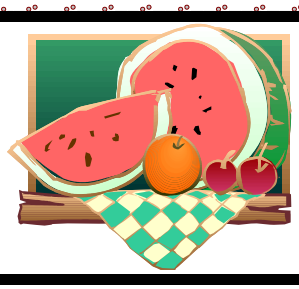
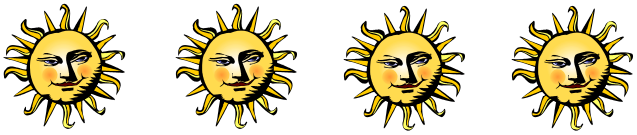
Summer 2002 Volume 6, Issue 2

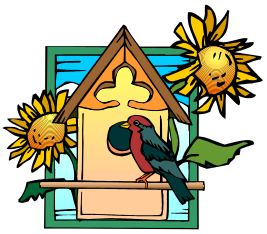
The WIHS Woman

The Connie Wofsy Women's HIV Study



SUMMER IS HERE !





75% of the New WIHS Participants have been Enrolled

By Nancy Hessol, Project Director

With only three more months of enrollment left, we are ¾ of the way towards meeting our target number of 149 new WIHS participants. We have seen over 185 women for screening visits and have successfully enrolled 110 new study participants!

It is not too late to refer women to our research study. We are specifically looking for HIV-positive women who do not have AIDS. HIV-negative women who are at risk for getting HIV may also be able to join WIHS. The new recruits can be either English or Spanish speaking and we are particularly interested in recruiting women who are *30 years old or younger*.

If you know of women who you think might qualify for enrollment, please ask them to call our *toll-free* telephone numbers at **(877)-262-WIHS** in the East Bay or **(866) 476-5109** in San Francisco and the South Bay.

Thank you for helping to refer women into this amazing study.

Our San Francisco phone number has changed! To make an appointment at our Mt. Zion or San Francisco General Hospital clinic or speak with the WIHS field staff, please call **415-353-9797**.

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This publication is made possible by the National Institute of Health, Grant # U01 AI 34989.

New Staff– Let's Welcome Anna!!

Hello! I'm Anna, and I'll be the new WIHS site coordinator when Paula leaves us this summer for medical school. That means I'll be interviewing some of you at some of your future visits, and I'll be organizing CAB meetings and events. If you have any ideas or suggestions for CAB events, please let me know! (You can reach me at 415-502-6284.) Now more about me: I'm an East Coaster, recently transplanted from Baltimore, and I absolutely love the Bay Area! It's an amazingly diverse and alive place to be, and the people I have met since I moved here make it even better. I am really looking forward to meeting more of you, and to learning and growing with you as we all try to increase awareness and knowledge about women living with HIV. See you soon!

CAB CORNER

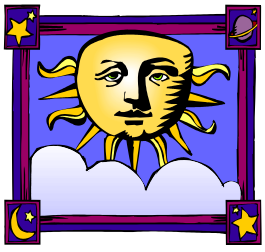
By Anna Groskin
CAB Liaison

April CAB meeting: The Spring CAB meeting was held on April 20th at the Mount Zion Hospital in San Francisco. Those of you who attended the meeting learned that Paula is leaving for Medical school this summer, and that I (Anna) am taking over as CAB liaison. You can read more about me in the WIHS BIOS section! First, I want to thank everyone who gave up part of their weekend to come to the meeting and talk about WIHS! Hopefully the good discussion and yummy sandwiches and cookies made it worth your time.

A few people also mentioned that the new test results format for CD4 count and viral load is confusing. We'll work on that and try to incorporate suggestions that were made at the meeting. (If you're having trouble reading the results, please let me know! You can call me at 415-502-6284 or email me at annag@itsa.ucsf.edu)

We also spent some time talking about the WIHS Mentoring Program, in which new women in the study are paired up with women who have been in the study for several years. This way, new WIHS participants can learn from other women in the study what their experience has been and what they can expect at their own WIHS visits. We're hoping that some good friendships will develop out of this, too! If you've been in the study for a long time, and you're interested in becoming a mentor to someone who has just joined, *OR*, if you're new to WIHS and would like to have a mentor, please let me know. (Give me a call at 415-502-6284.)

