

CANADIAN TREATMENT ACTION COUNCIL



Canadian Treatment Action Council

The Final Pass

CTAC wraps up study on drug safety monitoring

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National PASS Study

Testing methods to report effects of HIV-Drugs

Accurate, up-to-date drug information is essential for making informed treatment decisions. Although the majority of information on drug efficacy and toxicity is collected during pre-

approval clinical trials, toxicity data continues to emerge well after medications are approved. In fact, some estimates say that over half the drugs approved in Canada have serious side effects that are only detected after approval. Occasionally, this may have dramatic consequences—as when the anti-inflammatory drug Vioxx was withdrawn from the market due to unacceptably high occurrences of heart attacks and strokes.

The process for tracking adverse drug events (ADEs) after drug approval is termed a *post-approval surveillance system*, or PASS. In Canada, new information on post-approval ADEs is collected by the Canadian Adverse Drug Reaction Monitoring Programme (CADRMP)—a program of the Marketed Health Products Directorate. Health care professionals may report newly observed ADEs to CADRMP, but are not required to do so. Patients themselves may report ADEs directly, but very few people are aware of this, and the existing system is difficult for non-medical professionals to use. Only pharmaceutical companies are legally required to report new ADEs to CADRMP.

There is substantial evidence that, as a result of the essential passivity of the Canadian PASS, the information it collects is neither entirely timely nor complete. In response to these shortcomings, CTAC has been conducting the "PASS Study"—a community-based research project of ADE reporting methods. The project has entailed three main phases:

- Identifying and documenting the issue (1998–2000)

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- The PASS Study: development, data collection, and formal analysis (2001–2004)
- Dissemination, community dialogue, and final synthesis (2004–March 2006)

The earlier phases of the study have been extensively documented—see “PASSing it on” (CTAC newsletter Vol 6 #1, March 2004). As part of the dissemination phase of the project, we have also developed a “community education package”, three plain-language documents describing the background, methods, and findings of the PASS Study. These documents are available online at the CTAC website (www.ctac.ca). Apart from a brief summary of the research component of the project, this article will concentrate on the project’s final, dissemination phase.

The PASS Study—in brief

The PASS Study was formulated and supervised by a multidisciplinary advisory committee, including physicians and pharmacists in HIV care, and representatives from CTAC, Health Canada, and the pharmaceutical industry. The research protocol was designed and carried out with researchers from the British Columbia Centre for Excellence in HIV/AIDS. The main study objectives were to pilot test several community-based data collection methods, to evaluate their effectiveness and to identify key issues about how this kind of data is collected.

The specific data collection methods were:

- a **bilingual toll-free phone line**;
- data collection forms which could be **faxed or mailed** in free of charge;
- **face-to-face, one-on-one interviews**, held at community agencies in Toronto, Vancouver, and Montreal; and
- four **focus groups** with Aboriginal people, held in rural and urban areas.

The first three methods collected a total of 1070 adverse drug reports between November and July 2003, plus focus groups with a total of 22 aboriginal people. While all of the

collection methods succeeded in gathering data, the face-to-face interviews collected by far the most (and the highest-quality) data. A total of 933 reports were gathered through one-on-one interviews.

The information gathered by the PASS Study was generally consistent with existing clinical information. However, the study confirmed that there are disparities between what is important to the medical community, and what is important to people living with HIV/AIDS (PHAs) themselves. Existing reporting systems focus on specific biomedical problems (e.g., lipodystrophy, liver toxicity, hypersensitivity reactions). However, this kind of reporting typically does not describe social and psychological impacts of medications, and their long-term effects on quality of life.

Community Consultations

The PASS Study demonstrated that patient-centred, community-based reporting systems could be a feasible means of investigating emerging adverse drug events. To further explore this idea, we took the study results back to the PHA community, presenting and discussing the findings at a series of community consultations across the country. Between September 2005 and February 2006, eight consultations were held at venues in Vancouver, Montréal and Toronto, including sessions at the Canadian AIDS Society’s Skills-Building Symposium in October. Oral and poster presentations were also made at the Ontario HIV Treatment Network’s 2005 research conference and the 4th Urban Health Conference, both in Toronto.

Consultations consisted of a slide presentation of the study background and findings, followed by interactive discussion. Specifically, participants were asked the following five questions:

1. Do you support the advocacy work CTAC is doing towards improving the current PASS in Canada?
2. What are the priorities for further research in this area?
3. Is a face-to-face conversation with a trained community-

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based interviewer an effective way for you to report drug toxicities and side effects?

4. What could be the first steps toward developing such a community-based reporting system?
5. Are there any other key questions that should be discussed during these community consultations?

Feedback was generally very positive, with almost unanimous support for CTAC's work in this area. While acknowledging that face-to-face-based community interviews were a desirable way of reporting side effects, many participants acknowledged the possible practical limitations of such a system (e.g., training and human resources required). Discussions also acknowledged the developments that have taken place since the study was conducted, for instance, the role of online/Internet reporting. With Internet use having grown enormously since the inception of the PASS Study, many participants felt that online methods could play an important role in side effect reporting.

