Fall 2002 Volume 6, Issue 3

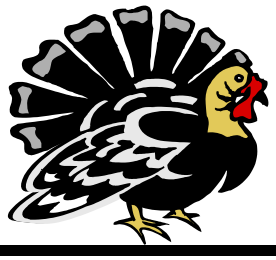
The WIHS Woman

The Connie Wofsy Women's HIV Study

FALL IS HERE !







BAY AREA WIHS MEETS, THEN EXCEED RECRUITMENT GOALS!

By Nancy Hessol, Project Director and Claudia Ponath, Field Manager

Eureka, we did it with your help! As of September 15th, we have enrolled 153 women (our goal was 149). Out of the 153, 66 are HIV-uninfected women (our goal was 61 women), 51 are HIV-infected women not on HAART (our goal was 48 women), and we have enrolled 36 HIV-infected HAART using women (our goal was 40 women). This means our Bay Area WIHS site, the Connie Wofsy HIV Study, has enrolled a total of 580 women in the past ten years.

Compared to the original cohort, the new group of women is younger, as we had planned. We purposely looked to recruit younger women, because over the last 10 year the original cohort has naturally grown older, and there are a number of research question that can only be answered by looking at women of childbearing age. Fewer of the women in the new group have a history of injection drug use (32% in the new group versus 59% in the original group), which shows that the epidemic is moving into a different segment of the population. In terms of ethnic makeup, the original cohort was 56% African American, 26% Caucasian, 12% Latina and 6% other, whereas the new group is 40% African American, 21% Caucasian, 4% Latina and 34% other. The "other" category largely consists of women of mixed ethnic backgrounds (30%).

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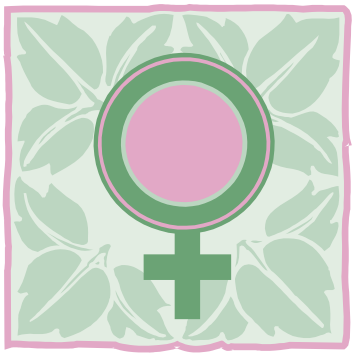
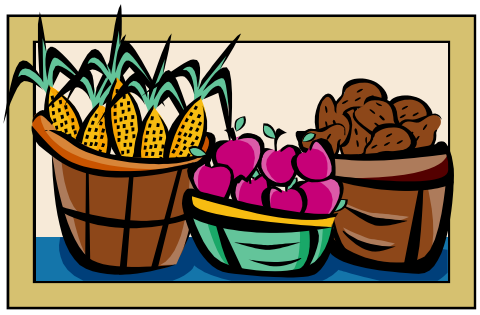
We welcome all the new women who joined the study and thank you for your time and commitment to this very important and valuable endeavor.

We also thank our longtime participants for all the referrals of new participants we got, and for their continued support and participation. We would not be able to perform this research work without you.

As a special thank you gift, when you come in for your Visit 17 study appointment you will receive a free 30-day supply of Theragram multivitamins (courtesy of Bristol-Myers Squibb).

Thank you all, and keep coming back!





WIHS PUBLICATIONS

By Anna Groskin, CAB Liaison

At the WIHS, we are often asked by participants about papers that are written using data we have collected for the study. Below, I've summarized two articles by WIHS researchers—one about HAART and one about anemia—that we published recently. Thank you again for being part of the WIHS—you make this research possible.

The effectiveness of highly active antiretroviral therapy (HAART) among HIV-infected women. (From Gange *et al*, Journal of Epidemiology and Community Health, 2002)

Highly active antiretroviral therapy (HAART) was approved by the FDA in 1996 and since then its use has increased greatly among WIHS women. As we reported in our last issue of the WIHS Woman, the overall number of women on any antiviral therapy has remained stable but now more and more of these women are using HAART. HAART is made up of three classes of FDA-approved therapies. One class is nucleoside reverse transcriptase inhibitors, which include zidovudine, stavudine, zalcitabine, didanosine, abacavir, and lamivudine. Another class is protease inhibitors, which include saquinavir, indinavir, ritonavir, and nelfinavir. The third class is non-nucleoside reverse transcriptase inhibitors, including nevirapine, and efavirenz.

