The STEP Ezine

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Issue #55

The Seattle Treatment Education Project's (STEP) EZINE is an electronic treatment resource newsletter distributed monthly to case managers, front-line workers, people affected by HIV/AIDS, physicians, other public health and allied health professionals and people living with HIV/AIDS.

STEP's contact information is: STEP at Lifelong AIDS Alliance, 1002 E. Seneca Street, Seattle, WA 98122
(206) 329-4857 o (206) 957-1659. We also have a toll free number 1-888-399- (STEP) 7837 Anywhere in the US

Correction to Last Month's *Ezine*

In last month's Ezine, an article about the OraQuick Rapid Test for HIV was posted. The intention of the article was to inform our community of the availability of the test. However, the OraQuick Antibody Test manufactured by OraSure Technologies, Inc. was approved by the FDA back in 2002 and it has been in use for a while. People of Color Against AIDS Network (POCAAN) and Public Health-Seattle & King County are using this test in various sites.

There is a new Rapid Test, now in use, approved in December 2003, and the one that our staff meant to print the news about. The information regarding this new test can be found below. Our apologies to the Ezine readers.

FDA approved, on December 23, 2003, the Uni-Gold Recombigen™ HIV rapid HIV test, a single use rapid test for the detection of antibodies to HIV-1 in plasma, serum and blood (venipuncture). It is the first device to be FDA approved for use with all three-sample types. Uni-Gold Recombigen HIV is intended for use in point of care settings as an aid in diagnosis of infection with HIV-1.

Use of Uni-Gold Recombigen HIV is restricted to clinical laboratory professionals in facilities having an adequate quality assurance program. **The test is not approved to screen donors of blood, plasma, cells or tissues, or for home use.**

Uni-Gold Recombigen HIV provides results in **10 minutes**. The test was approved by the FDA on the basis of clinical trial results demonstrating test sensitivity of 100% and specificity of over 99.7%.

Test subjects must receive the "Subject Information Leaflet" prior to specimen collection, and appropriate counseling when test results are provided.

Positive test results require confirmation. The test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results. This new test cuts result time by ten minutes, when compare to the OraQuick Rapid Test.

Vertical HIV Transmission Rate Down in U.S

Vertical HIV Transmission Rate Down in U.S.; Majority of Cases Associated With Lack of Prenatal Care, CDC Report Says

January 5, 2004

Although the percentage of HIV-positive women who give birth to HIV-positive infants has declined "dramatically" in developed nations due largely to the use of antiretroviral drugs, a lack of prenatal care increases a woman's likelihood that she will transmit the virus to her infant, according to a study published in the Jan. 2 issue of the CDC's *Morbidity and Mortality Weekly Report*, *Reuters Health* reports.

Researchers from the CDC assessed compliance with the U.S. Public Health Service guidelines recommending universal prenatal HIV counseling, voluntary HIV testing and provision of antiretroviral drugs to HIV-positive pregnant women and their newborns at Grady Memorial Hospital in Atlanta between 1997 and 2000.

Of the 253 infants born to HIV-positive women at the hospital during the time period, 17 were HIV-positive, according to the researchers. Between 1999 and 2000, nine HIV-positive infants were born at Grady Memorial. Of those infants, six were born to women who did not receive any prenatal care and three were born to women who received some prenatal care but for whom the antiretroviral drug regimen or timing was not optimal. During the same time period, no cases of vertical transmission were identified among HIV-positive women who received adequate prenatal counseling, HIV testing and antiretroviral drugs. During the four-year study period, the vertical HIV transmission rate ranged from 3% to 10% (*Reuters Health*, 12/31/03).

Before the introduction of antiretroviral drugs, approximately 25% of all infants born to HIV-positive women were born infected, according to Dr. Mary Glenn Fowler, who oversees CDC's perinatal HIV research.

Focus on Prenatal Care, Drug Regimen Adherence-Fowler said, "We know that if we get women into prenatal care, get them properly tested and start them early on antiretrovirals, we can reduce the [vertical HIV] transmission rate to about 2%," adding, "This study shows the failures, those who slipped through, and the numbers are reflective of what we see nationally" (Guthrie, *Atlanta Journal-Constitution*, 1/2).