The role of online reporting also led to discussions of Health Canada's new "MedEffect" program. Still relatively new and under development, MedEffect provides a means for patients to report drug reactions directly to Health Canada's drug monitoring program, including a preliminary means of online reporting. At present, the MedEffect program is almost unknown to the general public; however, any further development of community reporting methods will have to take the ongoing developments of the MedEffect program into account.

The Community as "Sentinel"

In the past, community-based AIDS organizations have often been the first to appreciate the true extent of emerging drug toxicity issues. (For example, in the early days of protease-based HAART, PHA treatment activists were well aware that lipodystrophy was a widespread, often severe medication-induced problem, while the medical community at large was often dismissive of such claims.)

A clear theme emerged during the consultations on the

PASS Study: that of a "sentinel" role in ADE reporting for community-based AIDS service organizations (ASOs). There was widespread support for the idea that ASOs already providing treatment information could also serve as reporting centres. This would leave PHAs with access to the existing range of reporting mechanisms, while also providing the option of reporting adverse drug events to ASOs where they might feel more comfortable. The ASOs would then serve as a conduit, forwarding the information to Health Canada and/or otherwise flagging it for early attention.

The current phase of the PASS Study project, funded by the Canadian Institutes for Health Research, is scheduled to conclude at the end of March 2006. With additional funding from the Ontario HIV Treatment Network and Ward Health Strategies, plans are already being generated for the next phase of work to pick up where the current phase leaves off: continuing dissemination and collaboration outside the HIV/AIDS community, and developing the preliminary ideas for "community-based sentinel reporting" into a workable reality. ■

CTAC's Annual General Meeting 2006

CTAC's Annual General Meeting (AGM) will be held in **Montreal, Quebec, November 3rd-7th**. All Members are entitled to participate in the AGM. Full members will receive information packages in July.

For more information, please visit

www.ctac.ca

HIV Testing and Care Among Aboriginal Youth:

A summary of findings related to the relationship between HIV testing and the decision to seek care

by Tracey Prentice, Chris Archibald, Judy Mill, Randy Jackson, Tom Wong, Catherine Worthington, Ted Myers and Susan Sommerfeld

This article is reprinted with the permission of the Canadian Aboriginal AIDS Network (CAAN).

As some of you may already know, the Canadian Aboriginal AIDS Network (CAAN) has been partnering with the Universities of Alberta, Calgary, Toronto and The Public Health Agency of Canada on a research project related to HIV testing and care among Canadian Aboriginal youth. This two year research project had the goals of: 1) examining why Aboriginal youth decide to have an HIV test; 2) describing the HIV testing experience of Aboriginal youth; 3) examining the relationship between HIV testing and the decision to initiate treatment; and 4) describing strategies used by Aboriginal HIV positive youth to choose care and treatment. This article is a summary of key findings specifically related to objectives 3) and 4) - the relationship between HIV testing and the decision to initiate treatment, and the strategies used by Aboriginal HIV positive youth to choose care and treatment.

Between January 2004 and February 2005, 413 Aboriginal youth between the ages of 15 and 30 completed our survey and an additional 28 Aboriginal youth participated in in-depth interviews. Participants were drawn from mostly (but not exclusively) urban areas across the country. Care was taken to include participants from all regions of Canada, including North, South, East and West. Care was also taken to include Métis, Inuit and First Nation participants, males and females, and those who had never tested, those who had tested and those who had tested positive.

The findings, as yet unpublished, presented below are significant because, to our knowledge, this is the first research study to examine HIV testing practices among Canadian Aboriginal youth. However, our sample is not representative of all Aboriginal youth. As a result of the way

participants were recruited for this study, our findings will be biased toward youth who are familiar with or who already access HIV/AIDS-related services.

Key findings on the relationship between HIV testing and the decision to access treatment

- Of the 413 youth who were surveyed, 210 (50.8%) had been tested for HIV at least once. Of these, 26 (12.4%) youth had tested positive. Of the 28 youth we interviewed, 25 had been tested for HIV and 9 had tested positive. ***These numbers are likely to be higher than those among Aboriginal youth in general. However, because of the number of youth in our sample who were experienced testers and HIV positive, they were able to provide valuable information on the relationship between HIV testing and HIV care.***
- Just over 30% of our survey sub-sample had symptoms related to HIV/AIDS at the time of diagnosis and 23% had AIDS at the time of diagnosis. Of the 9 HIV + youth in our interview sample, 2 participants reported having symptoms of HIV at the time of diagnosis. ***This suggests that some Aboriginal youth are getting tested late in the course of disease.***
- After diagnosis and at the time of the survey, less than 40% of the survey participants had seen a doctor to discuss HIV treatment options. Eighty percent (80%) of these were assessed for care within 1 year of diagnosis. Of the 9 HIV positive interview participants, 8 had been assessed for care within one year of diagnosis.
- Among the reasons for delaying care-seeking or not seeking care at all, interview participants reported: being scared, being pre-occupied with drugs or alcohol, not caring, not wanting to live, and not knowing anything about care. ***This suggests that post-test***

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HIV Testing and Care among Aboriginal Youth

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counselling could be an important point of intervention for Aboriginal youth.

