washington, D.C., some public health leaders see the strategy as a way to successfully stem HIV's spread, given models that suggest that universal testing and treatment, combined with other efforts like condom use, could block HIV's transmission in a decade. Critics claim the model downgrades proven behavior-based intervention strategies and poses serious ethical concerns for promoting potentially harmful drug treatments on persons for whom the benefits have not been fully demonstrated.*

Introduction: The national and local rise in the incidence of the sexually transmitted disease (STD) syphilis,[2,3] as hinted at in our case, raises questions among practitioners and the impacted communities about the efficacy of public health intervention strategies to curb STDs. In our case, our educator is at odds with the director of HIV and STD education for Public Health-Seattle & King County (PHSKC) over the correct intervention model to address STDs. Their discussion questions the efficacy of a biomedical approach to control and prevent bacterial STDs. Concerns over the new HIV test and treat program are also raised by our PHSKC educator's contact at the Lifelong AIDS Alliance, as our educator investigates the best means to develop STD prevention interventions. This paper will first highlight past interventions with syphilis as a model for biomedical approaches and also current best practices for STD interventions, and then it will outline the debates surrounding the latest development, using ART to decrease the spread of HIV.

Syphilis and the Biomedical Approach: In the United States, the bacterial-based STD syphilis was widespread by the 1940s and then declined rapidly with the introduction of penicillin to treat infected individuals and with broad-based public health programs. Between 1947 and 1956, rates fell for primary and secondary (P&S)

syphilis from 66.4/100,000 to 3.9/100,000 cases. Rates fell to their lowest levels in the 1950s, but then rose and fell in cycles by the 1990s in different populations.[4] The biomedical response, which nearly helped to eradicate syphilis during the 1950s, failed to prevent later epidemics. Nakashima et al. (1996), who studied its epidemiology over 50 years, conclude that a strictly biomedical approach to control syphilis likely will fail in the future because prevention efforts need to take into account the socioeconomic, behavioral, and cultural risk factors of affected groups, which do not fit within the biomedical intervention model.[4] Data appear to show Nakashima et al. were correct, with rates of P&S syphilis rising nationally each year during 2001-2009 (rising from 3/100,000 cases in 2001 to 7.8/100,000 cases in 2009), with overall increases in rates occurring mostly among men.[5] In King County in 2009, the early syphilis incidence rate was similar, at 8/100,000 cases, but among men who have sex with men (MSM), the rate was at "epidemic" levels (341.8/100,000 cases).[3]

Current Model for STD Interventions: The U.S. Centers for Disease Control and Prevention's (CDC) national guidelines for the control of all STDs, including syphilis and HIV, identify five major strategies. These include[6]:

- education and counseling of at-risk persons to avoid STDs by changing their behaviors;
- identifying infected persons unlikely to seek treatment or diagnostic services;
- effective diagnosis, treatment, and counseling of infected persons;
- evaluation, treatment, and counseling sex partners of those with STDs; and
- pre-exposure vaccination of persons at risk for vaccine-preventable STDs.

However, the primary prevention approach for all STDs begins with altering individual's sexual behaviors that put them at risk of infection.[6] The strategy for the prevention and treatment for each particular STD vary, but they involve a mix interventions outlined by the CDC, which are widely shared and adapted by health departments nationally. With treatment interventions alone, antibiotics can cure bacterial STDs (chlamydia, gonorrhea, syphilis), while viral-caused STDS (herpes, human papillomavirus, hepatitis B, HIV) can only be treated to reduce symptoms and complications.[7]

Back to Treatment (Test and Treat): The premise of treating HIV-infected persons to control the HIV/AIDS epidemic in order to benefit society, and not seeking to change an individual's behavior, lies at the heart of the test and treat concept.[8] Historically, this biomedical paradigm of STD prevention and intervention focused on

secondary prevention by treating infected persons.[9] More recently, STD interventions have encouraged behavior change. In fact a panel convened in 1997 on STDs by the National Institutes of Health (NIH) concluded that "intervention and behavior research be given the highest priority and coordinated with biomedical research," while noting that risk behavior was "embedded within personal, interpersonal, and situational contexts."[9]

