CANADIAN TREATMENT ACTION COUNCIL

INSIDE

JUNE 2003
VOLUME 5
ISSUE 2

What's new? Update on Treatments. 1
CTAC meets in Halifax. 3
CTAC holds Hepatitis C/HIV co-infection forums across Canada. 4
Announcements and Awards. 5
CROI report on treatment issues for women: More work is needed. . . 6
CTAC in Halifax: The joys of drug resistance!. 7
Provincial Updates 8
Clinical Trials – Update. 10
National Pass Study. 10
Action Alert Update. 10
Chair's Report. 11
Calendar of Events. 11
Board and Council Members. . . . 12
Annual General Meeting. 12

What's new?

Update on treatments

by Louise Binder

The recent U.S. Conference on Retroviruses and Opportunistic Infections (CROI) was somewhat uplifting for a change, with research news for both treatment naïve and experienced people.

NEW DRUGS/NEW TARGETS

Farthest along in development are entry inhibitors which stop HIV from entering the human immune cell. There are three types: CD4 receptor blockers, co-receptor blockers and fusion inhibitors.

TNX-355 is a receptor blocker in Phase 1-2 clinical trials. It produced a 1 log drop in viral load with no apparent side effects.

Co-receptor inhibitors, blocking either the CCR5 or CCXR4 receptor are in early clinical or pre-clinical trials. The CCR5 inhibitors included AK-602, TAK-220, and UK-427,857. In Phase I trials, they all look promising.

Fusion inhibitors, T-20 (Fuzeon) and T-1249, are well along in trials on treatment experienced people. Fuzeon has produced an additional 1 log viral load decrease compared to people on therapy without Fuzeon.

Unfortunately both drugs require subcutaneous intravenous injections daily, causing injection site infections and nodules under the skin that do not necessarily go away. Preparation is problematic, requiring stirring Fuzeon into water carefully for over half an hour before using each day.

The price of the drug is stratospheric. In the U.S. where it has been approved for sale, it can cost over $20,000 U.S. (about $30,000 Canadian).

In a short clinical trial, T-1249 remained potent against HIV in people taking a failing T-20 regimen.

Another new class of drug talked about at CROI was a maturation inhibitor, PA-457, made from pulp by-product. Its method of action is unknown, but in the test tube it appears to stop the virus from fully maturing. Human trials of this drug are planned for mid-2003.

The class of drugs called integrase inhibitors is still being developed. It targets HIV after entering the cell but at a different point in its development than nucleosides or protease inhibitors. One pre-clinical study of an integrase inhibitor, V-165, found that it was effective in inhibiting

continued on next page

SYSTEMIC TREATMENT ACCESS ISSUES FROM CROI

1. **NEW DRUGS/NEW TARGETS**

   CTAC will monitor the development of these drugs and will advocate for early compassionate and expanded access to successful candidates at the earliest appropriate time for those without other viable treatment options.

2. **NEW DRUGS/OLD TARGETS**

   CTAC worked with Bristol-Myers Squibb to ensure a fair expanded access programme for atazanavir in Canada.

   CTAC worked with Gilead to ensure a fair expanded access programme for tenofovir in Canada. When Gilead closed the programme in December summarily, CTAC was instrumental in getting the programme reopened at least for those most in need.

   CTAC continues to work with Boehringer-Ingelheim to ensure that there will be an expanded access programme for tipranavir as soon as feasible.

   CTAC is closely monitoring the drug review regulators at both the federal and provincial levels to ensure a timely, comprehensive review of each of these drugs for sale and for reimbursement. CTAC will intervene as required.

   CTAC will complete its Post Approval Surveillance System (PASS) research study and will advocate with governments for a consumer-centred PASS to track long-term side effects of approved drugs.

   CTAC is closely monitoring drug prices as well as the review of these prices by government agencies to ensure that prices are within guidelines. CTAC will intervene as required.

What's new? Update on treatments

continued from page 1

integrase, the enzyme required by HIV to insert its viral DNA into the host cell.

NEW DRUGS/OLD TARGETS

While awaiting new drugs, there is increasing recognition of the need for safer drug treatments. There were some reports of drugs that may meet these needs.

One of these is atazanavir (ATZ), a protease inhibitor that may not raise lipids (fats in the blood i.e. cholesterol and triglycerides) linked to heart disease and diabetes. At CROI, 108 week results were reported in a trial of naïve people comparing ATZ versus nelfinavir (NFV) with d4T and 3TC. Virologic and immunologic responses were sustained and equivalent in both arms.

Importantly, LDL (bad cholesterol) and triglycerides remained almost unchanged in the ATZ arm while rising significantly in the NFV arm. Switching from NFV to ATZ brought both these markers down somewhat. Regarding resistance, I50L, the ATZ signature mutation, may actually confer sensitivity to other protease resistant virus, however where more than 5 mutations were present cross-resistance to other protease inhibitors became significant.