- Of the 10 survey participants and 8 interview participants who were treating their HIV at the time of the survey, the following treatment methods were most frequently used: staying healthy through diet, nutrition and exercise; modifying lifestyles by stopping smoking/drinking/drugging; taking HIV meds; and traditional Aboriginal healing methods.
- ***Several interview participants reported that stable housing and social/family support were essential to helping them manage their HIV. Support services such as Aboriginal AIDS service organizations, AIDS service organizations and community/public health clinics were also important.***
- Of the 6 survey participants and 2 interview participants who were taking HIV medications at the time of the study, most reported that they started taking medications on the advice of a doctor once they experienced declining health, low CD4 counts or high viral load counts.
- Of those not taking HIV meds, a number of reasons were reported including the following: their doctor did not recommend them, they felt healthy, they were afraid of the side effects, their lifestyle got in the way and they did not want to take HIV medications.
- When asked if they would start medications in the future, most participants reported that they would take HIV medication when their health declines, when their CD4 count goes down or their viral load goes up, and/or when a doctor recommends it.
- A small number of participants reported that they would never take HIV medications or only when they absolutely had to.
- ***Of those participants who made post-testing recommendations, greater/better counselling after diagnosis and street outreach were suggested as effective means of getting Aboriginal youth into care.***

One participant had this to say about the importance of post-test counselling:

The counselling of one-on-one should be on-hand and available to anyone should they need it, because it's those first five minutes or half an hour [after] you get that information...when you can do the most good or the most damage to a person... If they don't have counselling to deal with it, then Lord knows where their path will take them if they don't understand it fully or realize that there's more help for them or that it's not as bad as [they'd] like to think it is.

(HIV+, First Nation, male, 27 years old)

If you are interested in learning more about the results of this research, a final report should be available from CAAN in May of 2006. Other forms of community-friendly dissemination are being discussed. Please contact Randy Jackson or Tracey Prentice for further details. ■

Acknowledgements

CAAN and the research team would like to thank all youth who shared their experiences of HIV testing or their thoughts on HIV testing and care with us. Without your participation, our research could not have gone forward. We would also like to thank the many participating organizations who helped us recruit participants and ensured that participants had a safe place in which to share their experiences with us. Lastly and importantly, we would like to express our appreciation to our national advisory committee for sticking with us through this process, for keeping us grounded in community concerns, and for your thoughtful contributions to the development and completion of this project. *Miigwech. Tshinashkumitan. Qujanaq. Welálin.*

Funding for this project was provided by the Canadian Institutes of Health Research.

Formularies Series:

British Columbia

By Derek Bell, CTAC's British Columbia Persons With AIDS Society (BCPWA) Representative

The purchase and distribution of antiretrovirals in British Columbia

Access to the numerous HIV/AIDS medications and methods for their distribution to patients differ dependent on where you live in Canada. These differences affect one's ability to access the most important component of HIV treatment. This article will discuss the availability of various antiretrovirals (ARVs) and the system for dispensing them in British Columbia (BC).

In BC, all ARVs are provided without charge to all residents of BC who have coverage under the publicly subsidized Medical Services Plan (MSP), regardless of their income level. Pharmacare provides the BC Centre of Excellence in HIV/AIDS (CfE) a budget for ARVs and their distribution. The CfE then decides which vital medications to fund. Endowed with the expertise of a world-renowned clinical and research facility, the CfE presently funds access to all ARVs that have completed a review by the federal Common Drug Review (CDR), regardless of the CDR's recommendation. However, notable access restrictions do apply to some of these drugs.

The CfE is also responsible for dispensing ARVs throughout the province. The CfE finances and oversees the purchase and distribution of ARVs through St. Paul's Hospital (SPH) ambulatory pharmacy. Acting as a central depot for ARVs in BC, the pharmacy uses four distinct modes of distributing the medication.

Firstly, SPH pharmacy supplies ARVs to several off-site, public and privately owned pharmacies established in larger communities (Victoria, Nanaimo, Kelowna) or specialty sites (BC Children's & Women's Hospitals, Provincial Distribution

Centre, Downtown Community Health Clinic). All of these sites receive bulk shipments from SPH and dispense the medication to patients in their geographic areas. Copies of all these prescriptions are regularly sent to SPH and entered in a pharmacy database. Clinical HIV/AIDS specialists from the CfE review each patient's initial prescription for compliance with the Centre's therapeutic guidelines.

