

Special Access Program failing Canadians with life-threatening illnesses



Dr. Julio Montaner, Centre Director, and Tiko Kerr, TMC recipient.

As more patients develop drug resistance and exhaust the current arsenal of anti-HIV drug treatments, experimental drugs may be their only hope. Patients with cancer or Parkinson's disease may also suffer as a result of this program's inadequacies.

The B.C. Centre for Excellence in HIV/AIDS is relieved that five of our patients now have access to the experimental drugs TMC114 and TMC125.

It is also promising that early blood results indicate the health of the five patients is improving under their new drug regimen. However, it is extremely worrisome that the drugs have only been made available after navigating a road fraught with numerous Health Canada roadblocks. Unfortunately, one of our patients died before the ministry finally granted access to these experimental drugs.

The government's delay was completely unnecessary because an appropriate fast-track route was readily available — Health Canada's Special Access Program (SAP).

SAP is specifically designed for patients with serious or life-threatening conditions who require "emergency" and/or "compassionate" access to drugs that are not authorized for sale in Canada. Doctors submitting to SAP on behalf of patients are required to provide data about the "use, safety and efficacy" of the drug.

The story is very simple. Over several months, our clinic identified six HIV-positive patients who became resistant to all conventional drug treatments. Their situations are life-threatening and the experimental drugs TMC125 and TMC114 were considered to be their only hope. Last April, we applied to SAP on a patient-specific basis. Our application and subsequent appeal were denied. SAP cited "lack of sufficient data" to support the use of these two products in combination. However, this reasoning is

confounding. By definition, data relating to experimental drugs or drug-combinations that are in early stages of development cannot meet the appropriate scientific standards required to constitute evidence for "use, safety and efficacy." If sufficient data existed, we would not need SAP.

Health Canada only reversed their decision due to public pressure. With their lives at stake, some of our patients were compelled to take their stories to the media. In the wake of negative publicity and a federal election nearing, Health Canada miraculously came up with a new last-minute option — a Compassionate Use Protocol, or special clinical trial. In essence, we were asked to redress our request under the pretense of "research." The same group of patients, the same drugs, the same doctors, but under a different name.

The lengthy delay until Health Canada's reversal, especially in light of one patient dying while waiting, should be of serious concern to all Canadians. One must ask why it is OK for these patients to accept the unknown risks of experimental drugs within the confines of a special clinical trial, but not within the parameters of SAP?

The consequence of this absurdity is that these patients have been denied treatment for up to nine months and their conditions had substantially worsened.

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Research reveals risks behind injection drug use, unstable housing

a Centre study reveals the risk factors underlying the higher HIV-infection rate among injection drug users (IDUs) living in unstable housing.

Few studies have included such a detailed evaluation, says researcher Dr. Evan Wood.

“Our analysis not only shows a higher rate of HIV-infection among individuals residing in unstable housing, but gives us an idea as to why there’s an elevated risk and what can be done,” says Wood.

Downtown Eastside:

The study’s findings should be of particular concern for major cities where poor housing conditions persist.

Between May 1996 and May 2003, 1,013 baseline HIV-negative IDUs were enrolled in the study and had at least one follow-up visit. During the follow-up period, 125 individuals became HIV-infected. A statistically elevated rate of HIV-infection was observed among those who reported residing in unstable housing.

Compared to IDUs from stable housing, IDUs living in unstable housing tended to use drugs more frequently and borrow needles more than their housed counterparts, according to the study’s research findings. Sex trade involvement was also more prevalent among individuals reporting unstable housing. Of particular concern, homeless individuals were more likely to have sought, but been unable to access, addiction treatment service and less likely to access methadone maintenance therapy, says Wood.

“It is evident that homeless individuals have difficulty accessing primary care or preventive services and that they may more often use high-cost services such as emergency departments and acute care beds.”

Previous research has highlighted that spiraling drug use often leads to homelessness.

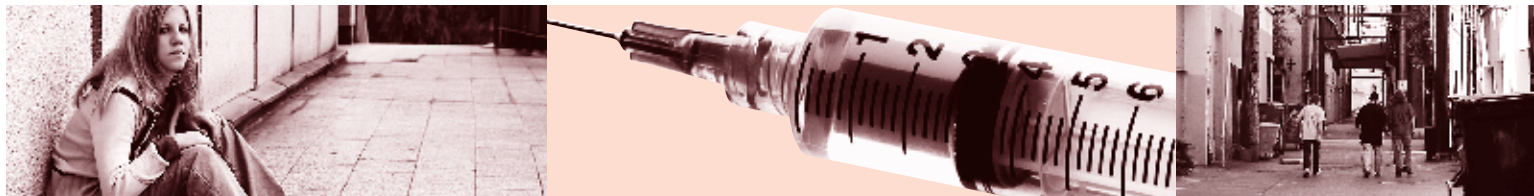


“Since it may be that drug use led many of these individuals to unstable housing arrangements, it is not surprising then that persons reporting unstable housing tend to use drugs more frequently than their housed counterparts,” says Wood.

The study’s findings should be of particular concern for major cities where poor housing conditions persist or are on the rise.

The study suggests expanding the continuum of addiction treatment services; focused interventions that facilitate positive change in high-risk HIV behaviours (specifically syringe borrowing, unprotected intercourse, and sex-trade involvement); and improving public housing programs.

The study, entitled *Unstable housing, associated risk behaviour, and increased risk for HIV infection among injection drug users*, was published in the journal *Health and Place*.