The last part of the meeting was very educational. Two doctors in the study, Dr. Ruth Greenblatt and Dr. Phyllis Tien, gave presentations on HIV and women's health. Ruth spoke about female hormones and their effects on HIV in the body, and how the virus acts differently in women than it does in men. Phyllis talked about HIV and the effects of the virus and medications on body fat. We hope to have more about the presentations published in upcoming newsletters, so stay tuned!



Our next CAB meeting will take place in September in the East Bay. It will be a mid-week lunch meeting at the Jade Villa. As soon

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as a date and time are set, you'll be hearing more about it!

NCAB Notes:

The NCAB is a national version of our WIHS CAB. The NCAB is responsible for providing input on the national WIHS agenda. There are several NCAB members from each WIHS site around the country. NCAB members bring the concerns of their local CAB and participants to the larger national audience, as well as bring information from the national WIHS to their own local site. NCAB representatives participate in monthly conference calls with other NCAB members and discuss WIHS updates. NCAB members also attend national WIHS meetings every three months in cities around the country. We are currently looking for additional NCAB representatives, so if this sounds interesting to you, please get in touch: 415-502-6284.

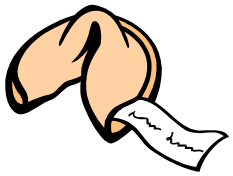
Sidney Green, one of our NCAB representatives, traveled to the national WIHS meeting this spring in Washington, DC. There, she met with other NCAB members for a one-day meeting about WIHS, and also attended a conference where she learned about the ethics of clinical research. She has provided us with a thoughtful reflection on her flight across the country:

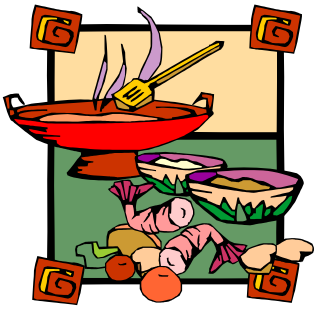
"Flying seems to wake up the sensitive in me." -- Sidney Green

Flying to Washington, DC for the WIHS National Community Advisory Board meeting in May, looking out at the earth below and the clouds, snow-peaked mountains, endless trails. There are different hues of green and brown, blocks of colors, squares, oblong shapes, even triangles. The clouds are right outside the window and they look like cotton all clumped together, big pillows.

Bodies of water and rivers look like lines drawn, straight and wide, and they go on forever. I could take all the pictures in my camera right now of the sights outside my window – breathtakingly beautiful.

And the earth speaks to me: "How grand I am!" it says, "Majestic, free and we belong to God." Flying seems to wake up the sensitive in me, at least the me that appreciates life and being whole.





SELECTED FINDINGS FROM THE WIHS

By Nancy Hessol,MSPH
Project Director

The Women's Interagency HIV Study (WIHS), a multicenter longitudinal study, was established in 1993 to investigate the impact of HIV infection in women. This includes monitoring the changes in the natural history of HIV and associated conditions that are occurring as a result of treatment advances and longer survival. The WIHS is located at six sites in the United States and includes participants from New York City, Washington DC area, Chicago, Southern California, Northern California, and Hawaii. The study is funded through the National Institutes of Health and is the largest prospective study of women and HIV in the United States. Below is a summary of some of the findings from the WIHS.

Participant recruitment: Women were enrolled in the study beginning in 1994 and are seen at six-month intervals for follow-up evaluations. A total of 2,641 women (2066 HIV positive and 575 negative) were enrolled between October 1994 and November 1995. More than half of the women were living below the federally defined poverty level. At entry, the women ranged in age from 16 to 73 years; approximately one-quarter self-identified as Latina or Hispanic, over one-half as African American, and less than 20% as white. Self-reported HIV exposure risk included injection drug use by 34% of the HIV-infected women and 28% of the HIV-uninfected women, heterosexual contact (42% vs. 26%), transfusion risk (4% vs. 3%), and no identified risk (20% vs. 43%). Demographic and HIV exposure risk characteristics of the HIV-infected women were comparable with characteristics of nationally reported AIDS cases in U.S. women.

