

POSITIVE VOICES - AUGUST 2012

Your Newsletter by Positive People for Positive People

Truvada receives FDA approval for the prevention of HIV

Today, the FDA approved the medication Truvada for use in lowering the risk of HIV infection in individuals who are at high risk of infection. According to a press release from the FDA, “Truvada is to be used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to prevent sexually-acquired HIV infection in adults at high risk. Truvada is the first drug approved for this indication.”

The FDA said Truvada for PrEP should be used as part of a comprehensive HIV prevention plan that includes risk reduction counseling, consistent and correct condom use, regular HIV testing, and screening for and treatment of other sexually-transmitted infections, stating that “Truvada is not a substitute for safer sex practices.”

Currently, Truvada (a fixed dose combination of emtricitabine/tenofovir disoproxil fumarate) is one of the most widely prescribed HIV medications in the country, combined with other antivirals to create a treatment regimen. Truvada now carries a Boxed Warning on its drug label alerting health care professionals and uninfected individuals that Truvada for PrEP must only be used by people confirmed to be HIV-negative before being prescribed the drug and tested at least every three months during use to reduce the risk of developing drug resistant HIV-1 variants. Both the antiviral and the PrEP dose is one pill taken once daily.

Truvada maker Gilead Sciences worked with the FDA to create a Risk Evaluation and Mitigation Strategy (REMS) for Truvada PrEP. The REMS focuses on a prescriber training and education program in counseling and managing individuals who are taking or considering Truvada for PrEP, looking at the important elements of a comprehensive HIV prevention strategy, the importance of adhering to the recommended daily dosing regimen, and the serious risks of taking Truvada for PrEP if already infected with the virus or of becoming infected with HIV while taking it.

The FDA based its approval on the efficacy and safety demonstrated in two large, randomized, double-blind, placebo-controlled clinical studies, iPrEx and Partners PrEP.

As a condition of approval, Gilead Sciences is required to collect viral isolates from individuals who become infected with HIV while taking Truvada and evaluate them for the presence of drug resistance. The company is also required to collect data on women who become pregnant while taking Truvada for PrEP and to conduct a study evaluating drug adherence and its relationship to adverse events, risk of HIV infection, and the development of drug resistance in people who become infected.

“Today’s decision is the culmination of almost 20 years of research involving investigators, academic and medical institutions, funding agencies and nearly 20,000

trial participants around the world, and Gilead is proud to have been a partner in this effort,” said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. “This advancement in the field of HIV prevention was made possible due to the leadership and commitment of the FDA and the Department of Health and Human Services to reduce the number of new HIV infections in the United States and worldwide.”

Love Your Liver

by Cindra Feuer (hepmag.com WINTER/SPRING 2012).

This vital organ works hard for you. Here's how.

Living (and Working) Large

The liver is your body’s biggest internal organ, reflecting its giant job as all-purpose filter. Tucked under the lower right side of the rib cage, it is a spongy mass of tissue that metabolizes, or processes, everything you eat, drink, breathe and inject. Carried there by the blood, all kinds of substances—from nutrients in food to HIV drugs to heroin and hooch—get broken down into wealth (used by the body) or waste (eliminated as urine, sweat, etc.).

Busy Body

The liver works overtime making bile (to aid digestion), immune agents (to fight infection), proteins (to build muscle) and clotting factor (to stop bleeding). The organ even stores up energy and has an awesome ability to regenerate. It can do this even when two thirds is removed, allowing for transplants and second chances.

Lowdown Hijacker

Into this finely tuned multitasking system crashes the hepatitis C virus (HCV), targeting the very liver cells—called hepatocytes—responsible for all the heavy work. Super sneaky C slips its own genetic mojo into the cell, so that when the infected hepatocyte reproduces, it will also birth the virus. No wonder the liver gets inflamed—that freeloading trick would enrage anyone.

Scar-Y News

In the months after they become infected with HCV, roughly 20 percent of people who also have HIV will clear hepatitis without treatment. The other 80 percent will go on to develop chronic hep C, though 20 percent of them may not have any problems at all (but they can still pass the virus to others). For the rest, hep C—if left untreated—will progress, damaging the liver slowly but surely over the coming decades. The damage can advance through four stages. First is inflammation: The liver gets swollen, even painful. Next up, fibrosis: Scar tissue forms over the inflamed cells. Then, possibly, cirrhosis, when knots of scar tissue block the flow of blood between cells and compromise the liver's structure and function. Last and worst is either liver failure or cancer.

