

Pharmacovigilance project celebrates success



Dr. Rolando Barrios and Kathy Lepik, BC Centre for Excellence in HIV/AIDS

The BC Centre for Excellence in HIV/AIDS (BC-CfE) has successfully completed a demonstration project that is helping B.C.'s health care system monitor side effects (adverse drug reactions) to antiretroviral medications.

Adverse drug reactions can gravely affect patients' health and compromise treatment success.

Although all drugs are tested for safety before they are approved for sale in Canada, pre-marketing clinical trials cannot study enough patients to be able to detect rare or delayed onset drug reactions, or reactions that predominantly affect special groups, such as women, seniors or specific ethnic groups. These types of adverse reactions may not be discovered until after a drug is marketed and widely used.

Ongoing surveillance of adverse drug reactions is required to detect unexpected toxicities as soon as possible, so that health care providers and patients can be warned of new safety concerns. This type of monitoring activity is conducted through pharmacovigilance programs which collect, evaluate and analyze reports of drug toxicity and use this information to understand and prevent drug-related problems. Health care professionals and patients themselves are the most important sources of information in identifying a drug's potential toxicity.

Since its inception, the BC-CfE has been active in collecting and reporting antiretroviral treatment-related information and has published numerous scientific studies and issued public safety alerts. However, until recently, the BC-CfE lacked the resources to operate an ongoing adverse drug reaction reporting and monitoring program. Thanks, in part, to the generous support of the Canadian Patient Safety Institute, the BC-CfE was

able to launch a pharmacovigilance program as a demonstration project in July 2008. The first HIV-focused reporting mechanism of its kind in B.C., the program provides an opportunity for all health care professionals and for patients themselves to submit reports of suspected adverse drug reactions to antiretroviral medications.

"Because the BC-CfE Drug Treatment Program provides all antiretroviral medications within B.C., we can estimate the proportion of people taking a drug or drug regimen who experience a particular adverse reaction," explained Kathy Lepik, project coordinator. "The BC-CfE sets the HIV treatment guidelines for the province, so we will also be able to respond rapidly and translate reports of unexpected drug toxicities into safety alerts for healthcare providers and people living with HIV/AIDS."

During the first nine months of pharmacovigilance program operation, approximately 5,000 people living with HIV/AIDS were treated with antiretroviral medications and the program received 435 reports of adverse drug effects via prescription forms and spontaneous reports. Approximately 80 per cent of these reports were submitted by physicians, and 20 per cent by pharmacists and nurses. Dr. Rolando Barrios, project leader, noted, "Reporting patterns to date have been consistent with the known adverse reaction profiles of the commonly used antiretroviral medications, which suggests that there are no identifiable biases in the reporting process. We are presently closely monitoring and investigating some potential safety concerns."

The BC-CfE hired Kathy Lepik, a licensed pharmacist with a master's degree in epidemiology, as Research Coordinator for the program. Lepik has a background in hospital pharmacy and also worked for many years at the BC Poison Control Centre. She was the project manager for the

IAS and other global health groups criticize new UN drug policy

A new United Nations (UN) drug policy has been criticized by the International AIDS Society (IAS), Human Rights Watch and the International Harm Reduction Association (IRHA).

The UN Political Declaration on Drugs, a resolution adopted by its member states on March 19, 2009, is designed to guide international drug policy for the next 10 years. However, the IAS, the IHRA and Human Rights Watch have expressed profound disappointment at the policy's exclusion of critically important measures for treating and stemming the spread of HIV and thereby protecting basic human rights.



The policy makes no specific mention of the need for harm reduction services, such as needle and syringe exchange and medication-assisted therapy (for example, with methadone), both inside and

outside prisons, as essential strategies to address the issue of HIV transmission among people who use drugs. Yet up to 30 per cent of all HIV infections outside of sub-Saharan Africa occur via unsafe injecting drug use.

There is clear evidence that harm reduction interventions can halt or even reverse HIV epidemics among people who inject drugs. In fact, the omission of a clear statement on harm reduction in the new drug policy was made against the direct

advice of UNAIDS, the Global Fund to fight AIDS, Tuberculosis and Malaria, and even the UN special rapporteurs on health and on torture.

"We can't understand why the UN has adopted a drug policy that does not support their own findings on health and human rights," said Dr. Julio Montaner, IAS president and director of the BC Centre for Excellence in HIV/AIDS. "The UN has an obligation to develop policies that are evidence-based and ethical. Despite incontrovertible evidence that it saves lives, they have stripped harm reduction services from their drug policy. In doing so, they have failed the international community and the millions of people worldwide who will be exposed to unacceptable and unnecessary risk of HIV/AIDS as a result."