The second way ARVs are dispensed is to patients who are able to come to SPH. The patients book a brief appointment with a clinical pharmacist to receive their medications. During the appointment, the pharmacist reviews any medication concerns (adverse effects, drug/food interactions, adherence) with the client and all information is recorded on the patient's CfE chart. The quantity of ARVs dispensed to clients depends on the complexity of the regimen, the clinical stability of the client as defined by CfE criteria, their adherence and the clinical judgement of the pharmacist. Standard quantities are a one month supply for new prescriptions, and two or three months for refills.

SPH ambulatory pharmacy also provides clinical support to specialized HIV/AIDS clinics. Pharmacists provide their services to patients at the Immuno-Deficiency Clinic (IDC) at SPH. Spectrum Health is a clinic with a large number of patients taking ARVs. The Maximally Assisted Therapy (MAT) program sees patients who have complex issues regarding non-adherence. All three clinics are located in downtown Vancouver.

Thirdly, patients are supplied with ARVs through community outreach pharmacies (e.g. Cool Aid Clinic in Victoria), which assists clients identified as high risk for non-adherence. Experience has indicated that patients at high risk for non-adherence are usually successful in taking their ARVs as prescribed if they are going to a pharmacy on a regular basis for other medications (e.g. daily methadone program).

The fourth means of ARV distribution is by using couriers to supply physician offices. The physicians provide the patient with information that a clinical pharmacist would offer during a medication counselling appointment.

The SPH pharmacy is also responsible for providing a 24 hour toll-free phone line for BC patients and health care professionals which offers callers ARV-related information.

Those who live in the Vancouver area have a significant advantage regarding accessibility to treatment, given the fact that the CfE, SPH ambulatory pharmacy and the

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Formularies Series: British Columbia

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ImmunoDeficiency Clinic (IDC) are all located in BC's largest city. In addition to the relative ease of renewing a prescription for ARVs, patients in Vancouver and other big cities are able to access all other treatment components required when taking ARVs, such as appointments with specialists and specialized blood testing. For those who require access to the latest medications still in clinical trials, living in a large centre is critical. To be accepted into a clinical trial, a patient must be able to attend regular appointments with researchers for monitoring and evaluation. For the many that live hundreds of kilometres from the clinical trial site (often Vancouver), this is impractical or impossible, especially given the lack of funding for the necessary, frequent transportation. Another challenge is distributing medication to those identified as high risk for non-adherence. These are people who

desperately need to take ARVs but are not doing so because of several possible reasons, ranging from drug abuse to mental illness. Many have benefited from community outreach pharmacies and MAT programs, but there are others for whom the existing system fails to work. Solutions must be found for all of the marginalized.

The most vital challenge in BC is the preservation of the CFe's ability to decide which medications to fund. Thus far, the provincial bureaucrats and politicians have authorized the HIV/AIDS experts to make these crucial treatment decisions and this has made BC a global leader in HIV/AIDS research and treatment. However, the CFe's authority is now under scrutiny due to rising drug prices and limited budgets, as all provincial governments attempt to contain treatment costs through formulary coverage recommendations from the federal Common Drug Review, which alleges it bases its decisions on "unbiased" pharmacoeconomics. Will it be the BC Centre of Excellence or Mediocrity in HIV/AIDS? 2006 will be a landmark year in deciding BC's future. ■

ARV distribution in BC –

A woman's personal perspective



by an Anonymous Contributor

I am an HIV positive woman living in semi-rural British Columbia. I live on Salt Spring Island, located in the Strait of Georgia between Vancouver and Victoria. I love the ocean, the fresh air and the quiet. I was already living here when I was diagnosed with HIV thirteen years ago, in January 1993. I have been living with HIV eighteen years or more. I am now almost fifty years old.

I have a family doctor on Salt Spring Island whom I see for minor medical issues. There is a small hospital and pharmacy nearby, in case something sudden arises. For more serious medical problems that begin with fevers and night sweats, I promptly go to Oak Tree Clinic in Vancouver, where I see a doctor well trained in treating HIV. I go to the clinic regularly every six to eight weeks for blood work, returning two to four weeks later for consultation about the test results. With the driving and the trip on the ferry, a visit to and from the clinic takes about twelve hours. This makes for a very exhausting day, but I know that I am getting the best

care available. Travel to and from specialist appointments is covered by the Transportation Assistance Program (TAP).

Accessing my ARVs has been relatively smooth. I phone in my order to St. Paul's Hospital Pharmacy, which sends the medication by courier to my family doctor on Salt Spring Island. Once, when I had a very low supply of ARVs due to an ordering problem with my prescription refill, I was able to arrange for someone to air courier my medication to Salt Spring on short notice.

We also have a small but dynamic support group on the island that meets monthly. Occasionally, someone runs low on medication, so the group helps by loaning them what they need if possible. In the past, I was very concerned about keeping my HIV+ status confidential; the only people I felt needed to know were my family, my closest friends and medical personnel. It took me a long time to find a local dentist whom I trusted. Recently, I have decided to come out about my health status with more people, but it is a slow process and sometimes difficult. I also know that it has already leaked out, so I don't know who knows and who doesn't.