Another protease inhibitor, tipranavir (TPV), is being studied in multiple drug-experienced people. At CROI, it was reported that comparing three doses of TPV, at 2 weeks all provided viral load drops of between 1.5 and 2 log drops in people with up to 3 protease mutations.

A dosage of 500 mg with 200 mg of ritonavir to boost was selected for Phase III trials.

OTHER DRUG UPDATES

The hotly awaited trial results of the head to head comparison of two non-nucleosides, nevirapine (NVP) and efavirenz (EFV) were reported. It was a large four arm study of 400 mg once a day NVP versus 200 mg BID NVP versus 600 mg once a day EFV versus 400 mg NVP + 800 mg EFV, each arm with d4T + 3TC. Whether the trial proved that NVP and EFV were equivalent depends on which researcher you ask. The consensus seemed to be that the two drugs had similar efficacy but very different side effect profiles.

continued on next page

What's new? Update on treatments

continued from page 2

Further research on the nucleotide tenofovir (TDF) was presented. At 96 weeks it is still showing good immunologic and virologic results in naïve people. In clinical practice, the most serious adverse events reported have been kidney impairment/failure. It was also reported that when co-administering ddI EC and TDF, the dosage of ddI EC should be reduced from 400 mg to 250 mg with a light meal as TDF increases the amount of ddI EC in the blood by 40%.

A study showed that the risk of myocardial infarction (heart attack) increases with the number of years on highly active antiretroviral therapy independent of other risk factors. Smoking, lack of exercise, high cholesterol, hypertension and high blood sugar are such factors.

STRUCTURED TREATMENT INTERRUPTION

For Virally Suppressed HIV+ People

Because of drug toxicities and adherence issues, structured treatment interruptions are an important area of study. They are potentially risky, e.g. CD4 cell drops, viral load increases, emergent resistance, side effect reoccurrence and inability to regain viral control upon restart.

In earlier studies all but 7 days on/7 days off has been found unsafe and ineffective. At CROI, this was compared to staying on continuous treatment or "guided" treatment interruptions for people with > 350 CD4s in one trial and > 500 CD4s in another. They returned to therapy when their CD4s were < 350 (in one trial) or < 350 or a 30% decline in the other trial.

7 on/7 off was not successful, but the guided arm had viral suppression after 48 weeks although lower CD4s than the continuous arm.

For Those on a Failing Regimen Before Switching

Two trials came to opposite conclusions on this point, one finding that a 4 month break before switching made no difference in the efficacy of the next regimen while another found that those in the 8 week interruption arm did better than those who immediately went on a new therapy. ■

CTAC meets in Halifax

by John Arenburg

Halifax, Nova Scotia was the site for CTAC's recent in-person Board meeting and skills building day. Nova Scotia representative, John Arenburg, kicked off the event with a "meet and greet" for about 30-40 people living with HIV/AIDS and community workers at the AIDS Coalition of Nova Scotia.

The skills building day was a successful event which included workshops on *Telling Your Story: How to Decide, Advocacy 101* and an interactive panel discussion.

The panel, which included Dr. Rod Wilson, Marg Dwyer, Arnold Wentzell and John Arenburg, discussed what they felt were the key issues in Nova Scotia related to HIV/AIDS and access to treatment. Many of the issues that were brought to the attention of the group were of rural concern. HIV positive persons sometimes have to travel one or two hundred miles to get to the HIV clinic in Halifax. Recommendations included satellite clinics throughout the province. Panelists revealed that the only place in Nova Scotia to get HIV meds is at the QEII Health Centre in Halifax and that there is a concern about confidentiality when distributing medications to rural areas. They also voiced concern over the lack of knowledge on HIV/AIDS related issues by rural doctors.

In a group discussion, there was agreement that the issue of non-HIV medications not being covered under the Pharmacare program in Nova Scotia is a major barrier to treatment for many people living with HIV/AIDS. There was a great enthusiasm within the group to try to fix this problem in Nova Scotia. Contact John Arenburg at john@ctac.ca for more information about how to get involved. ■

Louise Binder, Chair

Ron Rosenes, Board Member and John Arenburg, Nova Scotia Rep.

CTAC holds Hepatitis C/HIV co-infection forums across Canada

It is estimated that as many as 30% of individuals in Canada who have HIV also have Hepatitis C.

CTAC, in partnership with many stakeholders, is helping to organize Hepatitis C/HIV Co-infection Forums in British Columbia, Ontario, Quebec and Nova Scotia. The purpose of these forums was to develop integrated strategies that address the growing challenges associated with the Hepatitis C/HIV co-infection epidemic in Canada.