The HIV Angle

HIV targets the immune system, leaving the liver to hep C and other viral villains. So why is coinfection double trouble for the organ? Because HIV causes hep C infection to progress faster—one more good reason to take the meds that keep your HIV viral load low and your CD4 cells high. But beware of coinfection's catch-22: You need HIV meds, but certain ones can stress your liver—and push an HCV-infected organ over the edge. That's why it's important to pick the kindest, gentlest meds and test your liver during treatment.

Traffic Jam

Mixing meds can make a mess, which is a special concern if you're using HIV drugs and your doc wants to prescribe one of the new meds for hep C: Victrelis or Incivek. These drugs and many HIV treatments compete for the same processing pathway. This can cause too much of a drug to build up in the blood (producing side effects and toxicity) or too little of the drug to get through (causing resistance or lower efficacy). Treating HIV and hep C calls for the right balance—make sure your doc double-checks the meds you've been prescribed and, if necessary, switches your HIV meds to ensure magical matches.

ON GOING MEETINGS AND COMMUNITY SERVICES

Join/ Attend: Consumer Advisory Committee [CAC] Meetings

The STAP Consumer Advisory Committee is a committee facilitated by and made up of consumers (STAP clients) who welcome other consumers and their significant others, caretakers and family members to join them on the second Tuesday of each month. This collaborative effort provides a confidential space for clients to make recommendations regarding STAP client services and other programs in a non-judgmental environment. The meetings are held following the Friends Dinner @ 5:45 at Trinity Memorial Church (on the corner of Main & Oak Streets) in downtown Binghamton. Call 1-800-333-0892 for directions or more details. If you cannot attend these meetings, mail your opinions or suggestions to STAP, 122 Baldwin Street, Johnson City, 13790, Attention CAC. CAC is encouraging consumers in other counties to organize monthly meetings in their area.

Friends Who Care Support Groups

Broome County: “Friends Who Care” meets every Tuesday at 3 pm - 4:30 pm at Trinity Memorial Church located at 44 Main St. in Binghamton... come join us for Binghamton’s HIV/AIDS Support Group ******(open to clients only). Also stay for a good (free) meal afterwards at the “Friends Dinner”.

Chemung County: Men Living with HIV Support Group; 2nd Monday of each month; 6-7:30pm; Ivy Clinic, 600 Ivy St., Suite 206, Elmira. For more information people can contact me via phone or email. **Lynn Bassler, LMSW** Treatment Adherence Counselor, Ivy Clinic, 737-8188.

Tompkins County: The IVY Clinic is pleased to let all HIV+ men in the Ithaca and surrounding area know there is a support group that is held the third Tuesday of every month at the Ithaca STAP office. Time for the group is 6-7:30 pm and topics vary from month to month. If you are interested in attending please e-mail Shannon Sprague at ssprague@aomc.org for further information.

Friends Dinner

“Friends” meet every Tuesday evening for a time of fellowship and good food. Join us at Trinity Memorial Church (on the corner of Main & Oak Streets / across the street from the High School) in downtown Binghamton. Doors open at 5PM and dinner is served @ 5:30. No charge, just come with a smile and a friendly attitude - ready to meet and greet friends and have a hearty meal. Parking is available on Oak Street behind the Church Annex. Use the Oak Street entrance for the cafeteria. Call your case manager for details. Free Bus passes available for transportation to/from the Friends Dinner only. (STAP clients only) For more information about the “Friends Dinner, call STAP in Johnson City and they will get you in touch with Bill.

Free Anonymous Rapid HIV Testing

Walk-in *Anonymous* testing is available in our STAP Johnson City office every Monday from 1:00-4:30PM and Thursdays from 1:00-3:00PM. *Confidential* testing is available in our STAP Johnson City office Thursdays from 9:00AM - 12:00PM. STAP's office is located at 122 Baldwin Street Johnson City, NY 13790. Walk-in *Anonymous* Testing is also available at STAP's Ithaca office located at 501 S. Meadow Street, Ithaca, NY 14850 on Tuesdays from 9:00AM-11:30AM, and *Confidential* testing can be scheduled Thursdays, 9:00AM-11:30AM. For more information and other testing opportunities available throughout the month, please call (607)798-1706.

