

The WIHS Woman



The Connie Wofsy Women’s HIV Study

Changes for Visit 31

By Claudia Ponath, Field Manager

This summer we had happy news: Heneliaka gave birth to a baby girl – another WIHS baby, 6 pounds 8 ounces. Both mom and baby are healthy and well, and Heneliaka will be on maternity leave until December. While she is out, I’ll be coordinating some of the sub-studies.

What’s new?

There is no major news to report for this visit. We will ask you a few short questions about nicotine dependence at this visit and the next, and there are the usual minor changes to the questionnaires. Other than that, it is business as usual.

What’s back?

The questions about complementary and alternative medications have been added back to the medication questionnaire. There is also a questionnaire about your educational experience that will be asked only of those participants who have not answered those questions

at a previous visit.

What’s continuing?

It is extremely helpful if you can **bring either your medications in their bottles, your medication, or a list of the medications you have taken since your last visit to your study visit. For those of you on HIV meds, we’ll also need the dose information.** Those of you who have been bringing this information can attest to the fact that it makes the interview go much more quickly and smoothly. So, if you have been bringing this information, thank you very much! Please continue to bring it. If you have not been bringing it, please strongly consider bringing it in for your next visit. Both you and your interviewer will be glad you did.

Please **fast (don’t eat or drink anything, except water, for at least 8 hours)** before your WIHS visit 31. This is crucial for getting an accurate test result for your cholesterol, lipids, and glucose. These blood tests are important markers for diseases that affect women, including diabetes, heart disease, and high blood pressure.

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So please try to fast 8 hours before your next core WIHS visit.

For those of you taking HIV medications, we will continue to ask you to give us a small **hair sample** (about 20 strands). The hair samples you have given us are being tested for levels of HIV medications. The results are very interesting and we hope some day to be able to use the levels of HIV medication in hair to adjust medication dosage accordingly. There is also an article in this newsletter by Dr. Gandhi on the results of the hair study.

Last visit, we started a new component of the WIHS visit, a neuro-cognitive interview. You may remember being told about this when you went over the consent form with your interviewer. It consists of a number of mental tasks. The tasks are administered verbally, using paper and pencil, and using a pegboard. You will be asked to read words, recognize shapes, solve problems, memorize things and engage in other mental tasks. Some of the tasks will be familiar from previous WIHS visits and some will be new. The purpose of this new component is to look at cognition – that is mental processes such as memory and learning. This new component takes about an hour, and we reimburse you an additional \$20 for your time and effort to complete it. We will ask about one quarter of the WIHS participants to complete this additional component at each visit, so that over the course of four visits all participants will have completed it. We have had a good response so far so thanks to all of you who have already completed this assessment.

The **PK study** started back up again last visit. Women who are on Isentress (Raltegravir) are eligible to participate, if they haven't already. The PK study looks at the different factors that influence how HIV drugs are metabolized in

women. For this study, eligible participants bring their medication to the hospital, then have their blood drawn once before they take their dose and then 11 times after they take their dose over the course of 12 hours. It takes place at the main UC hospital on Parnassus. The reimbursement is \$150.

The **Metabolic Study** started up again during visit 29 and will continue for visit 31. Your interviewer can determine if you are eligible and refer you to Claudia or Heneliaka. For the metabolic study, you come to Moffitt hospital on Parnassus for a glucose tolerance test and a bone density scan. The visit is about three hours long and you will be reimbursed \$50.

The **Cardiovascular Study** also started during visit 29 and will continue during visit 31. Eligible women will be seen for ultrasounds at the VA medical center in San Francisco. Your interviewer can tell you if you are eligible and put you in touch with Claudia or Heneliaka. The visit takes about an hour, consists of an ultrasound of the right side of your neck and reimburses \$40.

The **Pulmonary Study** started up last visit and will continue during visit 31. It consists of a blood draw, interview, a lung function test and a chest CT scan. All procedures take place at the UCSF Mount Zion campus. The study visit takes about 3 hours, and you will be reimbursed \$60. Jane or Heneliaka are coordinating this study and if you are eligible your WIHS study interviewer will refer you to her. Please be patient though – we have many more women who are eligible than we have slots available to schedule.

Abbreviated visits will continue for women who are unable to have a full core visit.

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For women undergoing colposcopy, we will continue to ask if you want to **donate tissue** to the AIDS and Cancer Specimen Resource (ACSR). Women do not need to have cancer or HIV to enroll in this sub-study. Women who are eligible and wish to donate tissue to the bank will have an extra biopsy, oral rinse, and one tube of blood collected for this study at the time of their colposcopy examination. We continue to have a great response from you to this protocol and we thank you for your help!

What's gone?

The examination of your feet and ankle reflexes is taking a break this visit, but will come back again next visit.

