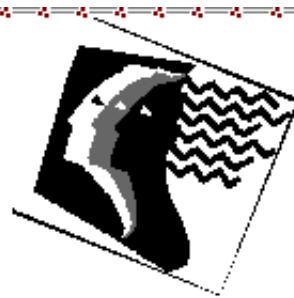


The WIHS Woman

The Connie Wofsy Women's HIV Study



Sperm Washing For Men Who Want To Be Dads

by Moher Downing

As the health of HIV+ men on highly active antiretroviral therapies (HAART) has improved and more couples have become motivated to bear their own children, more people are seeking information and assistance to conceive in the safest manner possible. This article discusses one of the more controversial assisted reproductive technologies

How & Where is Sperm Made?

- Sperm is present in semen.
- Four organs produce semen. They are the testes, epididymis, seminal vesicles and prostate.
- Semen contains seminal fluid, sperm cells and white blood cells, any of which could

contain or transmit HIV.

What is Sperm Washing?

Sperm washing is a procedure for separating sperm from seminal fluid. Sperm washing has been used for years in fertility clinics and sperm banks to help men boost the potency of their sperm. However, the use of sperm washing to reduce or eliminate transmission of infections like HIV to a mother or baby has only evolved over the last decade.

How is it Done?

Most labs or research projects use some form of the following method:

- First the semen and a more dense solution are mixed together.
- Next the sample is placed in a medical centrifuge (spinner) to separate the sperm from its surroundings. Because of their different densities, the sperm, the seminal fluid and other cells separate into three distinct layers.
- Next a salt solution causes the most active sperm to swim to the surface, where they

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are harvested.

- That sperm is washed twice in a chemical solution to remove more fluid and to kill any HIV or other viruses that may be clinging to the outside of the sperm cells.
- The sample is divided. One half is frozen and the other half is used for testing.
- All three parts of the sample (sperm, seminal fluid and other cells) are tested by PCR to detect infectious diseases, including HIV.
- If any one of the three parts contain detectable amounts of virus, the whole sample is discarded. A new semen sample must be collected and the entire process begun again.
- If tests cannot find HIV or other diseases in the sample, the frozen half of the specimen is retrieved.
- The sperm is then combined with an artificial semen solution and is ready to be used for fertilization.

How is the Egg Fertilized?

An egg can be fertilized by several different techniques, including:

- Artificial intrauterine insemination in which the sperm is inserted into the woman's uterus.
- *In vitro* fertilization in which the egg is fertilized in the laboratory and then put in the woman's uterus. (More costly, but potentially safer.)
- Intracytoplasmic Sperm Injection (ICSI), where just one sperm is injected into the egg.

Is Sperm Washing Available?

With infectious diseases (hepatitis, HPV, the virus that causes warts) or other serious illnesses (cancer, hemophilia, leukemia, or severe diabetes), providers will often refer couples to assisted reproductive technologies (ART), such as sperm washing. If the male

has HIV, however, only a few clinics or studies provide ART in the United States

Legal Restrictions in the U.S.

In 1990, the Centers for Disease Control and Prevention (CDC) came out against insemination with semen from HIV-infected men, because while techniques could reduce the presence of HIV, there was no evidence that any procedure could reliably eliminate HIV from semen. (MMWR, April 20, 1990). Part of their concern was based on a 1990 Virginia case where a doctor helped a discordant couple (one HIV+, one HIV-) get pregnant through sperm washing. The woman did not get pregnant but did get HIV. The CDC investigated but was unable to determine whether exposure to washed sperm was the cause.

Last April, the FDA announced proposed regulations, which would make it illegal for gay men to be sperm donors, because of their HIV risk status. (See:

<http://gayspermbank.com/fda.html>)

California law requires that blood be screened and tested for syphilis, gonorrhea, Hep B and C, and HIV. In California, sperm banks cannot accept any sperm (washed or not) from HIV+ men. Other states may be less stringent.

Is Sperm Washing Available in Other Countries?