The use of HAART by women in the WIHS has dramatically reduced the number of new

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AIDS diagnoses *and* deaths. The CD4 counts of women on HAART have also increased steadily from 1996 to the present.

Also in the mid 1990s, more treatments were being prescribed to treat and prevent opportunistic infections like *Pneumocystis carinii* pneumonia (PCP), tuberculosis, and thrush. The increase in these treatments could also be responsible for some of the decrease in new AIDS diagnoses and deaths. It is often difficult for researchers to tease out the exact impact of these treatments, but there is no doubt that new AIDS diagnoses have decreased among WIHS women since HAART was introduced.

The WIHS is an extremely important research project because it provides observations from a diverse group of women over a long period of time. Other research that has been done on the effectiveness of HAART has been done in controlled clinical trials made up of small groups of people that lasted for short periods of time (1-2 years). The WIHS allows a much broader view of women and HIV, and can provide valuable information that is used both to improve the health of women currently infected with HIV and those that may become infected in the future.

Prevalence and correlates of anemia in a large cohort of HIV-infected women: WIHS (From Levine *et al*, JAIDS 2001) and Anemia Institute fact sheets.

Anemia can occur when you do not have enough red blood cells in your blood. Red blood cells contain an iron-rich protein called hemoglobin, which carries oxygen from your lungs to other parts of your body. Your body needs oxygen in order to survive and function well. When you don't have enough red blood cells, there is less hemoglobin to bring oxygen to all parts of your body. When your organs and tissues don't get enough oxygen to do their work, you can end up feeling tired, weak, short of breath, or dizzy. There are a few things that can cause anemia: a poor diet; a diet specifically lacking in iron, vitamin B12, or folic acid; and blood loss from heavy menstruation, surgery or internal bleeding. Studies have also found that HIV and some medications used to treat HIV can cause anemia in HIV-positive people. WIHS researchers have looked at anemia rates in WIHS participants, and found that a total of 37% -- more than one in three -- HIV-positive women in the WIHS were anemic. (The researchers defined anemia as having less than 12 grams of hemoglobin per deciliter of blood.) Of the HIV-negative women in WIHS, 17% were anemic. HIV-infected women were three times more likely to be anemic than HIV-negative women, and were also much more likely to have severe anemia (less than 10 grams of hemoglobin per deciliter of blood).

WIHS researchers found that in both HIV-positive and HIV-negative women, anemia was more common among African Americans than other racial groups. WIHS researchers also found that among HIV-infected women, a higher risk for anemia was associated with lower CD4 counts and higher viral loads. Having a self-reported clinical AIDS diagnosis was also associated with a higher risk of anemia. Current use or recent use of zidovudine was also associated with anemia. Other nucleoside reverse transcriptase inhibitors (such as stavudine, zalcitabine, didanosine, and lamivudine) did not show an effect on rates of anemia in the women who used them.

Anemia in HIV-positive women is associated

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with a poorer prognosis – meaning anemia can cause a more rapid onset of AIDS and death. The causes of anemia in HIV-positive women can vary, and may include any of the following: reduced red blood cell production, lack of vitamin B12 or folic acid, decreases in certain proteins used in the production of red blood cells, various opportunistic infections, bone marrow tumors (red blood cells are made in the marrow), and the use of numerous medications that may suppress red blood cell production. Anemia is treatable, even in HIV-positive women. It is important to know if you are anemic, especially if you are HIV-positive. If you find out that you are anemic, make sure you discuss it with your health care provider so that they can begin working on a treatment plan with you.

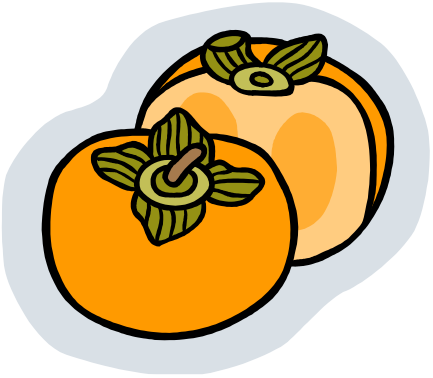
Questions you might have about anemia:

How often does the WIHS test for anemia?
Every time you come for your six-month visit, your blood-iron levels are tested. WIHS clinicians send the results of your blood tests to you and/or your provider (depending on who you decide to have your results sent to).