British Columbia

by Zoran Stjepanovic

Medical doctors and community provided information on co-infection transmission, treatment, prevention and support, recommending best practices for the cost-effective prevention and care of HCV.

Key strategies identified:

- There is a need to lobby the government for immediate Pharmacare coverage for Hepatitis C drugs, most notably pegylated interferon.
- The BC Centre for Excellence in HIV/AIDS already has a best practice model for the management of HIV-positive people. There was unanimous support that the BC Centre for Excellence be mandated and empowered financially to manage the care and treatment of persons co-infected with HIV/HCV.
- Improved access to liver transplantation for co-infected patients is essential.
- A Provincial Co-infection Steering Committee on HIV/HCV needs to be formed to carry out many of the strategies discussed in the report.
- The key areas identified in the report include public education, targeted prevention, addiction treatment, harm reduction, as well as collaboration and coordination in the prevention, care and treatment of HIV/HCV.
- There needs to be political lobbying at all levels of government for increased funding, access to treatment, prevention, community outreach and community control of services.

Ontario

by Enrico Mandarino

Over 30 participants including those living with HIV/HCV took part in the forum. Medical doctors brought the most up to date information regarding Hepatitis C/HIV co-infection including pathogenesis of HCV, clinical trials in co-infection, liver transplants, and current and new treatment options.

Key Strategies identified:

- **Government:** Need for political lobbying at all levels of government for increased funding for a cure for HCV and treatment for those who cannot be cured.
- **Education/Prevention:** Resources for media, public schools and AIDS Service Organizations to educate about Hepatitis C on epidemiology, prevention and populations at risk. Targeted prevention programs must be set up for at-risk population including prisoners, Aboriginal people and injection drug users.
- **Treatment/Research:** There are few options and drugs available to treat Hepatitis C/HIV co-infection. There must be expanded coverage to all HCV drugs. More research is needed on co-infection and liver transplants. National standards are needed on co-infection and liver transplantation. There needs to be special access/care for populations at most risk.
- **Clinical Partners:** Multidisciplinary professionals are needed including doctors, nurses, dieticians, complementary and alternative medicine specialists to act as co-infection "care teams" and to set up a Toronto clinic model.

Another Hepatitis C/HIV co-infection forum is being planned in Sudbury, Ontario.

continued on page 5

CTAC holds co-infection forums

continued from page 4

Atlantic

by George Clark-Dunning

The Atlantic HCV/HIV Co-infection forum took place in Halifax on April 9 with approximately 38 participants in attendance. In the Atlantic region the actual number of people living with Hepatitis C is very hard to determine, as family doctors are not asking the right questions of patients.

Medical professionals reinforced the message that early detection of Hepatitis C and/or HIV is critical to effective treatment.

Key strategies identified:

- The development of partnerships for action.
- Identification of patients with Hepatitis C/HIV co-infection.
- Increasing physician awareness of symptoms, risk, and the right questions to ask.
- Public education - both on the severity of the problem and the transmission of the disease.

Quebec

by Françoise Grothé

The Quebec Hepatitis C/HIV Forum will take place in September at the Hotel-Dieu Hospital auditorium. The treatment portion will be organized with the participation of CPAVIH and the "Programme national de mentorat du VIH au Quebec" providing HIV training programs for professionals. There will also be a discussion group for persons living with HIV/AIDS and the Hepatitis milieu to discuss strategies on Hepatitis C/HIV co-infection in Quebec. For more information about this forum please contact Françoise Grothé at Francoise@ctac.ca.

National

CTAC is now planning a National Multi-stakeholder Consensus Forum on Hepatitis C/HIV co-infection to be held in 2003. ■

A full report of these forums will be made available on the CTAC website at

www.ctac.ca

Announcements and Awards

Aboriginal AIDS Activist has passed on

CTAC regrets to inform its membership of the death of Alex Archie on May 7, 2003, at his home in British Columbia. Alex was a CAAN member and well-known and respected AIDS activist in Canada. Alex was a founding Co-Chair of the Red Road HIV/AIDS Network, a Board member of the Canadian Aboriginal AIDS Network and Canadian AIDS Society, and worked at Healing Our Spirit. His courage, his love, his respect for his Aboriginal brothers and sisters, and his commitment to the causes of Aboriginal people living with and affected by HIV/AIDS will never be forgotten.