Participant retention: In any prospective study (such as the WIHS), participants lost during follow-up can potentially bias the results due to differences between those who are lost and those who continue to participate. Therefore, having good participant retention is crucial for the success of a prospective study. For the first 10 study visits that occurred during a five-year period, the retention rate of WIHS participants was approximately 81%. Factors associated with not returning for follow-up visits among all women were: younger age, non-African American race, unstable housing, HIV-uninfected serostatus, no past experience in studies of HIV/AIDS, and site of enrollment. Among only the HIV-infected women, white race, no past experience in studies of HIV/AIDS, site of enrollment, and no reported use of combination or HAART HIV therapy at last visit were associated with not returning for follow-up visits. Among only the HIV-uninfected study participants, only site of enrollment was significantly associated with study retention. These results show that women with and at risk for HIV infection, especially African American women, can be successfully recruited and retained in prospective studies.

HIV therapy: Even as HAART (highly active antiretroviral therapy) use has prolonged life and significantly changed the treatment of HIV infection in developed countries, there has been concern that women, minorities, and other groups of disadvantaged individuals are less likely to receive these therapies. WIHS investigators examined the longitudinal trends in ART utilization by analyzing the data be-

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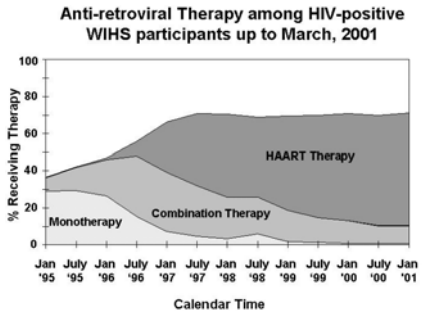
tween 4/1/96 and 9/30/98. Use of antiretroviral monotherapy (single drug treatment) declined substantially while use of HAART increased to 45% by the end of July 1998.

The accompanying **figure (below)** gives an update of these trends using data through 3/31/01, demonstrating that the overall number of women on therapy has remained stable and that most of the women on antiretroviral therapy are on HAART.



The WIHS has demonstrated that those individuals initiating HAART were more likely to have advanced HIV disease than their counterparts not receiving HAART. Individuals initiating HAART had lower CD4+ cell counts and higher HIV RNA levels than those who did not initiate therapy. Individuals who initiated HAART more recently had higher CD4+ cell counts and an increased proportion with HIV RNA levels ≤ 4,000 copies/ml than those who initiated therapy at earlier periods. For a given CD4+ cell count of 500 cells/mm^3 and HIV RNA level of 5,000 copies/ml, the probability of HAART initiation increased steadily from 0.5% in 10/95 – 3/96 to 16.9% in 10/97 – 3/98.

The WIHS found that women with college level education, private health insurance, and those with prior experience participating in clinical trials were more likely to report HAART use, while African American women and women reporting a history of injection drug use, or recent drug or alcohol use were less likely to report HAART use. This analysis supports the need for special outreach to women with less access to these treatments and appropriate medical education to providers about the vulnerability of disadvantaged groups of women receiving less effective HIV therapy. The WIHS also demonstrated that pregnant women meeting published criteria for HAART use were only slightly less likely to report using HAART as compared to non-pregnant women.

Adherence to HIV medications: The WIHS has strived to better understand the patterns and predictors of adherence to HAART in women with HIV. An analysis of women with CD4+ cell counts less than 200 cells/mm^3 showed that 77% reported adherence with prescription greater than 75% of the time, 14% of women reported taking their medications some of the time (between 25% and 75% of the time), while 8% of women reported taking their ART rarely or never (<25% of the time). The most common reasons for non-adherence included forgetting to take medication and unpleasant side effects. Depressive symptoms were common and were associated with decreased adherence to ART.