Free EDUCATIONAL Lunch/Dinner: August/September 2012

Good News: We now have 2 Drug Companies willing to come to our area to continue to teach/inform us about new and upcoming advancements in the treatment of HIV.

NEXT EVENT : MONDAY 8/13/2012 @ 12 noon.

Gilead will have a lunch on August 13th at Grande's on Vestal Ave @ 12 noon (* this is the old address again)

Bristol Myers will have a lunch on September 24th at 12 noon (location to be determined at this time - update by next newsletter.)

* As usual seating is limited (you & a guest only) and must be reserved with Martha at least a week before the event. *R.S.V.P. - Martha # 607-238-8350.*

These are “learning events” - please respect everyone’s right to learn.

Ask The Medical Advocates:

From Positively Aware online July/August 2012 – Helen C. KOENOG, MD, MPH

Q: I am in a relationship with an HIV-positive man with an undetectable viral load. I am negative. We refrain from oral and anal sex. Last night while masturbating some of his semen got on my hand and I had an open cut. I have not been able to sleep.

Since we are in a monogamous relationship and he is undetectable, should I get tested regularly? Going for testing freaks me out. I have not been tested since three months after his diagnosis, which was three years ago.

A: You bring up several important issues that should be addressed. Mutual masturbation is typically an excellent way to have safe sex with an HIV-positive partner, as are oral or anal sex with appropriately used condoms. In addition, the best way to prevent HIV transmission, as shown by the recent study in couples where one is positive and the other isn't (sero-discordant), is for the HIV-positive partner to have an undetectable viral load on consistent antiretroviral therapy. Although almost all (97%) of the couples in this study were heterosexual, it is still helpful in showing how difficult it is to transmit HIV when the HIV-positive partner is taking HIV therapy.

So is there still a risk of HIV transmission when your partner has an undetectable viral

load on medications? The answer is yes, since viral particles have still been detected in the semen of men who have an undetectable viral load in their blood. This is because the semen is one of the so-called “sanctuary sites” where HIV can continue to replicate, since many of the HIV medications we use today are not able to get into the semen.

This brings us to your first question regarding the risk of transmission of HIV from the semen of a partner with an undetectable viral load to you through an open cut in your hand. The risk of transmission through an open cut depends on the type and depth of your wound: a superficial wound with a scab would be extremely unlikely to allow HIV transmission, while an open wound with visible bleeding or exposed deeper tissue would put you at higher risk. Since this doesn't sound like a high-risk exposure, and your partner had an undetectable viral load, the risk of infection in your case is likely slim to none and I do not think that taking a 28-day course of post-exposure prophylaxis is warranted. If the cut was on the deeper side or if your partner's viral load may have been detectable, post-exposure prophylaxis might have been prudent, but it would have needed to be administered within 72 hours of exposure.

As for your second question: in my experience as a physician, patients often report being in monogamous relationships and then find out later that their partner was not being as monogamous as they were. In addition, your partner may believe that his viral load is undetectable, but he may not know if his viral load crept up since his last check-up several months prior (although the chance of this happening if he is 100% adherent to his antiretroviral therapy is extremely low). While the possibility of infidelity is never fun to consider, figuring out your level of risk is only as good as the information you have! Therefore, in general, all partners of HIV-positive individuals should be tested for HIV at least annually, and those at higher risk of acquiring HIV (those with multiple partners, those who share needles for IV drug use, those whose HIV-positive partners have detectable viral loads, etc.) should be tested more frequently. That said, mutual masturbation as the sole form of sexual activity, in the setting of an undetectable viral load, confers almost no risk of transmission.

In summary, you and your partner are to be commended for your safe sex practices

and your partner's excellent virologic control. Your risk of having acquired HIV from the exposure you describe is virtually nonexistent, but it never hurts to get tested for peace of mind, and on a regular basis as a healthy habit. In fact, the CDC recommends that all adults, regardless of risk, be tested for HIV in all healthcare settings.