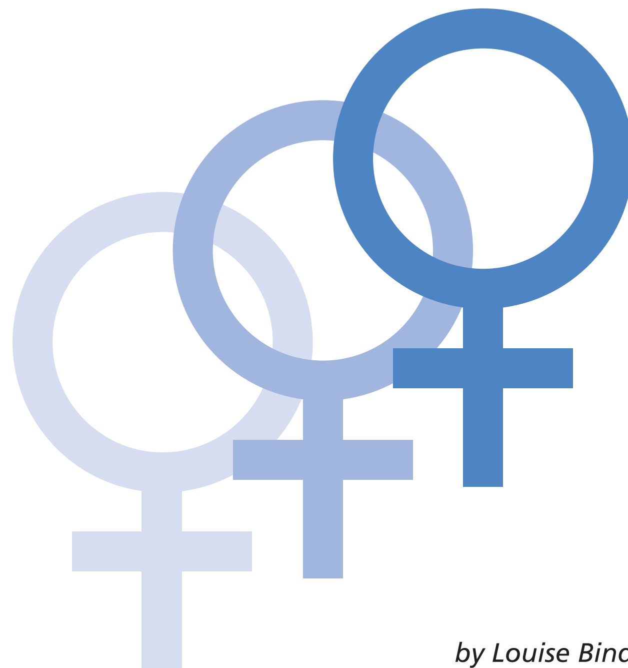
Board and Council Members are recognized for their achievements!

CTAC's contributions and achievements in the HIV/AIDS community could not be possible without the hard work of the individuals who make up CTAC's Board and Council, many of whose work has been recently recognized with awards. CTAC is pleased to announce that **Glen Hillson**, Vice-Chair, is this year's recipient of the **Canadian AIDS Society's Leadership Award**. At this year's Canadian HIV/AIDS Research Conference, **Paula Braitstein**, BCPWA representative to CTAC, was awarded the **Young Investigator's Award**. Congratulations Glen and Paula!

In commemoration of the 50th anniversary of the reign of Queen Elizabeth II over Canada, the Golden Jubilee Medal will be awarded to Canadians who have made a significant contribution to their fellow citizens, their community or to Canada. CTAC wishes to congratulate all the recipients from the HIV/AIDS community, and partner communities, in particular the following current and former Board and Council recipients:

- **Louise Binder**, Chair
- **Tony Di Pede**, Treasurer
- **Glen Hillson**, Vice-Chair
- **Shari Margolese**, Board Member and National Women's Representative
- **Ron Rosenes**, Board Member and AAN! Representative
- **Phil Lundrigan**, Board Secretary and Newfoundland & Lab. Representative
- **James Kreppner**, Canadian Hemophilia Society Representative
- **Tom McAulay**, former Co-Chair and BCPWA Representative
- **Bob Mills**, former Board Member and Alberta Representative ■

CROI report on treatment issues for women



More work is needed

by Louise Binder

The recent Conference on Retroviruses and Opportunistic Infections (CROI) in Boston provided little new information on women's treatment issues. Although researchers seem interested in addressing women-related issues, few clinical trials have included enough women to draw meaningful conclusions. One researcher looked at exclusion criteria in a number of trials compared to women in a large U.S. study and concluded that exclusion criteria such as taking antidepressants and intravenous drug use would exclude many women from trials.

One study showed that Vitamin A supplementation does not change the course of disease progression. A large trial indicated that the use of oral contraceptives and injectable depot medroxyprogesterone acetate (DMPA) at the time of HIV infection was associated with higher initial viral load and may accelerate disease progression.

Women generally have a lower viral load than men, but that does not seem to lead to differences in disease progression. Antiretroviral trials have not shown a great difference in health outcomes between the sexes but small female participation makes it hard to generalize.

Women may respond better than men to some antiretroviral drugs, like indinavir and nelfinavir, due to lower body weight. More studies need to be done to confirm this and to determine if women actually need as much drug as men. If not the risk and severity of side effects might be reduced and adherence enhanced. This is important because some studies do suggest that women have more severe side effects and toxicities e.g. kidney problems with Crixivan; more lipodystrophy, especially fat accumulation, generally attributed to protease inhibitors and nucleosides; more lactic acid in the blood, often accompanied by a fatty liver, generally thought to be caused by nucleosides. Women also experience more rash, especially due to non-nucleosides as well as to the nucleoside, abacavir. There is an increase in pancreatitis (swelling of the pancreas) in women on HIV medications.

Although unproven, women are possibly more prone to bone density loss (osteopenia and osteoporosis) due to drugs. Women have more bone loss at menopause and HIV drugs cause bone loss. Appropriate diet and exercise can help to minimize bone loss.

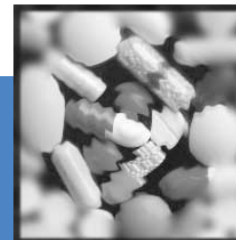
The jury is out on hormone replacement therapy (HRT) in women generally. For HIV + women, there are additional risks, since oral estrogen is processed through the liver (and gall bladder) and HIV drugs use the liver as a pathway. If you are at risk for diabetes (which you may be with HIV drugs), uterine fibroids or blood clots you should avoid HRT. Long term use of estrogen has also been linked to breast cancer.