Another analysis of WIHS data described factors related to adherence and determined the relationships between adherence and sexual risk behavior. Adherence data were collected from 766 HIV positive women participating in the WIHS between 10/01/98 and 3/31/99. Seventy-six percent of the population reported adherence levels at or above 95%. In multivariate analyses, greater adherence was associated with being older, with not being an active drug user, with having an undetectable viral load, and with higher quality of life. Among sexually active women, lower adherence was associated with a lower condom consistency

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after controlling for age, drug use, quality of life and HIV RNA viral load. This suggests that women who were less likely to adhere to their HIV therapy are also less likely to report consistent condom use.

Skin disease: Previous studies have shown that skin disease is very common among HIV infected individuals; in some studies up to 90% of the patients had some skin problem. However, most of these studies have focused in men. By looking at the WIHS cohort, we were able to study whether skin disease was also increased among HIV-infected women. We had the advantage of having a comparison group of HIV-uninfected women; many of the prior studies did not have comparison or control groups. A total of 2018 HIV-infected women and 557 HIV-uninfected women were included in this analysis. We found that skin disease was very common in HIV-infected women and was seen more frequently than in the HIV-uninfected women (63% vs. 44% respectively). A number of factors were linked with skin disease in the HIV-infected women: African American race, injection drug use, CD4 count less that 50, and high viral loads. The most common skin diagnoses in the HIV-infected women were: acne (8.5%), folliculitis (inflammation of a follicle, usually hair) (8%), xerosis (dry skin) (7%), onychomycosis (nail fungus) (7%), eczema (crusty or scaly skin) (4%), and cutaneous warts (3%).

Human Papilloma Virus (HPV): Infection with Human Papilloma Virus (HPV) can cause the development of genital warts and cancer. We tested the WIHS baseline visit samples of vaginal fluid for HPV genetic material (DNA). HPV DNA was detected in 30% of HIV-negative women, as compared with 63% of HIV-positive women. Among the HIV-positive women, detection of HPV DNA was associated with both lower CD4+ count and higher HIV RNA copies. At CD4+ counts above 200 cells/mm^3, a higher prevalence of HPV DNA was detected among women with an HIV RNA > 20,000 copies/ml. At CD4+ levels below 200 cells/mm^3, HIV RNA had no effect on HPV DNA prevalence. In addition, infection with multiple HPV types was common and was strongly associated with HIV infection and CD4+ cell level. Selected oncogenic HPV types were more significantly associated with CD4+ levels than others. HPV 16, the type most commonly associated with cervical cancer, was not strongly associated with CD4+ cell count, and neither were the HPV 16-related types (HPV 31 and 35).

Hepatitis C Virus (HCV): The Chicago WIHS investigators examined if high-risk sexual behavior was independently associated with HCV infection in the women from the Chicago WIHS. Women who had (n=243) or were at risk for HIV infection (n=53) were tested for HCV antibodies. Of 296 women, 42% were HCV antibody positive. Prevalence for HCV antibody was 90% in women who injected drugs, compared with 12% in non-injectors. Anti-HCV prevalence was higher in women with HIV infection 44%, versus women without HIV infection 30%, although this difference was not significant. A multivariate model revealed significant associations between HCV infection and injection drug use, prior gonorrhea, and sex with a male injection drug user.

Dental care: We conducted a survey of HIV-infected women enrolled in the northern California and Chicago WIHS sites to identify predictors of dental care use. We found 43% had not seen a dentist and 53% reported no dental cleaning in more than a year (although 67% had dental insurance coverage, mainly state Medicaid). Among nonusers of dental care, 78% reported that they wanted care but failed

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to get it. Barriers to receipt of dental care included fear of and discomfort with dentists, not getting around to making an appointment, and not knowing which dentist to visit. Multivariate analysis showed that lack of past-year dental care was associated mainly with unemployment, a perception of poor oral health, and an edentulous state.

Domestic violence and child abuse: Several WIHS investigators have examined factors that are related to a history domestic physical violence and sexual abuse. Sixty-six percent of HIV-positive women reported ever having experienced domestic violence, a rate that did not differ from the HIV-negative group. Childhood sexual abuse rates were slightly higher in the HIV-positive cohort than in the HIV-negative cohort (31% vs. 27%). After adjusting for HIV serostatus, age, race/ethnicity, and income, childhood sexual abuse was associated with having engaged in sexual activities for drugs, money or shelter, having 10 or more lifetime sexual partners, and a lifetime history of drug use.