What are some common symptoms of anemia?
Some key symptoms you should be on the look out for are fatigue, reduced color to the face, dizziness, a fast heart rate, shortness of breath, blood in your stools, or black tarry stools.

What kinds of things can I do everyday to make my anemia better?

- Keep track of your hemoglobin levels. Ask for your test results and discuss them with your health care provider.
- Make sure you get plenty of rest at night.
- Ask for help in doing your daily chores.
- Make sure you are eating enough and well. Green leafy vegetables are particularly high in iron.
- Once you figure out a treatment



CAB CORNER

By Anna Groskin, CAB Liaison

Please join us for the October CAB luncheon!

Where: WORLD in Oakland, at 414 13th Street, 2nd floor
When: October 16th from noon to 2:00 p.m.

What is the "CAB"?

CAB stands for Community Advisory Board, and is made up of interested WIHS participants and staff. We meet three or four times a year to talk about the WIHS, to see what we're doing right and what we need to improve on, to listen to presentations of WIHS data, and to hear the stories of WIHS women.

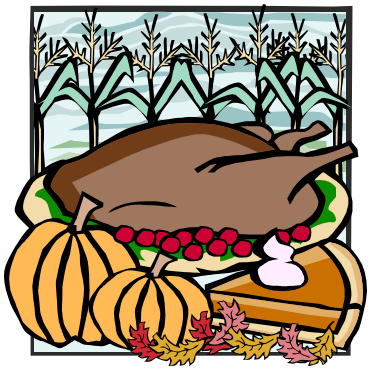
What's going to happen at the next CAB meeting?

First, we'll be eating some tasty Chinese food from the Jade Villa. We'll also be hearing from Sidney Green about her trip to the National CAB meeting in Anaheim, and from Dr. Claire Borkert of EBAC. Then we'll open up the floor, so bring things to talk about!

Please RSVP to Anna at (415) 502-6284. She can also help you out with childcare and travel expenses, so please give her a call.

Mark your calendar!

We will be celebrating and thanking all WIHS participants at a **Thanksgiving Luncheon on November 7th** at the UCSF Parnassus campus Millberry Union. Please join us for a delicious lunch, live music, door prizes, and more! Be on the look out for an invitation in the mail this month.



Barcelona Report-Back Events

By Anna Groskin, Community Advisory Board Liaison

I hope most of you had a chance to attend one of the Barcelona AIDS Conference Report-backs in Oakland, on August 15th or in San Francisco on the 22nd. They were both informative and inspiring. For those of you who did not make it, I hope you find this reportback from the Report-backs useful!

Dr. Monica Gandhi, with the WIHS, gave a clinical update on treatments that were discussed at the Conference. She spoke first about the impact of hepatitis C infection on the health of an HIV-infected person. Research has shown that HIV causes hepatitis C to progress more quickly, makes liver cancer tumors brought on by hepatitis C grow larger in less time, and causes more death overall. The good news is that using HAART and reducing your HIV viral load can slow down the progression of hepatitis C. Findings also showed that hepatitis treatments such as interferon and ribavirin work just as well to clear hepatitis C in HIV-infected people as they do in uninfected people. Monica also cited some work by UCSF researchers who reported liver transplants in HIV-infected people whose livers were damaged by hepatitis C were just as successful as those in HIV-uninfected people.

On a good note, Dr. Gandhi described studies that showed that women's immune systems responded better to antiretroviral therapy than men's. Women generally have higher CD4 counts and lower viral loads compared to men on similar therapy regimens. Regimens that included nelfinavir, in particular, were associated with positive results.

In terms of the side effects of therapy, an issue many of you may be interested in, women experience more neurologic complications, for example confusion, memory loss, difficulties concentrating, and restless sleep. Women also experience more lipodystrophy than men. Lipodystrophy is the shifting of body fat, and can happen in the arms, legs, face and belly.

Finally, Monica gave some statistics on women in HIV research, and stated something that we at the WIHS are trying to change – that women are not studied enough. Of 49 AIDS drug trials, which contained over 6,000 people, only 12% were women. Only two of these trials looked at differences in the drug responses of women and men. This is very disappointing, especially considering that women account for more and more new HIV cases each year.