Yes. In Milan, Italy's Sao Paulo Hospital, Dr. Augustus Semprini has reported 1000 insemination attempts in 350 couples using sperm washing and artificial intrauterine insemination. He said none of the women tested positive before or after delivery. As of 1998, more than 250 women became pregnant and 187 gave birth as of 1998. In other European countries, e.g. Spain, France, the United Kingdom, and Switzerland researchers have reported similar results .

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Sperm Washing Research in the US

Assisted Reproduction Foundation

Dr. Ann Kiessling's Assisted Reproduction Foundation (ARF) in Boston, Massachusetts has been doing research on sperm washing and other techniques to reduce the risk of HIV, such as:

- Using sensitive biological tests to identify remaining or hidden HIV in semen after sperm washing;
- Using IVF, and testing one cell from the embryo for HIV;
- Intracytoplasmic Sperm Injection (ICSI), where just one sperm is injected into the egg;
- Aspirating sperm from the testis (TESA) or from the epididymis (MESA) to be injected by ICSI.

The first six couples in Dr. Kiessling's study were interviewed on Minnesota Public Radio. (on the web go to -

http://news.mpr.org/features/199711Eiths_fertility)

Dr. Kiessling states that their program has stuck to her criteria of using sperm only from semen specimens with an undetectable viral burden. (An undetectable viral burden in the blood does not guarantee an undetectable viral burden in semen.) "I have concerns about sperm washing to guarantee removing all the virus because when you go through the numbers, you can only test a small percentage of what is destined to be used", reports Dr. Kiessling.

As of May 2000, 9 couples had completed cycles of IVF resulting in 3 pregnancies and no seroconversions. These produced one set of twins, one singlet, and one early miscarriage. Mothers were monitored every 3 months during pregnancy for HIV antibodies and the babies at 3 and 6 months after delivery.

Harvard researcher, Dr. Deborah Anderson, conducted her own studies on sperm washing and says sperm washing can reduce the level of HIV in semen 100,000 fold. She believes that by doing a sperm wash couples can conceive more safely than if they tried conceiving on their own.

Semen Testing Kit Now Available

Accessing sperm washing or other ARTs at ARF can cost thousands of dollars. However, ARF's sister organization, Duncan Holly Biomedical, has developed a semen testing kit which means couples will not have to travel to Boston to be tested if they can find a fertility center that is willing to help them. (This may be very difficult.) The kit costs \$250; plus an additional \$185 for analysis. If there is no detectable virus in the first sample, a second is performed for an additional \$250 plus \$185. Maureen Kearnan at 781-665-0750 can provide information about the kit.

IVF Study at Columbia University

Dr. Mark Sauer (212-305-4665), a professor of Obstetrics and Gynecology at Columbia University has enrolled 50 couples in a study to evaluate the safety of IVF using ICSI (with fresh untested sperm) to fertilize the eggs of HIV-negative women. The male partners are healthy, currently on standard antiviral therapy, and have stable CD4+ counts greater than 200, and viral titers of less than 10,000. Most of the 15 pregnancies are on-going with 3 delivered. All mothers and babies remain HIV negative.

Timed Conception & Other "Harm Reduction" Strategies

In Paris, Dr. Mandelbrot and other researchers reported their 10-year experience with 92 uninfected women whose infected partners had CD4+ counts ranging from 7 to 1273. Sperm

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washing was not used. Instead, couples limited exposure to periods when the woman was most fertile (timed conception). The couples received exams and treatment for STDs and other types of genital infections and were advised to use commercial ovulation test kits (<\$20 at drug stores). There were 104 pregnancies. Of these four women seroconverted (two during pregnancy and two after). However, all four who got infected reported inconsistent condom use (unprotected sex at times other than when trying to conceive).