Mammography: We investigated whether women in the WIHS were more likely to have reported having a breast mammogram than women in the general population and whether HIV-positive WIHS women (n=2059) were more likely than HIV-negative women (n=569) to have reported having a mammogram. We found that among women 40 years old or younger, fewer WIHS women reported screening than in the general U.S. population (67% HIV-positive, 62% HIV-negative, 79% general population). HIV-positive women reported more mammography screening than HIV-negative women, possibly because of greater opportunity to interact with the health care system.

Can I join the WIHS? The WIHS is now recruiting over 1,000 women including HIV-negative women, AIDS-free HIV-positive women who have never used HAART and AIDS-free HIV-positive women using HAART. Emphasis will be given to recruitment of younger participants. All six WIHS sites are recruiting for new participants.

If you are interested in joining the WIHS study, please contact one of our sites below.

Brooklyn, New York: Susan Holman (718) 270-1819 sholman@downstate.edu

Bronx, New York: Esther Robison (718) 654-7099 erobi220@aol.com

Washington, DC: Melanie Bacon (202) 784-2376 baconm1@gunet.georgetown.edu

Chicago, Illinois: Kathleen Weber (312) 572-4546 weberkathleen@ameritech.net

San Francisco, California: Jane Pannell (866) 476-5109 Pannell@itsa.ucsf.edu

Los Angeles, California: Yvonne Barranday (323) 343-8317 barranda@usc.edu

If you would like to know more about the WIHS, please visit our website at: https://statepiaps.jhsph.edu/wihs/.

Measuring Body Fat Changes in HIV

By Phyllis Tien, MD, MS

Body fat changes have been increasingly reported in men and women with HIV and are often associated with the use of antiretroviral therapy. Body fat changes seem to include loss of fat in certain areas of the body and a gain in fat in other parts of the body. Body fat changes however, also occur, as we get older regardless of whether or not we have HIV. In order to better understand these fat changes, measurements such as the skinfold measurements and circumference measurements are taken at each visit.

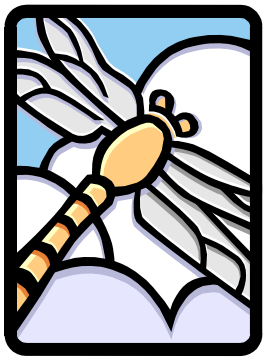
Our body includes a layer of fat that is directly under the skin that is called "subcutaneous" fat, when we perform the skin-fold measurement or pinching of your skin, we are getting an idea about the amount of fat under the skin. Our body also includes a different type of fat that surrounds our stomach and intestine that is called "visceral fat". An increase in this type of fat has been associated with diabetes and heart disease. When we wrap the tape measure around your waist to measure your waist circumference, we are getting an idea of the amount of fat that is under the skin around the waist, but also the amount of fat that is around your stomach and intestines. Of course, we are also wrapping the tape measure around other parts of your body to get an idea of the amount of fat in these areas too.

Other measures that we are now collecting to understand these body fat changes is your own feelings about body fat changes. We now ask you if you think there has been an increase or decrease of fat since your last visit in different parts of your body.

Beginning at visit 17, we will be using a more sophisticated measurement technique to give us a better idea of the amount of fat in your legs, arms, and trunk. We will be performing a DXA scan of the body. DXA stands for "dual energy x-ray absorptiometry" and is a low dose X-ray scan. Some of you may have already had DXA scans performed if you participated in the "Metabolic Toxicity" study. We will also have the clinicians do a quick exam of various regions of your body to see if it looks like there is fat loss or fat gain.

Because measuring body fat changes in different parts of the body is difficult to do, we are using different methods to measure these changes. All these measurements will allow us to understand what is causing these body fat changes – whether it is due to using highly active antiretroviral therapy, or due to using a particular antiretroviral drug, or if it is related to something else other than the antiretroviral drugs. Understanding these changes are also important, because some of these fat changes may be putting us at a higher risk for getting diabetes and heart disease.