One of the most notable drug-drug interactions specific to women is between protease inhibitors and non-nucleosides with oral contraceptives. **Nelfinavir, ritonavir and nevirapine should not be taken with oral contraceptives.** SUSTIVA (efavirenz) raises the amount of oral contraceptive in the blood. Crixivan (indinavir) has no effect.

There is still an ongoing need for much more work on women specific trials and for more women in planned trials. ■

CTAC in Halifax April 10-13

The joys of drug resistance!



By Philip Lundrigan

The 12th Annual Canadian Association for HIV Research (CAHR) Conference was held in Halifax, April 10th-13th, 2003. The potential benefits of drug resistance were discussed in a satellite symposium entitled *Perspectives on Planning for Treatment Success*. Dr. Elizabeth Race from Dallas, Texas presented on *Viral Fitness: Practical Applications in the Clinical Setting*. She described three classes of patients failing treatment:

1) those who begin treatment but do not fully suppress viral load;
2) those on treatment who achieve undetectable viral load but have a subsequent rebound; and
3) those on treatment who have never had undetectable viral load.

Some patients for whom treatments have failed appear to have decreased incidence of opportunistic infections (OI) if they stay on their failing regimen. Even a transient virologic response is associated with an increase in CD4+ cells.

Dr. Race defined three measures of viral activity:

1) **viral fitness** - ability to reproduce in a defined environment, i.e., under pressure of treatment;
2) **replication capacity** - ability to infect target cells under ideal conditions, i.e., test tube; and
3) **virulence** - ability to cause disease, otherwise known as pathogenicity.

Dr. Race indicated that an increase in drug resistance is significantly correlated with reduced replication capacity. Certain resistance mutations appear to render the virus less fit to replicate. The 184V mutation, associated with 3TC resistance, helps reduce replication capacity by 57%. Nucleoside reverse transcriptase inhibitor (NRTI) and protease inhibitor (PI) mutations reduce replication capacity while non-nucleoside reverse transcriptase inhibitor (NNRTI) mutations do not. Mutations associated with Nelfinavir resistance, such as D30N, appear to be very unfit to reproduce.

Increased numbers of resistance mutations result in less replication capacity, and reduced replication capacity results in lower viral load. To summarize, Dr. Race indicated, "HIV may be constrained in its ability to both become highly resistant and highly fit," and, "It may be reasonable to continue HAART [highly active antiretroviral therapy] despite persistent viremia when CD4+ cells are stable." She discussed an apparent paradox in that a patient can achieve immunologic stability despite virologic failure. There is still the ability to enhance CD4 recovery and delay changes in treatment regimens, saving future treatment options, even with a PI-resistant virus.

What level of viral load is acceptable?

According to Dr. Race, viral load levels less than 1,000 copies/ml are extremely good and present minimal risk of disease progression. Viral load levels between 1,000 - 5, 000 copies/ml are generally not problematic while CD4+ remains stable. Viral load levels between 5,000 - 10,000 copies/ml need to be monitored carefully. In this situation other factors such as CD4+, current or previous OIs, other illnesses/conditions and available treatment options must be considered. When viral load increases to over 10,000 copies/ml there is the potential for a further reduction in CD4+ cells and a reduced ability to regain CD4+ cells that have been lost. Dr. Race indicated that the clinical implications of maintaining detectable viral load levels are unknown and more research is required. ■

PROVINCIAL UPDATES

Formulary issues continue to be a concern in the provinces

ONTARIO

by Enrico Mandarino

Since the release of the November *Action Alert* "Ontario Formulary Coverage At Risk" (see www.ctac.ca), advocacy efforts have included meeting with government officials and sending letters to the Ministry of Health and Long Term Care, asking why badly needed medications and vaccines were not being provided in Ontario.

The government did not respond to CTAC's concerns. In January 2003 a group of leading health advocates, physicians and community groups held a media conference and spoke out against the Ontario Government for withholding life saving medicines from some of the province's sickest and most vulnerable people. The groups also released a list of medicines for life threatening and chronic diseases for which access was being restricted by the Ontario Government.

As a result of the media conference, the Ontario government has finally agreed to cover the cost of vaccines for HIV positive children in Ontario and to work collaboratively with the groups to improve access to the drugs.

While these advocacy efforts were successful, this group, led by CTAC, will continue to carefully watch the progress with regard to the other treatment access matters and Ontario formulary issues.

Plans are also underway for an Ontario CTAC Network workshop and skills building day in collaboration with the Ontario AIDS Network, scheduled for the end of September 2003. The day will include identifying access to treatment issues in Ontario and electing the Ontario Representative to CTAC.