Living so far from Vancouver is a disadvantage for access to clinical trials. Although some people from Salt Spring Island do participate in clinical trials, I find the travel too hard on my health and very inconvenient. The only trial that I participated in was for therapeutic drug monitoring (TDM). ■

WOMEN'S ISSUES: UPDATE

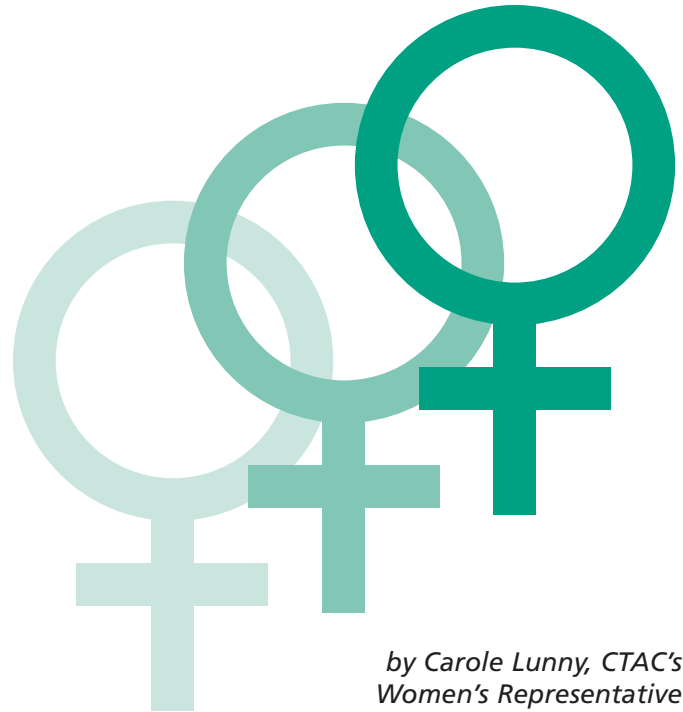
Blueprint for Action on Women and Girls and HIV/AIDS: Women and Leadership

Introduction

Over the past fifteen years, in which there has been a federally coordinated response to HIV/AIDS in Canada, attempts have been made to address the needs of women in prevention, awareness and other supports needed by women living with HIV/AIDS. Unfortunately, this response has not resulted in a lasting strategy to address a full half of the people in Canada who are at risk of contracting HIV—women and girls. There are a number of groups working at different levels, with differing mandates, on issues related to HIV/AIDS and women in Canada. Historically, there has been little coordination on larger policy issues and groups have generally focused on reacting to specific issues, rather than planning for more systemic change. This is a very serious omission given the rising rates of new infections among women, especially young women between 15 and 19, across Canada.

In recognition of this problem, Blueprint for Action on Women and Girls and HIV/AIDS in Canada was established in 2004. The founding organisations were Planned Parenthood Canada, which convened the group with a small grant from Health Canada, Voices of Positive Women, Positive Women's Network, the Canadian AIDS Society and the Canadian Treatment Action Council. These groups all work with and for HIV positive people, with some or all of their mandate being HIV positive women. Blueprint for Action on Women and Girls and HIV/AIDS has grown to include agencies, organisations and individuals serving diverse HIV positive women's populations in Canada and in many parts of the world. Consistent to all of these groups is the priority to address women's health, sexuality, and human rights.

Blueprint for Action on Women and Girls and HIV/AIDS



by Carole Lunny, CTAC's Women's Representative

has developed a comprehensive Blueprint in the areas of legal, ethical and human rights, research, stigma and discrimination, diagnosis and treatment, prevention and education, and care and support. This is a starting point for action to turn the tide of this epidemic that is desimating a generation of women and girls around the world.

A priority for Blueprint for Action on Women and Girls and HIV/AIDS is the involvement and leadership of women living with HIV/AIDS. Many of the individual members are women living with HIV/AIDS and HIV/AIDS advocates. It is a priority to ensure that women living with HIV/AIDS are included in all committees and as leaders of Blueprint for Action on Women and Girls and HIV/AIDS.

HIV+ Women in Leadership Roles

The complex medical and psychosocial issues affecting HIV positive women are often overlooked in population-level approaches to HIV prevention, research, service delivery and policy (CTAC 2005). Women's roles as caregivers, as well as their vulnerability to violence, drug use, economic dependence on their male partners, and fear of authoritarian positions, all prevent women from assuming leadership roles in their communities (PWN 2005). The invisibility of power and privilege affects women's participation in collaborative

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Blueprint for Action on Women and Girls and HIV/AIDS: Women and Leadership

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projects (Champeau & Shaw 2002). Yet women's activities in community groups working in social infrastructure can be defended, supported and financed on the basis of the fact that, by their work, women are producers of quality of life, health, education and culture—in short, producers of socialization and citizenship, and sources of social productivity and, ultimately, of social wealth (Toupin 2001). Blueprint for Action on Women and Girls and HIV/AIDS has recognized these barriers to women's leadership possibilities. Nonetheless, they have overcome them and brought women, some of whom have not previously taken leadership positions, to the forefront of this work.

