

Position Paper

**Strategic Initiatives:  
Addressing the Epidemic of HIV and Hepatitis Co-Infection  
in British Columbia**

Prepared for the Honorable Colin Hansen  
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## **Introduction**

Although the BC Persons with AIDS Society has long been aware of the magnitude of the HIV-Hepatitis C co-infection epidemic in British Columbia, it is only recently that the treatment and care obstacles facing people who are co-infected have come directly to our attention. The experience of one of our members in particular has magnified several systemic issues of critical significance to the appropriate care and management of persons who are co-infected. The purpose of the present document is to highlight these issues, and make recommendations regarding how best to address them. The issues can be broadly broken down into three categories:

- 1) Routine patient management issues
- 2) Pharmacare issues
- 3) Solid organ transplantation

It should be noted that a multi-stakeholder meeting regarding the care, treatment, and support of co-infected individuals and the prevention of new HIV/HCV infections that took place on January 24, 2003, independently raised and agreed upon virtually all the recommendations which follow (see Appendix One for the Final Report from this meeting).

## **Background**

### *What is Hepatitis C?*

Hepatitis C is a virus that directly affects the liver by infecting liver cells. Ultimately this process leads to the destruction of the liver [1]. In people who are mono-infected with Hepatitis C (i.e. those who only have Hepatitis C and not HIV), 10-20% will progress to end-stage liver disease in approximately 25 – 30 years. In people who are HIV-HCV co-infected, twice that number, 20-30%, will progress to end-stage liver disease at 2 – 3 times the rate, or in 7 to 10 years. Although there is presently no vaccine for Hepatitis C, the disease is potentially curable through the use of combination antiviral therapy. This is in contrast to HIV, for which although there are treatments available to suppress viral replication, it is impossible to cure because the virus integrates into an infected individual's genome. HCV does not enter the genome and is considered a curable illness.

### *How is Hepatitis C Spread?*

Hepatitis C is spread by blood, as is HIV. The two most documented routes of transmission are the use of blood products, and unsafe injection drug use. However, Hepatitis C is a highly infectious agent, hundreds of times more infectious than HIV, and is also spread through unprotected sexual contact, the use of intranasal cocaine equipment, non-sterile acupuncture needles and tattooing equipment [2].

#### *Who is Co-Infected?*

It is estimated that as much as 3% of the world's population is infected with the Hepatitis C virus (HCV) [3], including an estimated 1% of Canadians [4]. In British Columbia, there have been 43,000 reported cases Hepatitis C, but the BC Center for Disease Control believes this is a significant underestimate of the actual number of people chronically infected with the virus [5].

As of December, 2002, the United Nations had estimated that there were 42 million people living with HIV/AIDS in the world [6], including approximately 40,000 in Canada [7], of whom between 10,000-15,000 live in British Columbia.

HIV and Hepatitis C share many routes of transmission. In Canada and elsewhere in the Developed World, it is estimated that as many as 30% of individuals who have HIV also have Hepatitis C [8-10]. Thus although the number of co-infected individuals is relatively small compared to the number of people who are mono-infected (4000 vs. 40,000), this group of individuals requires more specialized and more intensive treatment and care than either HIV or HCV mono-infected patients.

#### *Why is Co-Infection with HIV and Hepatitis C Problematic?*

There is an important negative synergy between the two viruses. People who are co-infected with HIV and Hepatitis C have faster rates of liver fibrosis and development of cirrhosis compared to HCV mono-infected individuals [11-19], poorer responses to Hepatitis C treatment [10, 20-25], and overall worse survival [10, 14, 26-30]. Importantly, HCV is harder to detect in people who are HIV-positive using standard antibody techniques, presumably because of an impaired immune response [31].

However, these negative outcomes are partially alterable through a variety of factors. These include the patient's CD4 count and other immunological factors when they begin treatment [32-35], the type and length of Hepatitis C treatment they receive [20-22, 36-40], and whether they are using antiretroviral therapy for HIV infection at the same time [24, 34, 41-48].

The use of Highly Active Antiretroviral Therapy (HAART) has largely transformed HIV disease into a chronic, manageable illness [43]. However, most antiretroviral agents are metabolized through the liver, and can cause varying degrees of liver toxicity [46, 47]. Despite the gains made by the use of antiretroviral therapy, viral co-infection with Hepatitis C is becoming a leading cause of morbidity and mortality among people living with HIV [16, 49-51], and viral co-infection can further exacerbate drug-related hepato-toxicities [49, 52, 53].

### **The Situation in British Columbia Today**

In broad terms, the situation for co-infected individuals in British Columbia today is not very hopeful. Although co-infected individuals are filling the HIV Ward at St. Paul's hospital, there is little to offer them. The burden of this combined epidemic is only beginning to be understood. Research from the BC Center for Excellence in HIV/AIDS shows that although two years ago Hepatitis C was not an independent predictor of death among HIV-positive individuals receiving antiretrovirals, today it is [54]. Part of the reason for this is that the majority of co-infected individuals became infected with HIV and/or Hepatitis C during the outbreak among injection drug users in the mid- to late- 1990's. Given an average progression rate of their liver disease of 7 to 10 years, one can see that the medical complications are only beginning to surface. British Columbia is currently poorly equipped to deal with this emerging problem.

There are, however, several areas in which there are key opportunities to make significant improvements in the way in which people who are HIV/HCV co-infected are medically managed.