In conclusion

Thank you from everybody on the WIHS team for being a part of this important study and for helping it succeed. We all look forward to seeing you at your next WIHS visit or at one of the sub-study visits or at a CAB meeting. We will continue to do our best to make study visits as pleasant an experience as possible for you and to offer you enrollment in our exciting sub-studies.



“Hair” are the results of your hair!

Monica Gandhi MD, MPH

For those of you in the WIHS study who have been on HIV medications in the past five years, we have asked to collect from you a small hair sample from the back of your head. Thank you so much for all of your donations! The purpose of this hair collection was to measure the amount of HIV medications (antiretrovirals) in your hair in order to learn how much medicine each person gets into their system.

The reason we are looking at how much HIV medication gets into your system is because some people may be getting too much drug (causing side effects) or some people may be getting too little drug (causing treatment failure) despite being on the same dose! We know that some people fail HIV medications (meaning, their HIV viral load does not go down to an “undetectable” level in their bloodstream) because they have a hard time taking some of the complicated HIV regimens in the right way. However, other patients may fail therapy because they are absorbing or breaking down the medications differently from other people. This means that not everyone gets the same effect from the same HIV medication dose because each person is different – some people absorb a lot of the drug, some people absorb a little bit, some people break down the medication very quickly, some people break down the medication very slowly, etc. We have been measuring the amount of HIV medication each of you actually gets in your bloodstream by measuring the levels of these antiretrovirals in your hair.

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We recently published a paper that summarized the first batch of results from our hair testing. The paper was called “Protease Inhibitor Levels in Hair Samples Strongly Predict Virologic Responses to HIV Treatment”. This paper looked at women starting a new protease inhibitor (PI)-based regimen with either lopinavir/ritonavir (*Kaletra*®) or atazanavir (*Reyataz*®). We looked at 70 women starting *Kaletra*-based regimens and 154 women starting *Reyataz*-based regimens. We measured the level of lopinavir or atazanavir in hair samples from these WIHS women at the WIHS visit following the initiation of the new regimen.

We found that the level of the protease inhibitor in hair at the WIHS visit following treatment initiation was the strongest predictor of having an undetectable viral load. We also looked at the association between getting to an undetectable viral load after starting therapy and the pre-treatment or “starting” CD4 count, starting HIV viral load, how much drug the woman actually reported taking, and the amount of experience she has had in the past with protease inhibitors or antiretrovirals. None of those other factors was as important as the amount of HIV medication in hair in terms of predicting success on therapy.

What does this mean? This means that some-day clinics may use a routine test to measure the amount of your HIV medication in hair. That test would help us figure out whether to keep your dose as is, increase your dose or reduce your dose of medication. We still have a lot of work to do before hair testing is routinely done but in the meantime, we really thank you for contributing your hair to our study.

Have a hair-raising Halloween!



A Word on Thank You Gifts

As has been the case at prior visits, study participants who come to their study appointment within 15 minutes of their scheduled time will receive a \$5 Safeway card. Study participants who complete their study visit will receive the little brown bags with gift items. All of these items are meant as a thank you gift to study participants for completing their visit and will be given at the end of the visit. Sometimes visits have to be done in two parts; in those cases, the Safeway card and the gift bag will be given when you return to complete your study visit.

Thank you so much for participating!



New Studies Coming!

In collaboration with other women's health researchers at UCSF, we are starting several new studies which look at the immune cells in the cervix (the opening into the uterus, located at the top of the vagina) and in the lining of the uterus. Researchers have not paid much attention to these cells before, and these studies are an exciting opportunity for us to learn more about how they may affect HIV transmission and progression in women, but we need your help to do that.

Some of the studies will look at how certain birth control methods (N-9 gel, DepoProvera shots, and the Mirena IUD) affect these immune cells.

We are looking for *HIV-negative women up to age 45* who have regular periods and are in one of three categories:

- (1) You are about to start using the Mirena IUD.
- (2) You are about taking DepoProvera shots.
- (3) You are willing to use N-9 birth control gel for two-three weeks.

All women who participate will have several visits, including two biopsies of the lining of the uterus. These studies pay up to \$240 in cash, plus transportation and a \$25 gift card at completion.

We also want to see how menopause affects these cells. This study is open to *HIV-negative women and positive women not taking anti-retroviral medicines* in two categories:

- (1) You are younger than 40, with regular periods.
- (2) You are older than 50, with no periods for at least a year.

All women who participate will have blood draws and cervical biopsies. Reimbursement is up to \$70 in cash, plus transportation.

All of these studies are open both to WIHS women and to women who are not in WIHS. So, if you have any friends or relatives who might be interested, I'd love to hear from them! Please call Jane at 415-353-9767 or toll free: 866-476-5109



CAB CORNER



The Summer CAB meeting

By Karen Kavanagh

Hello Ladies, I have the pleasure of reporting on our last CAB meeting this past July because our CAB Liaison, Heneliaka "Ladybug", is on maternity leave. Congratulations to her and her family! We all wish her the best and look forward to her return.

