

# Importance of Including HIV-positive Women in Clinical Trials

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Despite many advances in HIV science, information on the natural history of HIV disease in women is still limited. In addition to having many of the opportunistic infections seen in men, women have gender-specific symptoms that are often hormone-related or gynecological. Recent information suggests that while women may have lower viral loads than men, HIV seems to progress at the same rate for both. Women most likely differ from men in absorbing, metabolizing and experiencing side effects of certain medications. Most medications have never been tested specifically in women.

In 1985 only 7 percent of newly reported AIDS cases in the U.S. were in women. That percentage grew to 14 percent in 1992 and 23 percent in 1999. Today, in 2002, women comprise 26 percent of new cases of AIDS in the U.S. while it's 47 percent worldwide and 55 percent in sub-Saharan Africa. Despite the increasing numbers of women becoming infected yearly, women are continually underrepresented in clinical trials.

Before 1993, women were, for the most part, excluded from participating in clinical trials. Researchers feared women might become pregnant and they didn't want to risk harming the unborn child with experimental drugs. Treatments, toxicity and medication safety information were studied in men and assumed to be the same in women. Because of strong activist pressure and the fact that women living with HIV were not responding well at all to many of the approved medications in 1993 the Food and Drug Administration (FDA) said that women could no longer be kept out of clinical trials. The argument that they may become pregnant no longer stood as a barrier. Unfortunately, women still make up only 12-23 percent of total participants in clinical trials.

The federal government spent about \$2 billion on HIV research through various programs in 2002. In addition, non-profit foundations, colleges and universities and pharmaceutical companies also sponsor clinical trials. Some of the federal dollars have gone to fund two major research projects for women: The Women's Interagency HIV Study, which investigates the nature and rate of disease progression in women, and the Women and Infants Transmission Study to investigate factors associated with perinatal HIV transmission. This is a start, but it's not enough. Women need to have a larger presence in most all of the HIV clinical trials being conducted in the U.S., whether specifically designed for women or not.

There are many clinical trial options for women and men with HIV in the Twin Cities. Most of these studies want to enroll large numbers of women so that gender-specific data can be gathered. The questions we have surrounding women and HIV can only be answered when more women become involved in clinical trials. Until then, women will continue to be treated based on information gotten from men. Become involved! Look for a trial that interests you or refer someone you know to join a clinical trial.

To learn more about HIV research, science and clinical trial opportunities, join the MN AIDS Clinical Trials Unit (ACTU) Community Advisory Board (CAB). This group welcomes your involvement to learn new information and to make research recommendations to the clinic staff. It meets every 2nd Thursday from 12-1:30 (lunch is provided) at the Minneapolis Urban League (2100 Plymouth Avenue North). To learn more about the CAB or to register for the next meeting, call Debra at 612-625-3205. To hear more about opportunities to participate in a clinical trial, please call an ACTU study nurse at 612-625-1462. Transportation assistance is available and many studies pay you to participate. Give them a call and they will help you determine if there's a clinical trial that's right for you. Be a part of the solution!

## Have You Heard About the WOMEN & FAMILIES NETWORK

The Women and Families Network (WFN) is a collaboration of HIV service providers and consumers. We have been meeting since March 2002 to brainstorm how we can use this network to improve the quality of medical care and social services for women and families affected by HIV. This work expands on the good work of the Women and Families Workgroup, W.O.M.A.N. and the other Minnesota organizations, which have existed in many forms during the past decade.

We have over 30 active members in the WFN. Network members contribute a wide range of experience and expertise that guides Network activities. Membership consists of both service providers and consumers. Service providers in our Network represent the following disciplines: case management, clinical trials, social work, medical care and HIV specialty care (including nurses, nurse practitioners, and physicians), psychology, health education, outreach, housing, legislative advocacy, research and evaluation, substance abuse and public health.

### How can you get involved?

The WFN has not been in existence for very long but we already have a lot to offer. We encourage participation in the network by consumers, providers and anyone else who is concerned with the needs of women and families affected by HIV. You can get involved in the network in a number of ways:

- Become a member of the Network. By being a member you commit to working on one of the two committees:
- Forums and Training Committee: This workgroup plans educational and social events for people living with HIV.
- Seamless Services Committee: This group works to create coordinated, comprehensive services across agencies and disciplines for people living with HIV.
- Sign up to receive our quarterly newsletter filled with news, articles and resources for both service providers and people affected by HIV.
- Come to one of our networking events! These networking events take place twice a year and are geared to service providers who want to share resources, discuss available programs and help improve services for those affected by HIV.

For more information on the network and to find out how to get involved contact Ribka Berhanu, MAP women and families systems advocate at 612-373-9175 or by email at [rberhanu@mnaidproject.org](mailto:rberhanu@mnaidproject.org)