Providing the Tools for Women to Mobilize and Take Action

Empowering women, strengthening them as actors and decision-makers in their own lives and guaranteeing their rights, increases the power of women as well as that of households, communities, and entire economies (Gupta 2001). The empowerment and leadership of women is needed to end the epidemic. UNAIDS (2000, June) said in its Report on the Global HIV/AIDS epidemic: "In retrospect, our thinking about how to tackle the epidemic was revolutionized by the community-based groups, non-government organizations and associations of people living with HIV/AIDS... Gradually, it was understood not merely that these groups had become key partners in the fight against the epidemic, but that their involvement would continue to be essential and needed to be strengthened."

Blueprint for Action on Women and Girls and HIV/AIDS has long recognized this reality and encourages the social contribution of women and the groups they have formed, and more particularly the value of the work they perform to the communal quality of life and social fabric (Toupin 2001). Specifically, Blueprint for Action on Women and Girls and HIV/AIDS has brought together diverse groups of women in the HIV community to develop a manifesto that is comprehensive and inclusive. It mobilizes all stakeholders to take action in each of their specific areas.

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Recent & Current Blueprint Activities

- Launch of the Manifesto on World AIDS Day 2005 – access it at www.mapleleafmedical.com
- Endorsement of the Manifesto
- Recruitment of International Partners
- International Women's Day, March 8, 2006 Press Release
- Development of Measurable Indicators from the Manifesto
- Preparation of the Manifesto's Backgrounder
- Report Card to Stakeholders to be Launched at the International AIDS Society (IAS) Conference
- Women & Girls' Rally & March at the IAS Conference

Do you want to endorse or participate in the Blueprint for Action on Women and Girls and HIV/AIDS? There are committees, ranging from International AIDS Conference Planning, to Stigma and Discrimination, which you are welcome to join. For more details on the committees, endorsement and other ways you or your organisation can participate, contact:

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CROI UPDATE

March, 2006

by Louise Binder, CTAC Chair

The Conference on Retroviruses and Opportunistic Infections (CROI), generally considered the best HIV scientific conference of the year, had a number of high notes this year.

Treatment experienced people are particularly concerned with research for new treatments, generally called second generation therapies that have a different resistance profile from those currently available. The news at CROI was quite promising on this front.

In the protease inhibitor (PI) class, TMC-114 is in a large Phase III trial. Reports at CROI showed that at 24 weeks, 600 mg. of TMC-114 boosted with 100 mg. of ritonavir taken twice daily was effective in reducing participants' viral load to below 50 copies. Participants were PI, non-nucleoside reverse transcriptase (NNRTI) and nucleoside reverse transcriptase (NRTI) treatment experienced on a failing PI-containing regimen with at least one primary mutation and a viral load of over 1000 copies. Even those who had resistance to PIs, including those who apparently had resistance to tipranavir (Aptivus®), generally responded to TMC-114.

Response to this drug diminished with the number of baseline mutations conferring resistance. If the number was above 10 mutations, there was definitely less response but, even above 10, the response to TMC-114 was better than current protease inhibitors in use.

Safety data suggest no apparent relationship between TMC-114 and rash, lipid elevations, cardiac and liver problems, or glucose intolerance. It does not appear to cause gastrointestinal, psychiatric, or nervous system problems.

This drug is presently available through an expanded access programme in Canada. Representatives from CTAC discussed the programme with Tibotec, a division of Ortho Biotech, the manufacturer of TMC-114. It is available to people experienced with the three existing drug classes who have limited or no options available, due to virologic failure or intolerance to multiple drug regimens. It does not matter what your CD4 count is for entry. There is no limit on the

number of entrants. If you are interested in entering this trial, you should speak to your doctor about whether you may be eligible for the program.

This same company also has a non-nucleoside, TMC-125. At CROI, 24 week Phase IIb data showed that this NNRTI with the best available background antiviral regimen, was active in people with resistance to the other NNRTIs (nevirapine and efavirenz), as well as at least three primary PI mutations. One important note is that TMC-125 should not be taken with tipranavir (Aptivus®) since it lowers the level of TMC-125 to sub-therapeutic levels. The need for a novel NNRTI is urgent, given the fact that resistance to present NNRTIs is conferred by one primary mutation and that cross resistance is common in this class. The company is presently enrolling for Phase III of this trial and there will be a number of sites in Canada.

CTAC representatives discussed this drug with the company after CROI and learned that the company is not planning an expanded access programme for this drug until sometime next year, so access will be limited to the trials.

In addition, there was a poster showing the first clinical results of the virologic response of ten heavily treatment-experienced people to TMC-125 plus TMC-114, boosted with ritonavir and two or more NRTIs. Eight of the ten, all of whom had substantial PI and NNRTI resistance, achieved an undetectable viral load below 50 copies by week 12. While this is preliminary, it is a hopeful sign that these new compounds may be a good treatment option for this population.