### **Routine Patient Management Issues**

**Problem:** Hepatitis C in the presence of HIV is a much more aggressive and complicated disease than in people who only have Hepatitis C, and seriously complicates the ability to manage HIV disease.

People who are co-infected need to be tested early in their HCV disease, and tested with more elaborate methods (i.e. PCR-based techniques which detect the actual virus instead of just antibodies to the virus). People who are co-infected need to be treated earlier in the course of their HCV disease, and they often require longer treatment than people who are mono-infected. People who are co-infected need to coordinate their HIV and Hepatitis C treatments, since factors

which predict treatment success in people who are co-infected include receiving treatment at a high CD4 count, before beginning HIV treatment with antiretrovirals. There are several other treatment and care related issues that are unique to people who are co-infected, indicating the need for a coordinated, evidence-based approach to the management of Hepatitis C among HIV-infected individuals.

***Solution:*** Empower the BC Center for Excellence in HIV/AIDS to medically manage co-infected individuals.

*Based on the model of managing HIV in the province, empowering the BC Center for Excellence in HIV/AIDS to manage Hepatitis C in people with HIV would enable:*

- *the development of evidence-based, state-of-the-art therapeutic guidelines for co-infection*
- *the management of accidental exposures to Hepatitis C (they already manage accidental exposures for HIV)*
- *the appropriate training of health care providers*
- *the cost-effective distribution of Hepatitis C drugs to eligible co-infected individuals*

### Pharmacare Issues

**Problem 1:** The best available, federally licensed treatment for Hepatitis C (pegylated interferon) is not covered by Pharmacare. Physicians are postponing treating their patients until the pegylated interferon is covered because it is approximately twice as effective with many fewer toxicities.

***Solution:*** Immediately provide Pharmacare coverage for pegylated interferon for the treatment of Hepatitis C infection.

**Problem 2:** Currently available treatment, Rebetron (a combination of regular interferon with ribavirin) is only available to individuals for 6 months, but research shows that the majority of people requiring treatment require at least 48 weeks of therapy. This results in prolonged treatment interruptions which severely compromises the opportunity to treat the disease effectively.

***Solution:*** Change Pharmacare policy to automatically allow patients to continue their Hepatitis C treatment for as long as it is required or recommended by their physicians.

**Problem 3:** Currently available treatment, Rebetron, has substantial bone-marrow toxicities, for which medication is available but not approved by

Pharmacare. Patients frequently have to discontinue their Hepatitis C treatment due to these toxicities.

***Solution:*** *Provide Pharmacare coverage of erythropoietin and G-CSF to manage the side effects associated with Hepatitis C treatment.*

### Solid Organ Transplantation

**Problem 1:** Hepatitis C is the leading cause of liver transplantation in the Developed World. Until recently, however, HIV has been considered an absolute contraindication to solid organ transplantation. Although the BC Transplant Society (BCTS) has developed a policy for HIV and transplantation, there are several outstanding issues which pose significant barriers to the timely and appropriate assessment and listing of HIV-positive individuals. These include:

- the need to assess people living with HIV more quickly than individuals without HIV because their liver disease progresses more quickly, and because their liver disease significantly impairs the ability to manage HIV;
- the requirement that people with HIV be taking antiretrovirals as a condition of getting activated on the waiting list is ethically problematic when the act of taking antiretrovirals poses immediate life threatening consequences to the individual because of their advanced liver disease and the substantial liver toxicities associated with antiretroviral medications.

***Solution:*** *Adoption by BCTS of adopt evidence-based and appropriate criteria, consistent with current knowledge regarding the management of HIV disease.*

**Problem 2:** There is a shortage of viable organs in this province for transplantation. Furthermore, the BCTS has no experience with transplantation in HIV-infected individuals.

***Solution*** *Given that there is considerable experience with organ transplantation in HIV-infected individuals in the United States, the BC government, through BCTS, should financially support three to five HIV-positive individuals to receive transplants in the United States, as provided for under the “Medical Services Commission Out of Province and Out of Country Medical Care Guidelines for Funding Approval”. This endeavour would enable the BCTS to acquire expertise in this area, as well as saving several lives.*

### An Ounce of Prevention

Clearly one of the most important approaches to addressing HIV/HCV co-infection is to prevent new infections, and to prevent those who are already

infected from developing end-stage liver disease. Preventing new infections can be accomplished through the immediate implementation of harm reduction strategies (such as more needle exchange programs, and safe injection facilities), and addiction treatment (note that the 17 beds designated for detoxification for women in British Columbia is shamefully inadequate).

Preventing people from progressing in their disease or slowing that progression down can be accomplished through providing access to the best available HCV medications on the market (i.e. pegylated interferon), providing access to medications to manage the toxicities associated with these medications, and providing access to medications for as long as they are medically required (note that most people do not require more than 48 weeks of therapy, in contrast to HIV treatment which is lifelong). The second major opportunity for preventing or slowing disease progression among co-infected individuals is to empower the BC Center for Excellence in HIV/AIDS to coordinate and manage Hepatitis C treatment and care for HIV-infected individuals.

### **Summary and Conclusions**

Although British Columbia is currently facing the beginning of a dual epidemic with a high case-fatality rate, there are opportunities available to mitigate the damage.

We urge the BC government to show leadership in addressing this important issue by implementing the recommendations provided within this paper, and substantiated through the multi-stakeholder consensus meeting report on co-infection held in January, 2003.

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