The three organizations have called on the international community to recognize that the current approach to international drug policy has failed. They recommended that concrete steps be taken to set forth a drug policy framework that addresses drug-related harm and the human rights obligations of the UN and of its member states. Fundamentally, this requires that evidence-based measures be reflected in the new drug policy, evidence-based measures which clearly and overwhelmingly support a harm-reduction approach.

"Harm reduction strategies have been shown to work. They save lives," said Dr. Montaner. "Punitive drug policies don't. In fact, they have taken a serious toll on the lives and health of millions of people. The UN must acknowledge that we need a new way forward."

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pharmacovigilance demonstration project and brings experience and continuity to the new program. "Patient safety is our top priority, both at the individual and the population level," says Lepik. "In addition to monitoring overall trends in adverse drug reactions, we are working with our advisory groups to develop a mechanism for making patients' adverse drug reaction histories available to their health care providers and the patients themselves, without compromising privacy or confidentiality."

The pharmacovigilance program will give thousands of people with HIV/AIDS in B.C.— and the health care professionals who treat them — greater reassurance that there is a timely, accurate system to identify and act on adverse drug reactions. For more information on the BC-CfE's pharmacovigilance program, or to submit information on an adverse drug reaction, visit the "Adverse Drug Reaction Reporting" page on the BC-CfE website www.cfenet.ubc.ca, e-mail ADR@cfenet.ubc.ca or call 604-806-8663 and ask to speak to a pharmacovigilance clinician.



Perceptions of HIV and Fertility Among Adolescents in South Africa

Forrest J, Kaida A, Dietrich J, Miller C, Hogg R, Gray G

The scale up of highly active antiretroviral therapy (HAART) for the treatment of HIV has raised new concerns relating to fertility desires and outcomes. Among these concerns is social stigma surrounding HIV and childbearing. High rates of infection and patterns of high fertility make adolescents a crucial demographic to qualify perceptions of HIV and fertility.

This study used focus groups to uncover and qualitatively characterize the attitudes towards HIV and childbearing among adolescents, using two focus groups (n = 11 males, n = 8 females) conducted with participants ascertained from an HIV adolescent community advisory board in Soweto, South Africa.

Adolescents raised concern over re-infection by HIV positive couples attempting to conceive. They also used this concern to justify their attitudes that HIV positive couples should adopt when faced with the desire to have children. Lastly, participants spoke of a need to revise adolescent sexual and reproductive health services to make them more youth-friendly where users could avoid stigma generated by community

healthcare workers. This study adds to the growing literature that calls for an evaluation of adolescent HIV educational programs and a healthcare worker intervention that specifically targets stigma surrounding HIV and childbearing. (*AIDS Behavior*)

Antiretroviral therapy in a population affected by conflict

Kiboneka A, Nyatia R, Nabiryo C, Anema A, Cooper C, Fernandes K, Montaner J, Mills E

This study set out to measure the clinical and immunological outcomes of 1,625 HIV-positive adults (aged over 14 years) receiving combination antiretroviral therapy in conflict-affected northern Uganda.

Sixty nine (4.2%) patients died during follow-up. The mortality incidence rate was 3.48 (95% confidence interval 2.66 to 4.31) per 100 person years. Patients started treatment with a median CD4 count of 157 (interquartile range 90-220) cells/mm³: most (1009; 63%) had World Health Organization stage 2 defined (asymptomatic) illness. Sixty two patients had pulmonary tuberculosis at the start of treatment. Of the 1521 patients with adherence data, 118 (7.8%) had adherence of less than 95% and 1403 (92.2%) had adherence of 95% or above.

Patients receiving combination antiretroviral therapy in conflict-affected northern Uganda had a mortality rate comparable to that of patients in peaceful, low-income settings and better adherence than patients in higher income settings. These favourable findings highlight the need to expand access to combination antiretroviral therapy in populations affected by armed conflict. (*BMJ*)

HAART Optimism, Fertility Intentions and Sexual Behaviours Among HIV-Positive Women in Uganda

Kaida A, Lima V, Andia I, Kabakyenga J, Mbabazi P, Emenyonu N, Patterson T, Hogg R, Bangsberg D

The objective of this study was to develop a reliable HAART optimism scale among HIV-positive women in Uganda and to test the scale's validity against measures of fertility intentions, sexual activity, and unprotected sexual intercourse. "HAART optimism" describes individuals' optimism about the efficacy of HAART and the corresponding beliefs concerning the decreased need to engage in safer sexual behaviours, including condom use.