48 week data were presented on the RESIST trials that compared tipranavir boosted with 200 mg of ritonavir to comparator PIs, in people previously treated with PIs, NRTIs and NNRTIs who were on a failing PI-based regimen. 33.6% of those in the tipranavir arm achieved a one or more log drop in viral load from baseline, compared to 15.3% in the other group. Higher CD4s and lower viral loads at baseline were independently associated with a better result. Unfortunately, tipranavir can cause serious liver problems, and elevated cholesterol and triglycerides.

Another very encouraging report concerned a second generation fusion inhibitor, also known as an entry inhibitor drug. Enfuvirtide (Fuzeon®), a first generation drug, is approved for sale in Canada. It has been shown to be

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CROI Update

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effective for multi-drug-class experienced people, particularly when taken with other active drugs. Unfortunately, this drug must be administered by injection twice daily, causing serious injection site reactions. Trimeris, the company that makes this drug, announced at CROI that two second generation candidates, TRI-999 and TRI-1144, have shown even better virologic response in vitro than enfuvirtide and are administered by a weekly injection. The company is looking into the possibility of an inhaled method of administration, which would be even more user friendly. While these are early findings, they are certainly encouraging for a class of drugs that is a much needed part of the HIV armamentarium.

The ongoing question of whether we can take breaks from our drugs (Treatment Interruptions) when we have high CD4s and low viral loads continued to be a topic of discussion. Among the studies presented was one that compared people who stayed on therapy to those who stopped when CD4s were above 350, and watched until their CD4s dropped to below 250. The conclusion was that those who interrupted therapy were at greater risk of

disease progression, serious complications and death than those who stayed on therapy continuously. There was much controversy and discussion about these results, so it appears that a definitive answer to this question has not been found.

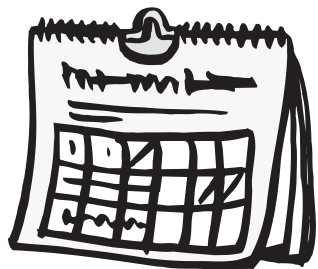
In addition to the encouraging news about new drugs in existing classes, there were reports of new classes of drugs that are moving ahead in trials. One such class is integrase inhibitors, integrase being one of three main enzymes required for HIV to replicate. Merck has been working on an integrase inhibitor for ten years and they appear to be finally succeeding. In early trials, MKO518 appears to bring HIV to undetectable levels when added to a failing drug regimen. Gilead's integrase inhibitor GS9137 appears to reduce the amount of virus in an early ten day trial.

Yet another new class, maturation inhibitors, has a candidate drug, PA 457 in early stage trials.

A third new class, entry inhibitors, is also moving ahead after a few false starts. Schering-Plough's vicriviroc, a CCR5 receptor antagonist, and Pfizer's maraviroc are still being studied, as are three CXCR4 receptor antagonists.

With all of these new drugs, and some in new classes in development, the future for research in HIV looks promising. ■

Save the date!



August
13 to 19,
2006

XVI International AIDS Conference – Toronto

Time to Deliver

The AIDS 2006 Conference Theme *Time to Deliver* underscores the continued urgency in bringing effective HIV prevention and treatment strategies to communities the world over.

The conference is one of the most important gatherings for the release and discussion of key scientific developments in the fight against HIV/AIDS. Some 20,000 researchers, doctors, epidemiologists and people living with HIV from around the world will convene in Toronto, Canada for the opportunity to share progress in scientific, social, policy and advocacy research in a combined effort to stem the tide of the pandemic.

For more information, and to register online, please visit:

www.AIDS2006.org



Blueprint for Action

continued from page 9

Conclusion

The Blueprint for Action on Women and Girls and HIV/AIDS continues to move forward in its goal to advocate for inclusion of HIV+ women's issues on the agenda for the International AIDS Society (IAS) Conference in August of 2006. Committees are currently working on developing measurable indicators for an upcoming report card on Women and HIV/AIDS to be launched at the IAS conference. For the Blueprint for Action on Women and Girls and HIV/AIDS women currently working on these issues, there is no shortage of challenges. Notwithstanding these challenges, women living with HIV/AIDS and their supporters have joined together in an endeavour that has helped to reshape the dialogue about HIV beyond health and social services, to include social determinants of health, human rights, social justice and harm reduction. Blueprint for Action on Women and Girls and HIV/AIDS will continue to lead the way in empowering HIV positive women to get

On a personal note...