Shalini Eddens from Project Inform gave the next presentation on several studies that were presented in Barcelona which she thought were relevant to women. She cited a study that reported that for HIV-infected women who are also infected with the human papilloma virus (HPV, the virus that causes cervical cancer), HAART was not effective in clearing HPV. These results suggest that HIV-positive women on HAART should be continually monitored by their provider for cervical abnormalities (what a Pap smear checks for). Shalini also reported on a few studies that looked at HIV-positive children. Two studies found that bone disorders and lipodystrophy were present in a number of children on antiretroviral

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(ARV) therapy. This research showed the importance of continually monitoring children on ARV therapy. Shalini also presented a study that showed that substance abuse during pregnancy for HIV-infected women increases the chances of the babies getting HIV. Ms. Eddens also reported on microbicide progress. A microbicide is a substance that can reduce the transmission of sexually transmitted infections (STIs) including HIV, by killing the agent (bacteria or virus) that is transmitted through sex. Similar to spermicides, which kill sperm, microbicides could be placed in the vagina in many forms: gels, creams, suppositories, films, or sponges. Microbicides are a women-controlled form of STI prevention, and could play a major role in reducing HIV infection in the future. Around 60 different microbicides are currently being tested, and the first should appear on the market in 2007. Lastly, Shalini recounted the most powerful event she attended at the Conference. It was a panel entitled "Women in Power Speaking Up!" and included the Princess of Cambodia, the Director of UNICEF, and the first ladies of Rwanda and Zambia. Shalini was moved by being a part of a group of women who were committing themselves to combating the AIDS epidemic in their own countries.

Next, Nancy Hessol, also from the WIHS, presented epidemiological findings that focused on the international impact of HIV. Of the 40 million people who are currently infected with HIV in the world, only 2% live in North America. In 2002, 5 million new infections occurred, and less than 1% of those occurred in North America. Sub-Saharan Africa accounted for 73% of the 3 million people who died of AIDS in 2001. It is estimated that 14,000 new infections occur each day, and that 95% of those are in developing countries. Studies presented at the Conference found that more new infections occur in trade centers in Africa than in rural areas, and that women already infected with an STI have an increased risk for contracting HIV. In Asia, HIV is associated with heroin trafficking routes; some populations along the routes have a 10%-80% infection rate. Despite these overwhelming numbers, Nancy reported some good things, too. In Lithuania, a population-based study of HIV found less than .0001% of the population was infected. In Western Europe, HIV infection rates have not increased after the introduction of HAART, suggesting that people are not taking part in more risky behavior despite the knowledge that effective treatment for HIV is available. A study done in New York City also showed that needle exchange programs were associated with a reduction of HIV infections in injection drug users. This is good news!

Anne Donnelly, also of Project Inform, reported back on the policy implications of the Conference. Anne observed a real change in the way people looked at the epidemic – instead of saying "Can we do this?" people were saying "How can we get this done and when can we do it?" People have recognized that we have successful prevention and treatment approaches, and that now we need to employ them in places where they are needed. We also must address the gender, economic, political, social and cultural issues that are holding up our progress in the fight against HIV/AIDS. Anne thought that this was a very political conference, and that a lot of people were angry with the US government for not taking a larger international role in the epidemic and contributing its financial share to combat HIV/AIDS. The Global Fund to Fight AIDS, Tuberculosis, and Malaria has been established to fight the diseases of poverty, and needs an estimated $10 billion a year. The world is looking to the US to pay $2.5 billion, a small sum in compari-

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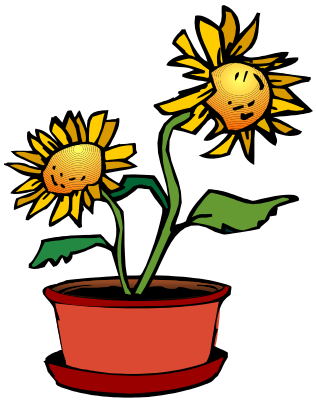
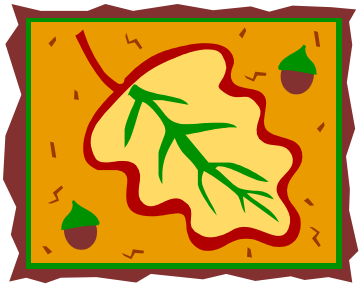
son to US military spending. Anne encouraged people to write their congress members in support of US funding for HIV and AIDS programs both here in the US and abroad. It's hard not to feel overwhelmed and powerless in the fight against HIV, but the small things that individuals and communities do can really have an impact on the greater world.