The study used cross-sectional survey data of 540 women (18–50

years) attending Mbarara University's HIV clinic in Uganda. 49% were HAART users with a median duration of HAART use of 15 months.

The survey included questions related to concern about sexual transmission of HIV to their partners and to unborn children through vertical transmission, and concern about severity of HIV disease.

Women who reported that they intended to have (more) children had significantly higher HAART optimism scores (median = 13.5 [IQR: 12–16]) than women who did not intend to have (more) children (median = 10.5 [IQR: 8–12]; P < 0.0001). Similarly, women who were sexually active and who reported practicing unprotected sexual intercourse had significantly higher HAART optimism scores than women who were sexually abstinent or who practiced protected sexual intercourse. The investigators reliable and valid scale, termed the Women's HAART Optimism Monitoring and Evaluation scale (WHOMEN's scale), may be valuable to broader studies investigating the role of HAART optimism on reproductive intentions and sexual behaviours of HIV-positive women in high HIV prevalence settings. (*AIDS Behavior*)

Dr. Bob Hogg addresses students and public during SFU's President Faculty lecture



Dr. Robert Hogg, BC Centre for Excellence in HIV/AIDS

There are currently 33 million people infected with HIV/AIDS around the globe, with the majority of these living in sub-Saharan Africa. On April 2, 2009, Dr. Robert Hogg took part in the President's Faculty Lecture series at Simon Fraser University (SFU) and described the impact of antiretroviral therapy on the demography of HIV/AIDS.

Hogg's presentation provided insights into current treatment options and their successes, the determinants of antiretroviral access and use, shifts in patterns of fertility, morbidity, mortality, and life expectancy, and the potential that increasing antiretroviral use will decrease HIV transmission.

One focus of Hogg's presentation was the recent establishment of the Canadian Observational Cohort Collaboration (CANOC), Canada's first integrated network of all registered HIV/AIDS treatment information from six cohort databases across British Columbia, Ontario and Quebec. This merger gives researchers the opportunity

to conduct large and detailed analyses of treatment outcomes and to assess variations across regions and practices.

"CANOC will reestablish Canada at the forefront of population level research into HIV/AIDS", says Dr. Hogg. "This emerging team collaboration is an essential first step to evaluating the impact of antiretroviral care on the health and well-being of persons infected with HIV/AIDS across various regions of Canada".

Dr. Robert Hogg has established a global reputation in population health research with an emphasis on HIV/AIDS, antiretroviral therapy, and marginalized populations. Dr. Hogg is the Director of Epidemiology & Population Health at the BC Centre for Excellence in HIV/AIDS; serves on a Canadian Institutes of Health Research (CIHR) advisory board for the Institute of Infection and Immunity; sits on an advisory board for the Michael Smith Foundation for Health Research; and is a Faculty member in the Faculty of Health Sciences at SFU. Dr. Hogg has published extensively in these areas and is currently supported by the CIHR and National Institutes of Health (NIH).

what's new

PHC Research Institute's "Researchers Abroad" lecture series

When: Thursday, June 18, 2009 from 12:00 – 1:00 pm

Where: Hurlburt Auditorium, St. Paul's Hospital

The series is designed to bring people from all over Providence together to highlight the international-calibre research being conducted by PHC Research Institute researchers.

Dr. Thomas Kerr will be speaking about "HIV Risks And Other Drug-related Harms Among Injections Drug Users in Thailand: Evidence From The Mit Sampan Community Research Project".

Dr. Kerr is Director, Urban Health Research Initiative BC Centre for Excellence in HIV/AIDS; Assistant

Professor, UBC Department of Medicine; Michael Smith Foundation for Health Research Scholar.

Space is limited so please RSVP by e-mail to research@providencehealth.bc.ca

Forefront Lecture Series

When: Wednesday, June 24th at 12:00 pm

Where: Hurlburt Auditorium, St. Paul's

Dr. Treena Orchard will be speaking to "What's left behind? Douching discourse as medico-moral regulation among gay men."

Treena Orchard is an assistant professor in the faculty of Health Sciences at the University of Western Ontario. She is a medical anthropologist who engages in community-based research with a wide array of social groups, including sex workers, Aboriginal men, women, and youth, and gay men.

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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