** DO YOU Know What the C.H.O.I.C.E.S. Program IS ?

C.H.O.I.C.E.S. is a self-paced educational series designed specifically for YOU to learn and understand HIV and your body. Whether you take one quick course or decide to go through the entire program and take charge of YOUR HIV, ask a Medical Advocate about C.H.O.I.C.E.S. today...

Medical Advocacy Coordinator: Stacy # (607)798-1706 Ext. 210

Medical Advocate: Autumn # (607) 426-9445

* Every 3rd Tuesday of the month at 4:30 pm *(new time) - just before the Friends Dinner come join us for our monthly C.H.O.I.C.E.S. module (open to everyone). We have found that we get more out of the program when we learn the modules as a group. Informative questions and discussions are raised.

* Next Program will be August 21st at 4:30 pm *(new time) with Autumn Cook, Medical Advocate, in the dining room at Trinity Church. Followed with a free dinner prepared by one of the local churches that supports our "Friend's Dinner".

**August 28th (Tuesday): Stacy will be coming with a guest speaker to talk us about Hepatitis A, B, & C infections and treatments. This special event will take place during our regular HIV support group meeting at Trinity Church, Binghamton from 3-4:30. Contact Stacy at STAP (Johnson City #798-1706) for further info / questions / transportation assistance. **And stay for the "Friend's Dinner".

Editor's Note: Jeff Berry @ PositivelyAware.com

Wish HIV Away.

Truth is a funny thing. It has a way of sneaking up on you when you least expect it, like a guest who shows up at a party, uninvited.

Wish Me Away is the name of a song by country music singer Chely Wright, and is also the title of her recently released documentary film, which chronicles her struggles coming out as a lesbian to her fans, the country music industry, and the world at large. It's a touching, sometimes sad, often intense, and ultimately empowering film that tells her truth, as she has lived it, in the hopes that it might help others who may also be struggling.

During the film's opening, Chely states that she is just trying to live her own life openly and honestly, because not doing so is nearly killing her. She knew from a very early age that she was different, that she was gay, and for decades she swore to herself that she would take that secret to her grave. Years ago, I made a similar vow to myself—that I would take to the grave my own secret that I had been sexually abused as a child by my father.

I have no doubt that a similar conviction exists for countless others when it comes to their HIV status. We live in fear—fear of losing our jobs, our family, our friends, our very safety. So we wish HIV away. We take our pills in hiding, so others won't ask questions. If there is a blood drive at the office, we call in sick, rather than have to explain why we can't donate. We drive hours to visit a doctor or clinic in another town, rather than be recognized at "that clinic" at home. We wish HIV away.

I'm sure we all have that one friend who has never been tested, and refuses to, because they would just rather not know. They wish HIV away by pretending it doesn't even exist. There is the family who hides the cause of death of their son or daughter by saying they died of cancer. The church that preaches that AIDS is God's punishment for being gay. The legislators who slash budgets and funding and deny lifesaving medications to people with HIV. They all wish HIV away, and sweep it under the rug,

erroneously believing it can't happen to them, attaching shame and stigma to simply having a virus.

We need to stop wishing HIV away, and it has to begin with us. I know for some of us the fear of losing our jobs, and hence our health insurance, is a very real, palpable fear. But we need to start by speaking and owning our own truth, if only in the mirror. In this issue, Jamar Rogers speaks very openly and honestly about his own struggles, and the power of speaking his own truth regarding his HIV status. However, there are some of us who continue to hide, or live in denial, because it's more comfortable, or it's easier, or we are afraid of the unknown. But it might be that we could have a real impact by coming out about our status, if only to ourselves. HIV is nothing to be ashamed of. The only stigma attached to HIV is that which we allow. It has no power to dictate our actions, our feelings, or our beliefs, other than the power that we choose to let it have over us.

Let's stop the fantasy. Let's stop pretending that HIV can be wished away. Until there is a cure, HIV is unfortunately here to stay. Just like that uninvited guest at the party, it can either be shunned, merely tolerated, or it can be embraced.

Remember, you are the host, and it's your party—what happens is up to you. So shine your light brightly, hold your head up high, don't be ashamed, and refuse to live in fear. It's only when we finally decide to embrace and rejoice in our own truth, that we can begin to see the truth and light in others. And by joining together, we create a force and a light so bright, so strong, that its presence is undeniable and it cannot be extinguished or ignored.

Take care of yourself, and each other.