The CDC researchers concluded, "For pregnant women who receive prenatal care and know their HIV status, prevention programs should focus on promoting adherence to recommended treatment regimens and administering (AIDS drugs) during pregnancy. Efforts to reduce (mother-to-infant) HIV transmission should continue to focus on increasing prenatal care rates and prenatal HIV testing, particularly in areas where missed opportunities for prevention of perinatal HIV transmission persist" (*Reuters Health*, 12/31/03).

The FDA has accepted the *filing* for an injectable poly-L-lactic acid called 'SCULPTRA' to treat facial lipoatrophy

BERWYN, PA, FEBRUARY 5, 2004
Dermik Laboratories, the U.S. dermatology arm of Aventis (another pharmaceutical company), announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted expedited review of the company's Premarket Approval Application (PMA) for SCULPTRA(TM) (injectable poly-L-lactic acid), a long-lasting, synthetically derived, dermal contouring agent to help restore lost facial volume in people with lipoatrophy. Facial lipoatrophy can be characterized by loss in fullness, shape and contour of the face.

SCULPTRA(TM) is marketed under the trade name NEW-FILL(R) in Europe, where it was approved by the Department of Evaluation of Medical Devices in 1999 as a wrinkles filling product. Sculptra ™ has been used by an estimated 100,000 people in more than 30 countries throughout Europe and South America, and in Australia, for the treatment of a range of facial imperfections, including signs of aging, such as wrinkles, folds and sunken cheeks.

"Facial lipoatrophy is a condition that results in loss of fat in the cheeks, temples and eye sockets. The sunken cheeks, hollow eyes, indentations and wrinkling may make a person appear exhausted and unhealthy," said Dr. Sharon Levy, senior director of Scientific & Medical Affairs for Dermik Laboratories. "Lipoatrophy can result from the use of anti-retroviral therapy in people with HIV and can have a devastating effect on self-image and confidence. The effects can be so severe that patients may even jeopardize their health by discontinuing their anti-retroviral treatment."

The objective of the studies submitted to the FDA was to determine whether SCULPTRA(TM) safely and effectively produced significant improvements in appearance and in restoration of lost facial volume in people with HIV. Researchers also evaluated the quality of life and anxiety and depression scores of study participants. The data from these studies are intended to show that SCULPTRA(TM) is well-tolerated, with adverse effects generally limited to reactions at the site of the injection.

"There is a significant unmet need in the United States for an FDA-approved lipoatrophy treatment that is safe, effective and long-lasting," said Robert J. Bitterman, president of Dermik Laboratories. "We are committed to working with the FDA to provide those who experience the symptoms of facial lipoatrophy with a treatment that can help improve their physical appearance and overall well-being."

Poly-L-lactic acid (PLLA) is synthetically derived from natural components and is a biocompatible substance that degrades to lactic acid. PLLA has been used in surgical products for more than 20 years as a component of dissolvable Vicryl(TM)(1) sutures and is used as a vehicle for several sustained release injectable medications.

According to John Leone, president of Aventis Dermatology, "The submission of the SCULPTRA(TM) PMA to the FDA represents a major milestone for our newly created global Aventis Dermatology division. The market and need for aesthetic dermatology is growing rapidly and SCULPTRA(TM) represents a significant advance for those individuals with signs of facial lipoatrophy."

Note: 'Filing' with the FDA doesn't mean that the medication or product has been approved for use. It is simply a process to which all medications and products have to go through before reaching the US market.

"A Dear Health Care Professional Letter"

From: Boehringer Ingelheim Pharmaceuticals,Inc., manufacturers of Viramune

February 2004

IMPORTANT NEW SAFETY INFORMATION

Re: Clarification of risk factors for severe, life-threatening and fatal hepatotoxicity with VIRAMUNE ® (nevirapine)

Dear Health Care Professional:

Boehringer Ingelheim Pharmaceuticals Inc. (BIPI) is writing to inform you of important new labeling information being added to the Boxed Warning for VIRAMUNE, a non-nucleoside reverse transcriptase inhibitor (Non-Nuke) indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. Specifically, we wish to draw your attention to the following:

Women with CD4+counts >250 cells/mm3, including pregnant women receiving chronic treatment for HIV infection are at considerably higher risk (12 fold) of hepatotoxicity. Some of these events have been fatal. This subset of patients was identified by analyses of CD4 count at the time of initiation of VIRAMUNE therapy.