MANITOBA

by Daryn Bond

The Manitoba Government has been full of surprises lately. After an eighteen-month battle, Kaletra was granted coverage under Pharmacare, the provincial drug formulary, December 1, 2002. Expecting similar delays, advocates were rendered speechless upon the sudden addition of DDI-EC, Trizivir and Pegetron (PEG-Interferon plus ribavirin for Hepatitis C) May 1, 2003. Looking ahead to tenofovir and T-20 only time will tell if these kinds of efficiencies will continue. Nevertheless, Manitobans living with HIV/AIDS are relieved to be able to access these important medications.

The Manitoba AIDS Cooperative recently held a consultation on the development of an Aboriginal Strategy on HIV/AIDS in Manitoba. An Aboriginal strategy needs to be Aboriginal-led, coordinated, and well-supported, to provide a comprehensive response to HIV/AIDS that includes Traditional therapies, treatment, healing and support.

PRINCE EDWARD ISLAND

by George Clark-Dunning

At the time of writing this report, the PEI Drug Review committee is meeting with its Atlantic counterparts. Discussions will likely include new drugs coming onto the marketplace for the treatment of HIV and Hepatitis C.

Currently drugs such as T-20 and Pegetron are not available. Fuzeon, which would be covered under the Drug Cost Assistance Program, has not yet been prescribed to anyone on this program. Rebetron is available and is being used, but the drug has failed for some, and the high cost of Schering's drug, Pegetron, has resulted in it not being listed on the formulary. However, it is hoped that the formularies will add Pegetron as Schering has recently lowered the price to be on par with Rebetron.

According to Statistics Canada there are now between 300-400 people living with HIV in PEI, but this may actually be higher as there is no anonymous testing so many people go off Island for their HIV testing and after care. One of the biggest barriers to treatment for Islanders is distance to Infectious Disease Clinics

continued on page 9

PROVINCIAL UPDATES

continued from page 8

which are located in Moncton, NB and Halifax, NS (which is over 120-300 km away). Transportation to the clinics is an issue and the Provincial Assistance allowance barely covers travel costs.

Another barrier to treatment is the absence of government funding for AIDS PEI, PEI's only AIDS Service organization. The government is funding a part-time position at AIDS PEI for Hepatitis C.

BRITISH COLUMBIA

by Glen Hillson

Over the past decade British Columbians with HIV/AIDS have enjoyed relatively easy access to the newest medicines and to competent care. The latter has been truer in the Vancouver area than in other areas of the province. Many regions do not have an infectious disease specialist, let alone physicians experienced in treating HIV disease.

These days the ease of access to medicines seems to be in some jeopardy. Escalating prices of new antiretroviral drugs have placed an increasing burden on formulary funding for these drugs. At the same time, rumours are afloat that the provincial government, which is intent on limiting drug costs from the public purse, is poised to freeze expenditures for the HIV/AIDS drug program. This could mean that access to some of the newer drugs like tenofovir, fuzeon and atazanavir is more constrained.

For people who are co-infected with HIV and HCV, Rebetron has only been available so far through special authority and the newer pegylated interferon is not covered at all. Many treatment providers are holding off treating patients until they have access to Pegetron, which is the new Schering combination of pegylated interferon plus ribavirin. Schering has recently lowered the price of Pegetron to the same level as Rebetron (the older product) which should remove barriers to formulary coverage, but so far there has been no change in government policy.

Treatment advocates will need to sustain pressure on governments and manufacturers to ensure access to the best treatments available.

Coherent management of patients co-infected with HIV and HCV has also been an advocacy issue that is receiving considerable community attention.

QUEBEC

by Line Carreau and Ken Monteith

On January 30, Abbott laboratories invited the provincial treatment committee to a conference with Dr. Jurgen Rockstroh from Germany on "Challenges in HIV-Infection-Advancing Patient Care." This was a great opportunity to discover ways in which people living with HIV in other countries receive care. Several people from the committee asked Dr. Rockstroh questions on the treatments.

The provincial treatment committee is organizing interactive training sessions with speakers offering updated information on current issues such as:

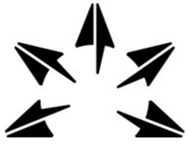
- Medical monitoring of an HIV patient in 2003
- Marketing strategy of the pharmaceutical companies
- Cessation of treatment study, called "STOP"
- Tuberculosis

The committee is working with other resources for the implementation of a procedure allowing "illegal" or "non-status" people living with HIV to have access to treatments in Quebec. A law with the same objectives is in force in France and the committee has identified potential partners such as the Legal Network and immigrant-assistance or cultural community groups.