Non-Directive Counseling and Informed Consent Reduce Harm

Since 1989, the Bay Area Perinatal AIDS Clinic (BAPAC) at San Francisco General Hospital (415/206-8919) has applied a "harm reduction" approach using non-directive counseling to outline the risks associated with conception when one or both partners are HIV-infected. With non-directive counseling, providers give individuals all of the available information, including the pros and cons, without the counselor's own biases, and allow the couple to make their own informed choices based on all of the information. BAPAC perinatologist Karen Beckerman says the couple's informed consent is critical because, there is absolutely no sure way to achieve conception and avoid transmission of HIV.

Rebecca Denison of WORLD agrees with the harm reduction approach. I've seen couples who took greater risks than were necessary, because no one was willing to help them. For those who resorted to unprotected intercourse, it would have been better to have sperm washing available. (This includes HIV+ women with undetectable viral load who could become infected with their partner's multi-drug resistant virus.) Information about the impact of lowering the man's viral load, or of giving the woman medications to

prevent getting HIV during conception (PEP) is also needed.

One Florida couple found a doctor that was willing to work with them after they presented the data from Semprini's study in Italy. They signed a liability waiver promising not to sue. They completed four attempts at artificial insemination using the husband's washed sperm. When this didn't work, they switched to another clinic to try the more expensive IVF (nearly \$10,000). This also failed. Returning to their original doctor, they tried IVF again. In May 1998, the couple gave birth to a daughter. Mother and daughter tested negative for HIV at 3 and 6 months postpartum.

How Safe Is Safe Enough? Who Decides?

Sperm washing has not yet been proven to be completely safe. Until more studies are conducted, scientists will not be able to guarantee these techniques are safe because the numbers of couples involved have not been large enough. Nevertheless, many would agree with Raffi Babakhanian who suggested in the AIDS Treatment Update (Issue 37, Jan. 1996) that sperm washing provides an alternative for couples who would otherwise resort to unprotected sex. (www.aegis.com/pubs/atu/1996/atu3702.html)

Education and informed consent should be the cornerstones of every individual's medical decisions, but that is not the case with sperm washing. The decision has been made by institutions and agencies that it shall not be offered until there is no possibility of transmission to the woman or the infant.

Couples living with HIV today are less apt to deny themselves the joys of family life, but only those with economic freedom are able to pursue the safest assisted reproductive conception technology available today. (These

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procedures are very expensive.)

In the absence of medical guidelines and safe and effective technologies, HIV affected couples must struggle with these decisions, along with their health care providers, praying that their difficult choices and best guesses will achieve the safe results they so desire.

You are not alone!!

This article was edited for WORLD by Rebecca Dennison .



CAB CORNER



by Moher Downing,
Community Liaison

CAB CORNER MOHER DOWNING

It is with great sadness that I write this column. After 4 years at the WIHS Study I will be leaving at the end of August. My time with all of you has been awesome. We had some great parties, didn't we? And we sure did eat. Most of all we learned from each other. You have taught me about courage and change. It has meant so much to me to watch you face, your HIV, and to make changes in your life based on the courage you got from dealing with it. I see your faces. You are part of my life even if I am no longer working on the WIHS. I will be around. I am leaving to spend more time on my other projects. I have recently joined the WORLD Board so you will see me at WORLD and other events in the Bay Area.

On August 10, the WIHS Study, WORLD, CAL-PEP, the AIDS Clinic of the East Bay, Highland Hospital, Alameda County Health Services, Project Inform, and the AIDS Research Institute and the Center for AIDS Prevention Studies at the University of California, San Francisco, sponsored a community update from the International AIDS Conference that was held in Durban, South Africa, in July. Speakers included two HIV-positive women, a treatment activist, an advocate for sex workers, and a clinician. We had a catered feast, complete with yummy desserts. We had a raffle with great prizes, and we were inspired by the speakers. They really gave us a sense of what it must have been like to be at the conference.

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Structure Treatment Interruptions (STIs) is the treatment news from the AIDS Conference. "Don't try this at home". There will be more information coming out over the next year about whether this is safe and the best way to do it. In the real world people take breaks from their medications because of toxicities and other reasons, but adherence to treatment is critical. People should not go off their medications without discussing it with their healthcare provider.