The greatest risk of severe and potentially fatal hepatic events (often associated with rash) occurs in the first 6 weeks of VIRAMUNE treatment. However, the risk continues after this time and patients should be monitored closely for the first 18 weeks of treatment with VIRAMUNE. In some cases, hepatic injury progresses despite discontinuation of treatment.

This new information is the result of recent post-marketing surveillance data and further analysis of the VIRAMUNE clinical trial database.

Special advisory note from the STEP Ezine editor:

If you are taking Viramune (nevirapine) and you believe the above description fits you, call your doctor. Please do not discontinue taking this anti HIV medication unless advised by your health care provider.

(The word '*hepatic*' refers to the liver.)

ADAP Funding Crisis

The STEP's Ezine is posting the following article to educate and inform about the fiscal crisis of the ADAP program and the possibility of future reductions in benefits to those living with HIV/AIDS in our community.

What are ADAPs?

AIDS Drug Assistance Programs (ADAPs) provide life-saving HIV/AIDS medications to uninsured and underinsured individuals living with HIV disease in the 50 states, the District of Columbia and the U.S. territories. ADAPs are not entitlement programs but are dependent on federal and state discretionary funding, which determines how many clients ADAPs can serve and what levels of service states can provide.

Why are ADAPs in fiscal crisis?

There are two major factors contributing to the ADAP problem:

- Inadequate funding: Since 2002, ADAPs have not received adequate federal funding with the FY 2002 budget for the program falling short by $62 million and the FY 2003 budget by $79 million. Adding to this effect is a FY 2004 budget that falls $180 million short in meeting current ADAP need. Moreover, many states are also under increasing fiscal pressure and are unable to contribute sufficient funding to make up for the federal shortfall.

- Increased utilization/demand for services: People who have access to antiretrovirals are living longer, increasing utilization of the program by 154% since 1996, the year highly active antiretroviral therapy (HAART) was made available.

What do ADAPs need?

- ADAPs will require $319 million in additional funding through FY 2005. The programs could be made whole immediately if $180 million of that funding were made available in a FY 2004 emergency supplemental. The President's preliminary 2005 budget provides $35 million, which, while welcome, is inadequate to meet the growing need.

- The passage of the Early Treatment for HIV Act (ETHA), which would provide states the option of covering patients under Medicaid at an earlier stage of their disease, *before* they become disabled and are vulnerable to life-threatening and expensive-to-treat opportunistic infections. A majority of ADAP patients would qualify under ETHA in any state that adopted this progressive legislation, thus immediately relieving pressure on that state's ADAP program.

What Are the Effects of the Fiscal Crisis on ADAPs?

- As of January 22, 2004, 791 ADAP-eligible clients are on state ADAP waiting lists, an increase of over 100 clients since November 2003. Due to capped enrollment, these people will not be able to access treatment until someone else moves off the program, dies, or additional funding is made available.

- As of January 22, 2004, 15 state ADAPs have taken steps to limit access to life-enhancing HIV treatments and 8 more have announced plans to do so in the near future. Steps taken included capping enrollment, reducing formularies, reducing eligibility or, in the worst cases, removing already enrolled people from the program.

- Due to insufficient funding, many ADAPs are no longer able to cover important new therapies for HIV or treatments for HIV/hepatitis C (HCV) coinfection, the fastest growing cause of death among people living with HIV.

Why Should ADAPs Be Adequately Funded to Meet Estimated Need?

- To conform to federal HIV treatment guidelines: The United States Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* recommend that antiretroviral treatment be offered to all patients with 350 or fewer CD4 cells or over 55,000 viral load.

- Treating HIV earlier in the course of the disease saves money: Numerous peer-reviewed studies have shown that it is both more medically sound and cost-effective to treat HIV early rather than late in the progression of the disease. A recent study from The University of Alabama at Birmingham showed that

treating HIV early costs an average of $14,000 per year, while waiting until the patient is disabled (when he or she would normally qualify for Medicaid) costs an average of $34,000 per year.

- Treating HIV saves lives: AIDS related death rates have declined by over 64% since the introduction of HAART in 1996. A 2003 study by Price-Waterhouse-Coopers demonstrated that early access to effective HIV therapy decreased AIDS-related death rates by 50%.

- Treating HIV lowers transmission rates: Medications can help reduce the spread of HIV to HIV-negative partners. A study conducted by the National Institute of Allergy and Infectious Diseases shows that risk of HIV transmission drops when a patient's viral load drops below 1500. A second study published in 2004 in the journal *AIDS* states that the widespread use of new HIV medicines reduced HIV infectivity by 60%.