Test and treat is based on recent World Health Organization (WHO) math modeling that suggests annual and voluntary universal HIV testing for those 15 years and older who initiate ART after testing positive, regardless of their CD4 T-cell count or viral load, could reduce the HIV pandemic in 10 years to just 1 incident of HIV infection per 1,000 persons.[8,10] HAART, also known as ART, involves the use of 3 or more antiretroviral drugs for HIV infections, and it has been available since 1996. It can suppress the level of the HIV virus to undetectable levels in plasma, and it has had a significant impact on HIV related morbidity and deaths [8] It is estimated to have saved 3 million years of life.[11] Today, ART is used when the count of infection-fighting CD4 T-cells falls below 350/μl. But the debate over test and treat as an HIV intervention strategy has raised concerns that a federal advisory panel call to start ART with CD4 T-cell counts at 500/μl or lower is linked to an alleged effort by pharmaceutical firms to boost market share under a "treatment as prevention" model.[12] PHSKC, whose local HIV intervention activities are at the center of our case, is promoting the 2009 testing guidelines of the U.S. Department of Health and Human Services that recommend persons with HIV start ART if their CD4 T-cell count is 500/μl or below.[13]

ART is used to help reduce the transmission of HIV from a mother to an infant and for post-exposure prophylaxis in health settings for needlestick exposures. It was not until 2009 in the United States that a plan was launched for increasing coverage levels with ART among HIV-positive persons in order to reduce infectiousness and stop the spread of HIV.[11] Given more than 1 million Americans are living with HIV, interest in such a program is high. The first two test sites, the Bronx in New York City and the District of Columbia, are part of a joint CDC-NIH study, with involvement of local health departments and community groups.[14] The goal of the $26 million pilot project is to determine if such a strategy could work, to see how rapidly infected patients can be linked to care and successful treatment, and to analyze its cost-effectiveness. It will run

three years.[15] Researchers at the University of California San Francisco (UCSF), whose general hospital will expand ART to HIV-infected persons already in care, predict that new HIV infections could fall 76% among gay and bisexual men in the next 5 years with roughly the same test and treat approach. UCSF researchers say the approach will help to prevent organs of patients from being attacked by the virus through early intervention, though no evidence has been released that the policy has led to any reductions in HIV infections in San Francisco.[16]

The head of the National Institute of Allergy and Infectious Diseases (NIAID) and the most influential HIV/AIDS official in the country, Dr. Anthony Fauci, is a proponent of test and treat, among other influential researchers. Fauci and those promoting this universal, voluntary test and treatment effort acknowledge that numerous barriers prevent HIV-infected persons from seeking care, even if diagnosed. These include lack of health insurance, substance abuse, and mental illness. Other concerns include risk-taking by persons who repeatedly test HIV-negative and antiretroviral drug resistance.[8] Fauci and his NIAID co-author, Dr. Carl Dieffenbach, both claim behavioral research issues for this model would be built into a test and treat agenda. They conclude that for the paradigm to succeed, all persons who are infected must be treated to benefit society, so long as there is also long-term benefit to individuals and no drug toxicities or long-term complications with therapies.[8]

Criticisms of Test and Treat: The change from a behavior-focused approach has been criticized. Sean Strub, a lifelong AIDS survivor, ACT UP member, and founder of POZ Magazine, sharply attacked the assumptions underlying the new approach to HIV prevention and treatment. Noting past human studies that led to the Belmont Report to prevent unethical human subject experiments, Strub claims this approach amounts to coercion of people into unneeded treatment, who will suffer harmful side effects from the drugs. “Those of us with HIV are now viewed by much of the public health establishment primarily as potential infectors, ‘viral vectors of disease,’” he writes.[12] Strub claims that test and treat as an HIV prevention strategy lacks empirical evidence and is based on mathematical models only. Such an approach, he says, is not supported by current science or even U.S. Government guidelines for HIV prevention. “It is as though a decision has been made to redirect the country’s public health response to AIDS from proven behavioral interventions, like condoms and prevention intervention,

to the use of anti-retroviral medication."[12] Strub claims San Francisco's Department of Health's support of the "treat everyone" approach—which complements the UCSF general hospital's HIV test and treat strategy—has included cuts to behavior-based HIV preventions. "The single biggest obstacle to getting tested is stigma," he writes. "A smarter strategy to get more people tested would be to combat stigma and discrimination against people with HIV."[12]

Still another recent critique of test and treat strategy, written by Joep Lange, suggests that reduction in HIV incidence with increased ART will only occur if there is "sufficient engagement in HIV care by those infected."[17] He further notes that while increasing the number of HIV infected persons on treatment may reduce the rates of HIV infection, it is "unlikely" that test and treat methods alone, even under a robust regime, will sufficiently end the HIV epidemic. [17]