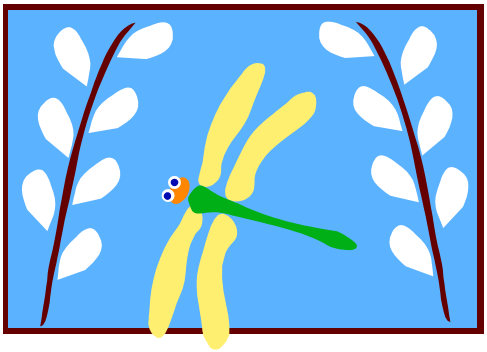
California AIDS Lifecycle Ride



This is the official cycling event of the San Francisco AIDS Foundation and the L.A. Gay & Lesbian Center. It is the only long distance cycling AIDS fundraiser in California produced by the organizations that will benefit from the funds raised by the event.

This event took place on May 13 – 19, 2002. Cyclists traveled 600 miles through beautiful California from San Francisco to Los Angeles. Participants camped along the way and were provided with food, tents, hot showers, medical services, rest stops, and just about everything one could possibly need.

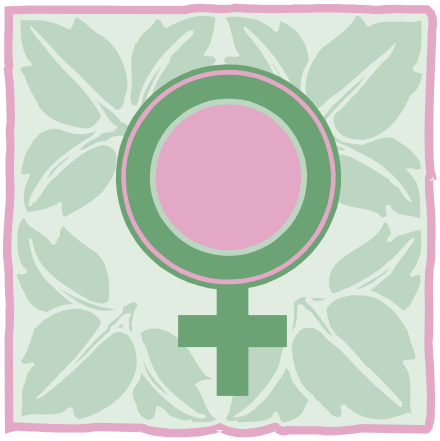
Our SF WIHS project Director, Nancy Hessol, an avid bicyclist, volunteered her time to assist the bicyclists with flat tires, adjustments, etc. She is shown below taking a break from her duties:

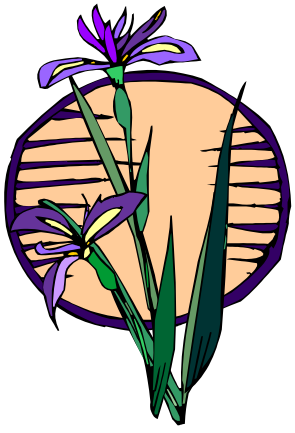


What is WIHS?

The purpose of 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 four 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





JOIN THE WIHS!

What is the WIHS?

It is the largest study of HIV among women in the United States. The study is being conducted by researchers at the University of California at San Francisco (UCSF) and includes women who are living with HIV and women who do not have HIV.

What will happen if I join?

You will have a study visit twice a year including an interview, physical exam and laboratory tests. You will receive ***$50*** for each study visit, your travel will be compensated, and food and thank-you gifts will be available. All information collected is confidential.

Who can join?

Approximately 150 Bay Area women will be enrolled. Participants will include women of all backgrounds to represent the diversity that the Bay Area is known for.

How do I join WIHS?

Call our toll free telephone number and speak with a member of the WIHS staff. They can determine if you are eligible for the study and answer your questions.

Call (toll-free) **1-866-476-5109**

While there's still room!!!

This is a **UCSF** research project.

Join us for the 14th Annual International AIDS Conference Report Back!

Want to hear about new scientific breakthroughs, new ideas, and new understandings in the global fight against AIDS? Find out what more than 10,000 scientists, activists, policymakers and people living with HIV talked about in Barcelona, Spain!

Presentations will be held in two convenient locations:

In the East bay
When: Thursday, August 15, 2002
2:30-5:30 p.m.
Where: Alameda County Department of Health
1000 Broadway
Oakland, CA

In San Francisco
When: Thursday, August 22, 2002
5:30-8:30 p.m.
Where: San Francisco AIDS Foundation
995 Market St, 2nd floor
San Francisco, CA

For more information please contact: Anna at 415-502-6284