The impact of a sex partners' HIV status among injection drug users

The Centre evaluated the HIV status of the sex partners of injection drug users (IDUs) and rates of subsequent HIV infection among a prospective cohort study of IDUs. Through IDUs enrolled in the Vancouver Injection Drug Users Study (VIDUS), we determined the cumulative HIV incidence rate was significantly higher among those who reported having an HIV-positive sex partner. These findings may aid public health workers in

their efforts to identify IDUs who should be targeted with education and prevention efforts and indicate the need for ongoing development of prevention interventions for IDU sex partners who are HIV discordant. (*Journal of Acquired Immune Deficiency Syndromes*)

The Centre sought to determine the impact that hepatitis C virus (HCV) infection has on CD4 cells during the first 48 weeks of antiretroviral drug therapy (ART) in HIV-infected patients. CD4 cells are responsible for coordinating much of the immune response and are one

of the main targets damaged by HIV. HCV antibody-negative patients had increases of an average of 75 cells in the absolute CD4 cell count, compared with 20 cells and in HCV antibody-positive patients, during the first 48 weeks of ART. HCV antibody-positive HIV-infected patients may have an altered response to ART. (*Journal of Infectious Diseases*)

Drastic elevations in mortality among female injection drug users

Since few studies have examined rates and correlates of death among addicted women in Canada, the Centre characterized patterns of mortality among female IDUs in Vancouver. Between May 1996 and May 2002, 520 female IDUs were recruited from the Vancouver area, among whom 68 died during the study period. Elevated rates of mortality were observed among those who reported sex-trade involvement, HIV-infection, and living in unstable housing. In Vancouver, female IDUs have rates of mortality almost 50 times that of the province's female population.

Our findings demonstrate the need for an appropriate evidence-based strategy to address the health and social needs of addicted women. (*AIDS Care*)

Binge drug use independently predicts HIV infection

The Centre sought to evaluate the potential association between binge drug use and HIV infection among a cohort of IDUs. Of 1,548 participants enrolled in VIDUS between May 1996 and May 2003, 1,013 individuals were HIV-negative at enrolment and had at least one follow-up visit. Of those, 125 (12%) became HIV positive during the study period. Binge drug use was directly linked with HIV-infection. Borrowing and lending syringes, sex trade work, frequent cocaine and heroin injection were independently associated with binge drug use. Methadone was protective against binge drug use. Given the unaddressed public health risks associated with bingeing, a public health response protocol should be developed. (*Substance Use and Misuse*)

New Forecast a more current, easier read

Welcome to the new Forecast.

Forecast has been revamped to provide you information that's more current and easier to digest.

Forecast has moved to a monthly format, providing you emerging treatment and research information sooner. Forecast's smaller size also provides information in a more concise format, making the publication an easier and quicker read.

The newsletter's revamp also coincides with ongoing improvements to the Centre's website.

We look forward to your feedback. Comments can be forwarded to info@cfnenet.ubc.ca

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It's important to underline that while this limited clinical trial opens the door for a few selected individuals to access these experimental agents, it shuts out additional HIV-infected Canadians who may need to avail themselves of these drugs in the near future.

As well, a true clinical trial typically requires a hypothesis that can be tested, random use of two or more viable treatments, a sample size much larger than five people and eligibility criteria that would necessarily restrict who can and cannot participate.

Our intent is more simple: healing our patients who are very ill.

The lack of transparency regarding the way Health Canada has handled this situation poses a serious problem that must be immediately rectified. For instance, as more patients develop drug resistance and exhaust the current arsenal of anti-HIV drug treatments, experimental drugs may be their only hope. Patients with cancer, Parkinson's disease and other life-threatening conditions may also suffer as a result of this program's inadequacies.

SAP, in its current form, is poorly governed and renders arbitrary decisions. The program is inconsistent with the principles of "emergency" and/or "compassionate" access. A fully revamped SAP is urgently needed. A transparent decision-making process and full accountability are mandatory. SAP should be a viable option for future patients with life-threatening conditions.

The B.C. Centre for Excellence in HIV/AIDS is focused on providing patients with the best possible chances of survival. We count on Health Canada to help us meet this challenge.

—Dr. Julio Montaner, Director, and
Dr. Timothy Christie, Health Care Ethicist,
B.C. Centre for Excellence in HIV/AIDS

what's new

Website

On March 1, the Centre debuts a new homepage and online access to its wealth of research. As part of ongoing improvements to the Centre's website (www.cfenet.ubc.ca), the homepage now features the most recently published study, news release and video presentation. The website's "Published Paper" section includes links to the three most recently published Centre studies, as well as a search function allowing you to locate an article by keyword and/or year.

Now on video

The issue of HIV and immigrant health is detailed by Dr. Rolando Barrios, assistant director of the John Reudy Immunodeficiency Clinic. The Jan. 26 presentation can be viewed or downloaded on the Centre's website under Education/ Video Presentation / Rounds.

Drug Treatment Program statistics

The Centre's new DTP update can now be downloaded from the Centre's homepage. The update includes information on number of participants, gender, age, location, viral load and type of combination therapy. The update also includes current HIV/AIDS drugs available through the Centre.

Events

As part of the Centre's ongoing AIDS Care Rounds presentation series, Dr. Laura Chapman will speak on *Clinical Applications of Cannabinoids*, March 9, and Dr. Julio Montaner will speak on *Emerging insights regarding the impact of HAART in B.C.*, March 23. Both presentations take place 8-9 a.m., in St. Paul's Hospital's Conference Room 7 (Level 1).

What's New welcomes event submissions from all HIV/AIDS-related agencies. Please e-mail submissions to info@cfenet.ubc.ca

BC Centre for Excellence in HIV/AIDS

- > Improve the health of British Columbians with HIV through comprehensive research and treatment programs;
- > Develop cost-effective research and therapeutic protocols;
- > Provide educational support programs to health-care professionals;
- > Monitor the impact of HIV/AIDS on B.C. and conduct analyses of the effectiveness of HIV-related programs.

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How you want to be treated.