Next, Deborah McSmith and Alejandra Cano from WORLD presented their impressions of the Conference. Deborah reported that women played a key role in this year's Conference. Women speakers opened and closed the Conference and made gender issues part of all aspects of the Conference. Deborah also reported on several grassroots women's groups that were working to fight HIV/AIDS. One was a village trust in Pretoria, South Africa that looked after AIDS orphans, trained food sellers in nutrition so that they could advise child buyers, helped people who wanted to die in the comforts of their home, and provided small loans for local women who wanted to start their own businesses. In Calcutta, India, sex workers became employees of local STD clinics where they promoted condom-use, turned their clients into condom promoters, and are now recognized by the government and local police. They have recently unionized and are now working to stop child trafficking in the area.

Barcelona was the first international AIDS conference that Ms. Cano has attended. She was very excited to go and learn about current treatments and vaccines – important information she was looking forward to bringing back to the women that she works with at WORLD. She was a little disappointed by the technicality of many of the more scientific presentations, but learned about new concepts and models and is excited to share what she has learned. She too was inspired by the number of people gathered in one place to learn and talk about HIV/AIDS.

Lastly, we heard from Gloria Lockett of CalPEP (California Prevention and Education Project). Gloria thought that the Conference was well run, but did not feel at home in Barcelona as she had the year before at the 2001 AIDS Conference in Durban, South Africa. Gloria spoke about the fact that people of color, and specifically women of color, are disproportionately affected by the HIV epidemic. This is seen in our own communities here in the Bay Area. She encouraged everyone to take a look at what is going on around them, to recognize that it is not right, and to start to organize and make changes. She brought the distant Conference back to our own neighborhoods and communities – a necessary part of taking the message home and using it to enact change locally.





Gender Impacts HIV Blood Levels

Dr. Greenblatt, WIHS Principal Investigator, thought this article maybe of interest to you.

This article is from Reuters Health (09.09.02): by Jacqueline Stenson.

At similar stages of HIV infection, women tend to have lower levels of the virus in their blood than men, according to a new report. Although previous studies have yielded conflicting findings on this issue, the new report, which examined 13 earlier studies involving more than 10,500 patients, concluded that the majority of the evidence shows a clear gender effect.

Since doctors use HIV blood levels to guide them in many of their treatment decisions, the difference could be an important one. Yet there is no good evidence to suggest that giving women medication at different times than men will confer benefit, especially since both men and women appear to develop AIDS at similar rates, said study author Dr. Monica Gandhi of the University of California-San Francisco. Would women benefit from earlier treatment? Answers to that question will only come with more research involving women, Gandhi said. Most AIDS studies have been conducted with men, which is why doctors have little understanding of how gender affects HIV progression or treatment, Gandhi said.

In the article "Does Patient Sex Affect Human Immunodeficiency Virus Levels?" in the August 1 issue of Clinical Infectious Diseases (2002;35:313-322), Gandhi and colleagues reported that more than three-quarters of the studies they reviewed showed that at similar stages of infection, women had blood levels of the virus that were two-fold to six-fold lower than men. The researchers took into account various factors that could have affected the results, including patient age, race and how the virus was contracted. The precise reason for the difference is unclear, according to Gandhi. But she said she is not surprised that it exists because female sex hormones, namely estrogen, have an impact on a variety of diseases. "This study adds to the accumulating data that there are major differences between men and women in disease progression," Gandhi said.

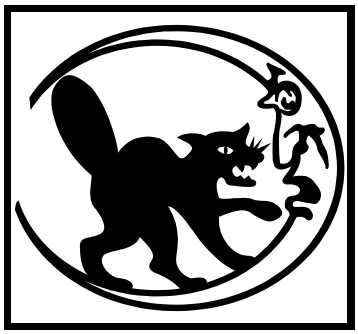
Hair changes in the Northern California WIHS

By Nancy Hessol, Project Director

We have just begun collecting a few strands of hair from some of the women in the WIHS. This is not the first time we have ventured into gathering data on hair. You may recall that in visit 12 we asked you some questions regarding your hair, eyebrows, and eye lashes. Below, we report on what we learned from the hair questionnaire we administered to the women from the San Francisco Bay area WIHS sites.