Who do ADAPs Serve?

- Over 90,000 unduplicated clients per month in November 2003, an increase of nearly 10,000 clients per month since June 2002.

- Predominantly low-income individuals: Over 80% of ADAP clients have incomes at or below 200% of the federal poverty level (FPL), and about half of all ADAP clients earn 100% or less of the FPL ($8,860 per year.)

- Uninsured or underinsured individuals: 71% of ADAP clients have no other form of insurance, while 29% have insurance that does not adequately reimburse for the HIV treatments they are prescribed.

- Predominantly racial and ethnic minorities: 33% of ADAP clients are African American, 24% are Hispanic, 37% are white and 5% are other races or ethnicities.

[1] All data is from the National Association of State and Territorial AIDS Directors and the National ADAP Monitoring Report, April 2003, Henry J. Kaiser Family Foundation.

Note from the STEP Ezine editor: Washington State APDP (AIDS Prescription Drug Program) has added coverage for Hepatitis C treatment to its program.

Clinical Trial at Swedish Medical Center

Tipranavir Early Access Program

There are limited openings in this program. **Please contact Heather Algren at (206) 386-2820.**

Protease Inhibitor Study

You may be eligible to join a research study of a medication for HIV disease if you have taken HIV medications in the past that no longer work for you and you are currently taking a combination of HIV medications and your viral load is over 1,000 copies. **Please contact Janice Price at (206) 386-2523.**

AIDS Clinical Trails Unit (ACTU) has a new study!

Correlation between Drug Levels in the Blood & Resistance Testing

The study will evaluate the correlation between drug blood levels and resistance testing with viral load suppression for each of the three Ritonavir-boosted protease inhibitors.

Eligibility:

*On stable HAART for 90 days, with exposure to NRTI, NNRTI, and PIs
*HIV RNA of 2,500 copies/mL or above and evidence of RESISTANCE

*13 years of age or older

*Men and Women
(Women must not be pregnant)

Treatment: The study will provide the following PI drug combinations + optimized background regimen of ZDV,3TC, or Abacavir are chosen as background drugs.

1.Lopinavir/ritonavir + Ritonavir

2.Fosamprenavir/ritonavir (The FDA has approved GW-433908, which is a form of Amprenavir that requires fewer pills. However, its use in this trial is investigational)

3.Indinavir/ritonavir

4.Tenofovir added at day 15

Study will run for 24 weeks.
Exams and testing provided at no cost. $20 per study visit and $150 for one all-day visit
Contact Carol Glenn at Madison Clinic or call the ACTU (206)-731-3184
and ask for the screening nurse on call.
Thank you.

The STEP Program at Lifelong AIDS Alliance wants you to know…

The STEP Program here at Lifelong AIDS Alliance would like to inform our readers about the Peer Counseling Sessions that now are part of the array of services that STEP offers to the community.

What are Peer Counseling Sessions?

These are one-on-one sessions designed to inform and educate clients about the healthcare continuum as it relates to treatment options. Individuals learn how to access medications and be adherent to them, where to gain information on complementary therapies and how to manage side effects of treatments. STEP promotes self-sufficiency and empowerment of the individual by providing information free of charge.

Call STEP at (206) 957-1659 or 1-888-399-7837 to talk to a peer or simply let your case manager or health care provider know that you will like to participate.

Do you know that Seattle Treatment Education Program gets over 33,000 hits a month on their Web site link to ***thebody.com***?
Curious?

Visit us online at www.thebody.com/step/steppage.html

ACKNOWLEDGEMENTS

- Please note that this is not a complete list of all HIV-related treatment information. STEP strives to provide the very latest in HIV/AIDS treatment information, research and drug development information. The most current research directions and antiretroviral drug data are provided throughout the Ezine publications. You will find highlight reports as well as extensive follow-up reports from many of the AIDS research and science conferences on the Ezine. In addition, all STEP quarterly treatment journals are available on our Web site at http://www.thebody.com/step/steppage.html or by calling our National Talkline at 1-888-399-STEP (7837). STEP works hard to give unbiased treatment information to all interested parties. If you have comments, questions, suggestions or grievances, please contact step@lifelongaidsalliance.org.

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