Because of the devastation that AIDS is causing in Africa, this conference is very important and significant. "It is predicted that there will be 44 million children orphaned by AIDS by the year 2010. Nelson Mandela spoke at the closing session asking for a partnership with the international community "to combine efforts to ensure a future for our children."



Changes for Visit 13

By Nancy Hessol, Project Director



Lucky visit 13 begins 10/1/00 and will end 3/31/01. Here is an update on what the protocol changes are for visit 13.

What new? We are please to announce that if you keep your first visit 13 appointment you will receive an extra gift from the WIHS. So please try not to cancel or skip your first study visit appointment. We are adding new questions regarding HIV medication use for visit 13. This information, along with past data collected from study participants, will be used as part of a new Viral Resistance Study. If you meet certain study criteria, you may be eligible to participate in this substudy. See the article by Claudia Ponath on [page 7](#) for more details.

We are also trying to collect better data on risk factors for certain diseases so we will be asking you to try and fast prior to your visit 13 study appointment. The reason for this is to get a more accurate measure of key laboratory tests for things like cholesterol, lipids, and glucose. These blood test are important markers for diseases that affect women, including diabetes, heart disease, and hypertension.

What's ending? For visit 13, we will skip the blood tests called CBC's (complete blood counts) and flow cytometry (t-cell testing) on women who are not infected with HIV. For HIV-negative women, these special

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blood tests will be done once a year at every even numbered study visit. We will also skip one of the modules (form 26) of the interview for visit 13. For all study participants, the administration of form 26 will be done once a year at every even numbered study visit. Visit 13 also marks the end of the HHV-8 substudy.

What's back? For visit 13, we will be doing the tuberculosis (TB) test (call PPD). The TB test will be done once a year at every odd numbered study visit.

What's continuing? The Interim Event telephone interview for HIV-infected women whose most recent (within the last 3 months) CD4 cell count was under 200.

For women undergoing cervical colposcopy, we will continue enrollment into a cancer tissue bank called the AIDS Malignancy Bank (AMB). Women do not need to have cancer, AIDS, or even be HIV-infected to enroll in this substudy. Women who are eligible and wish to donate tissue to the bank will have an extra cervical biopsy and blood specimen collected for this study at the time of their colposcopy examination.

The oral substudy is still going strong. If you are part of this group, our field staff will set you up with an appointment with the dentists at UCSF.

Thank you very much for being a part of this important study. We look forward to seeing you at your next WIHS visit!



New Protocol at Visit 13

By Claudia Ponath



At WIHS visit 13 we will start a new protocol. It is called the WIHS Virologic Rebound and Resistance Study (or VRS). We hope to enroll about 120 women nationally and about 20 in the Bay Area. This is a very important study. We want to find out more about why HIV medicines work better for some women than for others.

Participation will mean coming in for two additional visits a year, for two years, in between the regular WIHS visits. During some of those visits, participants will be asked to take their HIV medicines in the clinic and have their blood taken four times over the course of two hours. This is done to measure the level of medication in the blood. If possible, a catheter (similar to an IV) will be used to draw blood, so we will not have to stick participants four times. We will also test the blood for viral load and genotyping (that is a test that looks at the kind of virus a person has in her blood). In between the blood draws, participants will be asked a series of questions, some of the same questions that are asked during a regular WIHS visit, and some new ones. If you are eligible for this protocol, a clinician will approach you at visit 13 and ask if you would like to participate. She will also be able to answer any questions you may have about this study.





The Women's Study

Lucky Visit 13

Keep your first visit 13 study appointment and receive an extra gift from the WIHS! Women who cancel or do not show up for their first appointment are not eligible.

WIHS visit #13 runs from ➡ October 2000 through March 2001

To confirm your appointment, call:

In San Francisco (415) 476-5109 *OR*
(415) 476-6018

In the East Bay (510) 437-8551 *OR*
(510) 437-5080