Hair changes such as diffuse hair loss, changes in hair texture, and trichomegaly (longer eyelashes) have been reported in HIV-infected patients. Our objective was to determine the prevalence of hair changes in a large group of HIV-infected women and a comparison group of HIV-uninfected women and to identify any relationship between hair changes and socio-demographic data, viral load and lymphocyte subset measurements.

In the 196 HIV-infected women and 50 HIV-uninfected women surveyed, there were no significant reports of differences in family history of hair loss, in eyebrow length, or in hair grooming practices. Older age (but not HIV status) was associated with a report of decreased hair density. HIV-infected women were more likely to report finer hair (28%) as compared to HIV-uninfected women (12%). HIV-infected women with finer hair had significantly higher viral load counts and showed a trend toward lower CD4 counts. Medication use (HAART) in the HIV-infected women was not associated with finer hair. Five HIV-infected women reported having longer eyelashes whereas no HIV-uninfected women reported this change.



Viral Resistance Study – Initial Results

By Monica Gandhi and Claudia Ponath

It is widely known that highly active antiretroviral therapy (HAART) prolongs the lives of many people living with HIV. Nevertheless, large studies have shown that about half of the patients who take HAART are not able to totally suppress their HIV viral loads. This is considered treatment failure. Researchers think that treatments might fail because a person doesn't get enough of the drug in her system. That may happen because she doesn't take her medication as prescribed all the time, because the medication is not absorbed properly in her body, or because it is cleared out of her body too fast. These can all be affected by interfering substances such as other medications, herbs, or drugs. "Adherence" is the medical term for taking ones medications as prescribed. So, a person with total adherence will take all of her prescribed doses all of the time, a person with 80% adherence takes about 8 out of 10 doses and so forth. This analysis looks at the relationship between adherence as reported by participants in the Viral Resistance Study and the concentration of HAART drugs in their blood plasma.

We were able to include data from 87 participants at 5 WIHS sites in this study. All of them came to clinic before taking their medications the day. They had their blood drawn to determine the "trough" plasma concentration for their respective HAART medications. (The "trough" is the lowest concentration a drug will fall to before the next dose is taken). Participants also reported when they took their medications in the last 24 hours, and how good their adherence had been in the last 3 days and in the last 6 months.

Here is what we found:

The trough concentrations varied a lot between participants and were often quite different from what might be expected after seeing concentrations that have been published in the medical literature. Most published numbers were from studies done in groups of mainly men or volunteers who are HIV negative, so that may be part of the reason why our numbers were different

The plasma levels we measured did not correspond very closely with the self-reports of adherence. There was some correlation between the plasma drug levels and the self-reports of adherence over the last 24 hours, but hardly any relationship was seen between plasma levels and the self-reports of adherence over the past 3 days or 6 months. This might be due to the fact that it is harder to remember doses of medication taken far back in the past, and that there are lots of other things that figure into a drug getting into the system besides adherence. Some of those other things may include differences in how people metabolize drugs, how they absorb medications, or how they clear the medications.

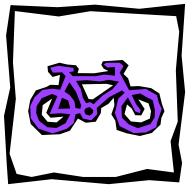
Having the correct drug levels in your body is obviously important for two reasons. First, if there is too little drug in a person's system, the HIV virus will not be stopped from replicating. If the virus keeps replicating, it's likely to develop resistance to the medication, and then the medication is not as useful anymore. Secondly, if there is too much drug in a person's system, it is more likely that she will have unpleasant or even toxic side effects.

We are now looking into other ways to meas-

ure women's exposure to medications because we don't know so many of the other reasons (besides adherence) why people have such different drug levels, and because a single drug level may not tell us very much in what a person's drug levels are long-term. One of the new ways we're looking to develop is to measure medication levels in the hair. This may tell us how much drug gets into the body over a longer period of time. Stay tuned for more results from this study, and the next time you come in for a study visit and we ask to cut some of your hair (just 10 strands), you'll know why!