The last CAB meeting was held in Oakland at Highland Hospital. We received a very informative presentation from Dr. Victor Valcour who spoke about memory loss. He reviewed his current research at UCSF regarding memory loss in aging HIV patients. If you are HIV+ and over 60 years of age, you may qualify for his study. Everyone came to the meeting with insightful questions and concerns for Dr. Valcour. He discussed how HIV can affect cognition, memory loss, concentration, mental slowing, and comprehension. In addition he provided us a list of "What To Do" that we all can follow; and if you believe your memory and thinking is a problem talk to your doctor. So what can you do? 1) Take all of you medicines as directed. Don't miss doses. 2) Don't use illicit drugs that can make thinking worse. 3) Be active mentally and physically. 4) Don't smoke. 5) Maintain good body weight and pay attention to high blood pressure, diabetes, high cholesterol. 6) Treat depression when present. 7) And finally, talk to your doctor.

During this interactive discussion, we all enjoyed a delicious lunch meal from Mission Bay Catering. Yummy sandwiches, healthy salads, fresh fruit and tasty cookies! Thank you all for participating in this well attended CAB meeting. See you next time!

Diet & Nutrition

Fruit & Veggies



Top 10 Reasons to Eat MORE Fruits & Vegetables

1. **Color & Texture.** Fruits and veggies add color, texture and *appeal* to your plate.
2. **Convenience.** Nutritious in any form - fresh, frozen, canned, dried and 100% juice, so they're ready when you are!
3. **Fiber.** Fruits and veggies provide fiber that helps fill you up and keeps your digestive system happy.
4. **Low in Calories.** Fruits and veggies are naturally low in calories.
5. **May Reduce Disease Risk.** Eating plenty of fruits and veggies may help reduce the risk of many diseases, including heart disease, high blood pressure, and some cancers.
6. **Vitamins & Minerals.** Fruits and veggies are rich in vitamins and minerals that help you feel healthy and energized.
7. **Variety.** Fruits and veggies are available in an almost infinite variety and there's always something new to try!
8. **Quick, Natural Snack.** Fruits and veggies are nature's treat and easy to grab for a snack.
9. **Fun to Eat!** Some crunch, some squirt, some you peel and some you don't, and some grow right in your own backyard!
10. **Taste Great!**



<http://www.fruitsandveggiesmorematters.org>

Got Depo?



You can help researchers at UCSF with an important study about how Depo-Provera, the birth control shot, affects immune cells in the uterus and cervix.

You may be eligible if:

- You are HIV negative
- You are 18-44 years old
- You have regular menstrual cycles
- You are about to start using Depo-Provera

Participants will have 6 visits at Mt. Zion Hospital and will be reimbursed up to \$240 in cash plus gift cards and transportation reimbursement.

Please call Jane at 415-353-9767 or toll free 866-476-5109



Female Volunteers Needed!



You can help UCSF researchers learn about how menopause affects immune cells in the cervix.

You may be eligible if:

- You are generally healthy (HIV negative or positive)
- You are age 18-40 and have regular periods

OR

- You are at least 50 and have not had a period for at least a year

Study participants will have 2 or 3 visits at Mount Zion and will be reimbursed up to \$70, plus transportation.

Please call Jane for more information: 415-353-9767 or toll free 1-866-476-5109

Thinking about Mirena?



You can help UCSF researchers learn how the Mirena IUD affects immune cells in the uterus & cervix.

You may be eligible if:

- ✿ You are 18-44 years old*
- ✿ You are HIV negative and generally healthy*
- ✿ You have regular periods*
- ✿ You & your doctor have decided that Mirena is right for you*

Participants will have six visits at Mount Zion Hospital and will be reimbursed up to \$240 cash plus gift cards and transportation costs.

*Please call Jane at 415-353-9767
or toll free at 866-476-5109.*

CONTRACEPTIVE GEL STUDY



You can help us learn about how birth control gels affect immune cells in your uterus and cervix.

You may be eligible if you:

- ✿ are 18 to 44 years old and have regular menstrual periods*
- ✿ are HIV negative and generally healthy*
- ✿ are not using an IUD, contraceptive gels or birth control pills*
- ✿ are willing to use two different vaginal gels, each for about 10-14 days*

Study participants will:

- ✿ be helping in the fight against HIV in women!*
- ✿ come to six visits at Mt. Zion Hospital (part of UCSF)*
- ✿ be reimbursed up to \$240 in cash, plus transportation and a \$25 gift card*

*If you are interested, please call Jane
at 415-353-9767 or toll free at 866-476-5109*