

# New study highlights women's issues

by Jennifer Chung

Women make up more than 40 percent of all HIV cases globally and 27 percent of new cases in Canada. While the number of women living with HIV worldwide continues to climb, little research is available on the way the virus and HIV drugs affect women differently than men. To generate more evidence for this field of research, Dr. Mona Loutfy of the Women's College Research Institute in Toronto is spearheading a new study to observe HIV-positive women on combination antiretroviral therapy. Loutfy hopes to gain more data on antiretroviral drug levels in women and its link to adverse events.

"Understanding the reasons for the differences of adverse events between HIV-positive men and women is critical and needs to be evaluated within a large cohort. We don't know whether these differences relate to hormonal influences, drug metabolism, adherence, fat distribution, or other factors," says Loutfy.

This trial (CTN 233) will examine levels of antiretrovirals and how these drugs are processed in HIV-positive women. Historical data from HIV-infected men will enable Loutfy's research team to compare variances in drug levels between men and women. The study will also investigate whether antiretroviral drug levels are associated with body weight in women, as well as higher frequency and severity of adverse events such as nausea, diarrhea, liver toxicity, and lipodystrophy.

"If we find there are increased drug levels in women, then we could propose that it might be beneficial to adjust drug dosages if women are really suffering from side effects. Also, this study will allow us to understand the drug levels, side effects, and their predictors in women so that we can better counsel them on all these issues," says Loutfy.

According to Loutfy, when HIV clinical trials began in the 1990s, women were excluded due to concerns over pregnancy and lactation. However, over the past decade, as more women have become infected with HIV, there has been an increasing need to understand how antiretroviral drugs affect this group.

Enrolment of women in clinical trials continues to be a challenge for a number of reasons. For instance, women tend to be primary caregivers and have childcare responsibilities, making it difficult for them to attend clinic and follow-up visits regularly. This study is unique because it attempts to address these issues through higher reimbursement fees for participants and the inclusion of AIDS service organizations (ASOs) in trial recruitment.

Louise Binder, a member of the CTN's Community Advisory Committee which reviewed and approved the study protocol, feels this study will provide much-needed data on HIV drugs and women.

"This study will help fill some gaps in the information available about how women metabolize HIV drugs in the body," says Binder. "There are few pharmacokinetic studies that involve women only and we are very glad that Dr. Loutfy is investigating this area further."

CTN 233 is seeking to enrol 80 female participants across Canada, including ten volunteers at the Oak Tree Clinic in Vancouver. ☉

*Jennifer Chung is the information and communications coordinator at the Canadian HIV Trials Network in Vancouver.*



## Trials enrolling in BC

- CTN 194** — Peg-Interferon and Citalopram in Co-infection (PICCO)  
*Study sites:* Downtown Infectious Diseases Clinic (DIDC), Vancouver
- CTN 214** — Effect of a One-Year Course of HAART in Acute/Early HIV  
*Study sites:* DIDC, Vancouver; Cool Aid Community Health Centre, Victoria

- CTN 222** — Canadian Co-infection Cohort  
*Study sites:* DIDC, Vancouver

For more information about these trials and other CTN studies, please visit [www.hivnet.ubc.ca](http://www.hivnet.ubc.ca) or call 1.800.661.4664