What barriers stand in the way of accessing the HIV treatment that you need? Do you have a story to share about how you advocated for access to a treatment or therapy for yourself or on behalf of someone else? We want to hear your stories! **The next issue of the newsletter will have an article on Lipodystrophy and one on Aboriginals.** If you have a story to share about access to treatment related to these stories, tell us! Contact the CTAC office (see page 14) for more information. *Confidentiality will be respected. We may not print all stories submitted.*

involved in the fight for equal rights, opportunities, needed services and access to treatment. ■

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CALENDAR OF EVENTS

SPRING/SUMMER 2006

● May 2-6

Embracing Our Traditions, Values, and Teachings – Native Peoples of North America HIV/AIDS Conference

Anchorage, Alaska

Contact: (301) 628-3123, 1 800 749-9620, or embracingourtraditions@s-3.com

● May 25-28

Canadian Association for HIV Research (CAHR)

Quebec City, Quebec

Contact: (418) 658-8850 or cahr2006@agoracom.qc.ca

● June 4-7

HIV Prevention Leadership Summit

Dallas, Texas

Contact: (202) 483-6622 or info@nmac.org

● June 14-18

Canadian AIDS Society (CAS) 2006 People Living with HIV/AIDS Forum & Annual General Meeting

Ottawa, Ontario

Contact: (613) 230-3580 ext. 135, 1 877 998-9991, or darrenf@cdnaids.ca

● June 21-23

International Symposium on HIV & Emerging Infectious Diseases (ISHEID)

Toulon, France

Contact: +33 (0) 1 41 92 01 20 or hivcongress@overcome.fr

● August 12

Indigenous People's Satellite

Toronto, Ontario

Contact: (416) 933-9300 ext. 226 or 231, or info@2spirits.com

● August 13-18

The XVI International AIDS Conference

Toronto, Ontario

Contact: (416) 840-3334 or info@iasociety.org

● November 3-7

Canadian Treatment Action Council Annual General Meeting and Skills Building

Montreal, Quebec

Contact: (416) 410-6538 or www.ctac.ca

Join CTAC at its AGM and for a day of skills building in Montreal! All members are welcome to attend.

Please www.ctac.ca for details and to register for the day.

CHAIR'S REPORT

SPRING 2006

by Louise Binder



SPRING IS THE SEASON of hope and renewal. So, I would like to share a few of my hopes with you. First, I hope that

all of the new medications and classes of drugs that we have been hearing about lately are as safe, effective and durable as early trials suggest. We need safer drugs and, particularly for treatment-experienced people, we need effective and durable drugs that have a resistance profile different than current treatments. Time, trials and post market surveillance will tell.

I also hope that we are going to have a health care delivery system and a drug reimbursement plan for Canadians to access these treatments. Here, I find myself less hopeful by the day. At the provincial level, governments are announcing new health care strategies and programmes that are pushing people toward private health care. These plans are proposed in the name of shortening wait times, which is certainly laudable, but the approaches being proposed will definitely erode, if not actually breach, the law requiring public medical care.

The new federal government, which is supposed to be the protector of our public system, has lauded one provincial plan and is said to be studying another for later comment. This new government in itself is not a hopeful sign, in terms of its health care platform. Some of its Ministers have been proponents of private health care in previous political careers. They have also shown a lack of enthusiasm for any form of a national drug reimbursement plan that would ensure access to the best available medications across the country and for all populations.

Because of its minority position, it has been keeping as low a profile as possible about health care issues, except wait times. It hopes we won't notice.

The HIV/AIDS community has always been in a leadership position when it comes to health care issues. It is time to renew and reinvigorate our efforts. We must demand from all of our governments an accounting of how their plans for health care in this country will meet the minimum requirements of the Canada Health Act and the needs of the Canadian people. Our system is the envy of the world and the "world" will be watching as Canada hosts the 2006 International AIDS Conference in Toronto in August. What better time to expose Canada's lack of commitment to this system at every level. ■

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 Ward Health Strategies

CTAC POSITION PAPERS

Papers

- 2001 - "Improving our Health: The Need to Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada", author: David Garmaise.
- 2001 - "Making Treatments Accessible: A Policy Paper on Determining Appropriate Pricing for Brand-name Pharmaceutical Treatments for HIV/AIDS in Canada", author: Glen Brown.
- 2000 - "Position Paper on Direct to Consumer Advertising (DTCA) of Prescription Medications", author: Philip Lundrigan.
- 1999 - "Timeliness and Transparency: Assessing the Review Process for HIV Drugs", author: David Garmaise.

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Membership applications are available by contacting the CTAC office or by visiting the CTAC web site at www.ctac.ca/en/membership.

Full Membership

- Person living with HIV/AIDS
- Group, organization and/or project with a substantive HIV/AIDS mandate

Associate Membership

- Any individual
- Group, organization and/or project with a partial HIV/AIDS mandate which coincides with the objectives of the Corporation

CONTACT US

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Website: www.ctac.ca

CTAC's Mandate

To secure and ensure access to therapies and treatments for people living with HIV/AIDS by working with the public, private and not-for-profit sectors.

CTAC...

- Informs research and public policy, and promotes public awareness;
- Provides mentoring and skills building in these areas to people living with HIV/AIDS;
- Encourages and facilitates the exchange of related information to stakeholders;
- Builds and works with coalitions to address broader health care issues impacting access to therapies and treatments.

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