CPAVIH will be providing basic AIDS training to HIV+ persons once per month. Also financed by GlaxoSmithKline in the form of a project, Dr. Robert O'Brien and Dr. Marc-André Charron will be providing basic drug training sessions for newly infected people living with HIV/AIDS or those considering treatment (based on the example of the current Toronto program).

The committee is working on a project for transferring information to rural areas. The Internet has been considered as a means of exchanging specific information between physicians and patients. We anticipate doing this in the form of an electronic bulletin board on the CPAVIH web site, with the support of the committee and the member groups of COCQ-Sida. ■

Clinical Trials – Update



by Jim Boothroyd,
Communications Manager
at the Canadian HIV Trials Network

Safety warning closes co-infection study

A safety warning has prompted the Canadian HIV Trials Network to stop a pilot study of treatment options for people co-infected with HIV and Hepatitis C.

The decision follows a meeting of the Network's Safety and Efficacy Review Committee in Halifax on April 9 with Dr. Marina Klein, the Principal Investigator of CTN-141. At the meeting, members discussed a recent recommendation of the Food and Drug Administration (FDA) in the United States that two of the study drugs, ddI and ribavirin, should not be used together in this population because of the toxicity risk.

The FDA decision is based on concerns that the combination might put people at an increased risk of mitochondrial toxicity. Common symptoms of this condition are pancreatitis, lactic acidosis, abnormal liver function, and hepatic steatosis.

Dr. Klein gave a comprehensive presentation of what is known about the relationship of this drug combination to mitochondrial toxicity. The committee felt that there was sufficient worry about the use of this combination that the trial should be suspended in its current form. The committee, however, reiterated its general support for the trial design and the importance of the research question and urged Dr. Klein and her team to seek out other treatment options for this research protocol.

Since it began in 1990, the Network has implemented more than 80 clinical trials. It has stopped only two owing to safety concerns.

For plain language descriptions of HIV clinical trials now enrolling in Canada, please visit the CTN web site at www.hivnet.ubc.ca/ctn.html. ■

Taking HIV Medication?
Can we have 15 minutes of your time?

Study ends June/July 2003

Adults living with HIV/AIDS and currently on antiretroviral therapies wishing to participate in the study can do so in 2 different ways:

1. **By telephone** - **<u>From January to the end of June 2003</u>**, people living with HIV/AIDS can call toll-free at **1-866-253-7277** to complete the survey with a bilingual interviewer.
2. **By Mail or Fax** - people living with HIV/AIDS can pick up a survey at various ASO's and other locations*, complete it and fax it (toll free) or mail it (postage-paid) to the PASS study offices **<u>until July 2003</u>**.

*For more information, please call **1-866-253-7277** or visit the CTAC website at **www.ctac.ca**. ■

Action Alert Update

by Shari Margolese

CMA reviews testing of pregnant women

When the Canadian Medical Association (CMA) approved routine, opt-out testing of all pregnant women in August of 2002 CTAC, other AIDS service organizations strongly opposed this move and launched a letter writing campaign to encourage the CMA to adopt an opt-in approach. In response to CTAC's letter, the President of the CMA has asked its Committee on Ethics and Council on Health Care and Promotion to review the matter and, if appropriate, to recommend modification of the policy at the 2003 annual meeting. This is an important step toward policy change on this issue. CTAC will report any further developments. ■

CHAIR'S REPORT

SPRING 2003

by Louise Binder

Spring is finally here. The world feels fresh and new at least on an individual and personal level, but as a species we seem bent on annihilation, not creation. We always seem to find enough money to kill or maim each other but never enough to save and to heal each other.

This reality is being played out large in the international arena. A coalition of countries is dropping bombs on impoverished people in the holy name of freedom. But freedom to do what? To die of diseases caused by factors including malnutrition, lack of safe drinking water and lack of even basic treatments. The international AIDS effort has seen this repeatedly. The Global Fund for malaria, tuberculosis and HIV/AIDS is profoundly underfunded. Even the recent U.S. promise of $15 billion for AIDS in Africa is now in jeopardy, with some even arguing that condoms should not be purchased as they are not 100% effective.

In Canada, we are in for a rocky treatment access road too, thanks to the pharmaceutical industry and to the government regulators. The two newest drugs soon for market will be priced far outside anything we have seen before. Tenofovir, a nucleotide, may be as much as twice as expensive as other nucleoside drugs. Even worse, the first entry inhibitor will probably be priced at about CDN$30,000 a year. Drug formularies would groan under this weight. This comes just at the time when most provinces are trying a new common formulary review process, whereby each province will not necessarily decide individually which drugs to cover, but will decide collectively based on the advice of this common drug review agency.