WIHS BIOS

My name is Alana Kane. I graduated from San Francisco State University with a degree in Urban Studies with an emphasis on public policy. For the past two years I have worked in Seattle and San Francisco helping women from all backgrounds access services. Most recently I worked at the Women's Community Clinic, a free clinic for women in San Francisco. Presently I live in San Francisco and enjoy riding my bike, going to parks, and traveling to different countries with nice beaches. I started working with the Women's Study in June, and I usually work at the East Bay clinics. I am very excited to be a part of such an important study, and work with such great participants and a wonderful staff!

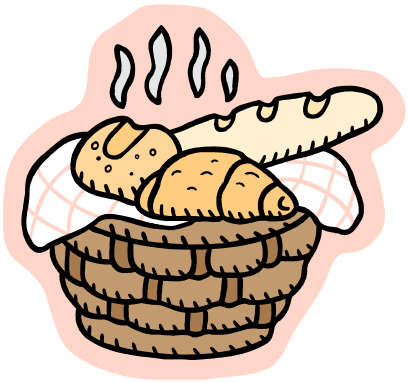


My name is Sivappiriyai Veluppillai or many of you know me as Piri. I have been hired to replace Dr. Kahn Phan for the Oral WIHS sub-study. I was born on a small island south of India, called Sri Lanka (formerly known as Ceylon). Then my family moved to Sweden, where I qualified as a dentist. Soon after graduating, I practiced general dentistry in Nottingham, UK for sometime. With that experience I wanted further training in Oral Medicine, which brought me to San Francisco, the best place for such a training, especially in the areas of my interests in research.

My life in different countries/continents is probably the reason why I like learning about traditions and history around various cultures. I don't travel as much I like to so I am visiting the historical places in the bay area. This becomes even more interesting when I take my guests from all over the world to see the Bay Area. I also enjoy hiking with my husband Kethees when I get a quiet weekend.

What is the WIHS?

The purpose of the Women's Interagency HIV Study (WIHS) is to learn about the effects of HIV infection on the physical, emotional, and social health of women. The results of this study will be used to help improve the health of women with HIV. In the San Francisco Bay area there are five hospitals that take part in WIHS:



- Alameda County Medical Center – Highland Hospital, Oakland, CA
- Alta Bates Medical Center – East Bay AIDS Center (EBAC), Berkeley, CA
- SFGH Medical Center, San Francisco, CA
- UCSF-Mt. Zion Hospital, San Francisco, CA
- UCSF-Womens's Specialty Clinic, San Francisco, CA

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Oral Wart Study
Dr. Sivappiriyai Veluppillai
415-502-4691 or Dr. Deborah
Greenspan 415-476-3080

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Dynamic Study

For women living with HIV

A study to find out if women's hormones effect viral load and the immune system.

If you are a woman with HIV infection and you

- are between 18 and 45 years of age
- do not take antiretroviral medicine now (*it is OK if you have taken these in the past*)
- have regular menstrual cycles
- do not take "the pill" or other hormones

You may be eligible for the study.

What will happen if I join?

You will be asked some questions about your menstrual period, medicines you take and your recent health. We will ask you to call us when your period begins. You will have vaginal ultrasound tests done twice during your monthly cycle to look at your ovary and blood drawn each time. Each visit will take about 30 minutes. You will be reimbursed **$15** for each ultrasound, **$10** for the first blood draw, **$20** for the second blood draw, as well as transportation costs. All information collected is confidential.

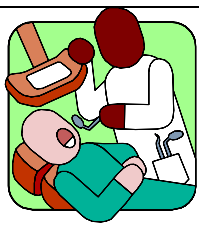
How do I join the Dynamic Study?

Call to speak with a member of our study staff. They can determine if you are eligible for the study and answer your questions.

Please call (*toll-free*) 1-866-476-5109

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
STOMATOLOGY CLINICAL CENTER

DO YOU HAVE
Oral Warts ?



Persons with oral warts who are willing to donate tissue for research purposes are wanted for a study to find out which type of papillomavirus causes oral warts.

$100.00
REIMBURSEMENT

For More Information Please Call

Dr. Deborah Greenspan 415-476-3080

or

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