Back to the Case: The gulf between public health professionals promoting test and treat and some who consider the strategy ill-advised falls along the fault lines of scientists and medical professionals working on drug-based interventions and others who align themselves with impacted community and who see problems with a prevention and treatment regime that downgrades behavioral interventions. The syphilis "epidemic" among MSM in King County, as was alluded to in the case, indicates, perhaps again, that a biomedical model alone is insufficient to reduce the incidence of STDs. Strategies must address broader issues in communities that result in the emergence of high-risk groups.[4] Concerns over the motives of industry and government, historic prejudice against groups with high rates of HIV infection, and changes in STD strategies promoted by federal public health agencies likely will cloud buy-in of test and treat if it moves beyond its pilot sites to other cities.

1. Is there mistrust among communities with high rates of HIV infection that a test and treat approach would create a database by governmental health officials that could be used to harm individuals, despite federal and other privacy protections?
2. How closely tied is test and treat to the long-term vision outlined within the Obama administration's National HIV/AIDS Strategy.

REFERENCES:

1. The White House. *National HIV/AIDS Strategy*. 2011; http://www.aids.gov/federal-resources/policies/national-hiv-aids-strategy/what-is-the-nhas/executive-summary.html. Accessed April 20, 2011.
2. U.S. Centers for Disease Control and Prevention. *Syphillis elimination effort (SEE) toolkit*. 2011; http://www.cdc.gov/std/see/media.htm. Accessed April 19, 2011.
3. Public Health-Seattle & King County. *2009 King County sexually transmitted diseases epidemiology report*. 2009; http://www.kingcounty.gov/healthservices/health/communicable/std/statistics.aspx. Accessed April 20, 2011.
4. Nakashima AK, Rolfs RT, Flock ML, Kilmarx P, Greenspan JR. Epidemiology of syphilis in the United States, 1941--1993. *Sex Transm Dis*. Jan-Feb 1996;23(1):16-23.
5. U.S. Centers for Disease Control and Prevention. *Syphilis & MSM (men who have sex with men) - CDC fact sheet*. 2011; http://www.cdc.gov/std/Syphilis/STDFact-MSM-Syphilis.htm. Accessed April 19, 2011.
6. U.S. Centers for Disease Control and Prevention. *Sexually transmitted diseases treatment guidelines, 2010*. 2010; http://www.cdc.gov/std/treatment/2010/clinical.htm. Accessed April 20, 2010.
7. Public Health - Seattle & King County. *STD Program summary*. 2011; http://www.hiv.va.gov/patient/diagnosis/labtests-single-page.asp. Accessed April 20, 2011.
8. Dieffenbach CW, Fauci AS. Universal voluntary testing and treatment for prevention of HIV transmission. *JAMA*. Vol 301. United States2009:2380-2382.
9. U.S. Centers for Disease Control and Prevention. *Program operations guidelines for STD prevention: community and individual behavior change interventions*. Atlanta: U.S. Centers for Disease Control and Prevention; 2007: http://www.cdc.gov/std/program/community.pdf. Accessed April 19, 2011.
10. Granich RM, Gilks CF, Dye C, De Cock KM, Williams BG. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. *Lancet*. Vol 373. England2009:48-57.
11. Johnston R, Collins C. Can we treat our way out of HIV? *AIDS Res Hum Retroviruses*. Jan 2010;26(1):1-4.
12. Strub S. Medical ethics and the rights of people with HIV under assault. April 28, 2010; http://blogs.poz.com/sean/archives/2010/04/test_and_treat.html. Accessed April 19, 2011.
13. Public Health - Seattle & King County. *HIV/STD Program*. 2011; http://www.kingcounty.gov/healthservices/health/communicable/hiv.aspx. Accessed April 20, 2011.
14. Oakie S. Fighting H.I.V., a community at a time. *The New York Times*. October 27, 2009; http://www.nytimes.com/2009/10/27/health/27hiv.html. Accessed April 19, 2011.
15. National Institutes of Health. *NIH and D.C. Department of Health team up to combat district's HIV/AIDS epidemic*. January 12, 2010; http://www.nih.gov/news/health/jan2010/niaid-12.htm. Accessed April 19, 2011.
16. Bajko M. HIV study: 76% drop in cases with expanded treatment. *The Bay Area Reporter*. April 14, 2011; http://www.ebar.com/news/article.php?sec=news&article=5628. Accessed April 20, 2011.
17. Lange J. "Test and treat": is it enough? *Clinical Infectious Diseases*. Mar 2011;52: 801-2.