So, enjoy this spring respite, but do not be fooled into thinking it will last without a collective voice speaking loudly, to be heard above those who prefer destroying instead of building. ■

CALENDAR OF EVENTS

SPRING 2003

● **June 17th-22nd**
Annual General Meetings and PLWHIV/AIDS Forums for:
Canadian AIDS Treatment Information Exchange
Contact: info@catie.ca or 1-800-263-1638
Canadian AIDS Society
Contact: CASinfo@cdnaids.ca or 613-230-3580
Montreal, Quebec

● **July 13th-16th**
International AIDS Society Conference
Paris, France
Contact: http://www.ias2003.org/start.aspx or +33 (0)1 40 64 20 00

● **July 27th-30th**
Stemming the Tide of STDs and HIV Conference
Ottawa, Ontario
Contact: information@confersense.ca or 613-232-4414

● **September 12th-14th**
Legal Network Annual General Meeting
Montreal, Quebec
Contact: info@aidslaw.ca or 514-397-6828

● **September 26th-28th**
ICAD Skills Building Workshop and AGM
Ottawa, Ontario
Contact: info@icad-cisd.com or 613-233-7440

● **September 27th-28th**
La Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-Sida) AGM
Montreal, Quebec
Contact: info@cocqsida.com or 514-844-2477

● **October 26th-30th**
11th International Conference For People Living With HIV/AIDS
Kampala, Uganda
Contact: kampalaconference@gnpplus.net or +31 (0) 20 423 4114

● **October 26th-27th, 2003**
Canadian Treatment Action Council AGM and Skills Building
Toronto, Ontario
Contact: ctac@ctac.ca or 416-410-6538
Join CTAC for a day of skills building in Toronto! All are welcome to attend. Please see www.ctac.ca for details and to register for the day.

COUNCIL MEMBERS

BOARD OF DIRECTORS

● CHAIR **Louise Binder** Toronto People with AIDS Foundation (TPWAF)

● VICE CHAIR **Glen Hillson**

● TREASURER **Tony Di Pede**

● BOARD SECRETARY **Philip Lundrigan** Newfoundland & Labrador

Emerald Gibson

Françoise Grothé

Enrico Mandarino Ontario

Shari Margolese National Women's Representative

Ron Rosenes AIDS ACTION NOW! (AAN!)

George Clark-Dunning Prince Edward Island • **John Arenburg** Nova Scotia • **Line Carreau** Québec • **Daryn Bond** Manitoba • **Mark Randall** Alberta • **Daryle Roberts** British Columbia • **Paula Braitstein** British Columbia Persons with AIDS Society (BCPWA) • **Darren Greer** Canadian Aboriginal AIDS Network (CAAN) • **Patrick Cupido** Canadian AIDS Treatment Information Exchabnge (CATIE) • **Ken Monteith** Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-Sida) • **Marc Lapierre** Comité des personnes atteintes du VIH du Québec (CPAVIH) • **James Kreppner** Canadian Hemophilia Society (CHS) • **Patrick McIntyre** Canadian AIDS Society (CAS) • **Richard Elliott** Canadian HIV/AIDS Legal Network

2003/2004 FUNDERS

Health Canada
Ontario HIV Treatment Network (OHTN)
Abbott Laboratories • Agouron Pharmaceuticals • Boehringer Ingelheim • Bristol-Myers Squibb • Gilead Sciences • GlaxoSmithKline in partnership with Shire BioChem • Hoffmann-La Roche • Merck Frosst • Schering Canada

CTAC's Annual General Meeting 2003

CTAC's Annual General Meeting (AGM) will be held in Toronto, Ontario, October 26th-27th. 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

MEMBERSHIP

Membership applications are available by contacting the CTAC office or by visiting the CTAC web site.

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 whose substantive mandate coincides with the objectives of the Corporation

PUBLICATION CREDITS

This newsletter is a quarterly publication.

Editorial Board: Daryn Bond / George Clark-Dunning / Enrico Mandarino (Chair) / Tom McAulay / Françoise Grothé / Ken Monteith • **Editorial Committee:** Shari Margolese / Glen Hillson • **Editorial Co-ordination:** Michelle Marchione • **Translation:** Alain Boutilier, Florinda Lages

Printing: The Printing House

CONTACT US

Canadian Treatment Action Council (CTAC)
P.O. Box 116, Station "F"
Toronto, Ontario M4Y 2L5

Phone: (416) 410-6538
Fax: (416) 761-1012
Email: ctac@ctac.ca
Website: www.ctac.ca

Permission to Reproduce:
This newsletter may be copied for personal use. Content may not be edited and all reprints must include the following text: "From the Canadian Treatment Action Council Newsletter, Volume 5, Issue 2 (June 2003)".

Disclaimer: The content of articles represents the views of the authors and does not necessarily reflect the official policy of CTAC, or of any of its funders. CTAC does not recommend or endorse any therapy or treatment described within any of its print materials.