



Section 1 — General Information	
Name of the therapeutic review	Drugs for Chronic Hepatitis C Virus Infection
Name of patient group	HepCBC Hepatitis C Education and Prevention Society
Patient group's contact information:	HepCBC Hepatitis C Education and Prevention Society PO Box 46009, 2642 Quadra St. Victoria, BC V8T5G7 250-595-3892 <a href="mailto:info@hepcbc.ca">info@hepcbc.ca</a> <a href="http://www.hepcbc.ca">www.hepcbc.ca</a>
Date of submission:	January 14, 2014

## 1.1 Submitting Organization

HepCBC is a non-profit society run by and for people infected and affected by hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. Our office with our only paid employee (an office mgr.) is in Victoria, BC. We also have activities and groups in Vancouver, BC, Nanaimo, BC and Surrey, BC. Our representatives attend provincial and federal-level conferences and we give information and support world-wide through our website. We publish a monthly bulletin, the hepcbull. We focus on providing "clean and sober" peer support groups, anti-stigma activities, prevention education to young people, and encourage testing among at-risk groups -- including those who are no longer at risk but may have contracted hepatitis C decades ago. We work alongside local HIV/AIDS organizations in support of co-infected people.

## 1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last three years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boehringer-Ingelheim, and AbbVie.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

The author of this report and two individual submitters have attended one to four educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

- 1) HepCBC invited HCV+ (genotype 1 only) people through our website, monthly bulletin, and via a targeted email notice to 650 individuals. We received 21 individual submissions.
- 2) The author of this report is a volunteer who has actively manned HCV+ phone and email support systems for several years, and has extensive knowledge of patient concerns and experiences.
- 3) Aggregate input from one of our monthly support groups has also been added.

### 2.2 Impact of Condition on Patients

"I have been challenged with a variety of symptoms. Extreme fatigue, intense joint pain, sleep disturbance, digestive issues, itching, Lichen Planus in the mouth (sores), cognitive impairment, emotional up and downs (mood swings), loss of memory, anger and frustration, blurring vision, economic hardship, depression and anxiety, loss of relationships, Isolation. Hep C has been a total life impact on a physical, emotional, mental, and financial (level). It has been completely devastating."

(Many mentioned they deal regularly with "Stigma, especially with healthcare professionals who often assume a history with addiction (which I have not had)."

"I've always been very friendly and social, but have become isolative because, I'm just too damn tired. Life is becoming a little more lonely because of that. When I'm off work, I usually stay home. When I'm at work, I drag myself through the day and live in fear, that, due to brain fog, I will make a horrible mistake."

"I have been unable to work. The result has been a very significant drop in income to a life well below the poverty line, financial instability, isolation, poor housing and the negative effects on self-esteem that result from the inability to be self-sufficient."

"What will my quality of life be as time progresses? I know that I will not feel well, but will I end up in hospital or will I have to have a liver transplant or worse, will I get liver cancer? Doctor costs, hospital costs, drugs, blood tests and medications, etc. will be an immense cost to the health care system so I am really hopeful that I be cured before any of this happens...If one's body is constantly stressed with worry, that is not healthy for anyone. As Hep C progresses it is more difficult to treat and cure. I need to be on medication soon!!!!"

### 2.3 Patients' Experiences With Current Therapy

(Triple therapy) "treatment was challenging as I experienced quite a few intense side effects. I experienced: Skin rash, nausea, tinnitus, sinus dryness - bleeding and infection, blurry vision, dry eyes, dry mouth, bad taste, anemia (hemoglobin dropped to 87), neutropenia, low white blood cell count, brain fog, exhaustion, dry skin, split fingers, joint & muscle pain, hair loss, hair increases on face and lashes, restless leg syndrome, diarrhea, fever and chills."

(Most difficult to tolerate side-effects of INF/RIBA regiments were)... "Uncontrollable anger/behaviour issues, cognitive skills affected, anxiety/depression" (The worst adverse event described was) ... "after 30 days of

taking boceprevir, my body rejected it. I had cerebral edema, brain seizures, and could not walk a week after taking it. I continued with the INF+RIBA until Nov. 25th when treatment was stopped in week 45/48. The drugs induced myositis and interstitial lung disease. I was anemic the entire time and had 5 blood transfusions. Cured, and lucky to be alive. On oxygen and learning to walk again..."

"When I was on the three combo drug therapy, I developed 'firehea' from the telaprevir. This is something that only someone on this therapy can understand. It is an unbearable burning sensation when you go to the bathroom."

"Boceprevir can make everything taste REALLY BAD. It's like sucking on a rubber tire and not being able to spit it out."

INF+RIBA:"I just about died and it didn't work. Side effects lingered for months post-treatment. In the middle of treatment I was forced to retire early and close up my home business which had involved substantial computer use and strict deadlines. As this had been my primary source of income, shutting down my business created much stress in my life, which may have contributed to my treatment failure."

"(After taking INF+RIBA+Victrelis, I am)... possibly Hep C free...(but) now have rheumatoid arthritis...(I) still experience incontinence, tremors, weight loss, (and) poor appetite; (I am still) unable to work."

"(Non-prescription medications and creams to ameliorate side-effects of triple therapy) were in addition to what the Plan covered, and came to an average of \$150 per month on top of the prescription."

d - Followup and support for individuals who have not responded to treatment: "We seem to be just tossed aside. More support groups are needed for those who have no hope."

"(Most people on my website who) didn't cure with the older drugs are now refusing treatment and are holding out for the new drugs that will cure us all without frying our brains at the same time. How could we ask that our citizens be given drugs that cause so much harm when these new treatments are so effective? What price do we put on human life that we would even consider giving someone a lesser drug simply because it might be a bit cheaper than the new drugs coming out? The Gilead and AbbVie drugs have proven to be very effective and should be fast tracked and approved for everyone."

"I was on INF mono, then Intron A + RBV, then Pegasys + RBV over the years. I am INF intolerant. I hate the stuff. It took years to clear from my system. Makes you crazy."

"INF/RIBA treatment did not work. I am waiting for new drugs to be introduced in order to be re-treated with my HBV and HIV co-infections. The doctors tell me that it will be at least 2-3 years before treatment is available for me. In this waiting period, there is a strong likelihood that I will die from complications of one of my infections. With successful treatment for Hep C, my chance of survival and the possibility of some sort of recovery will increase considerably."

"the drugs (trial in 2008 with INF, RIBA and protease inhibitor) did something to my brain, it seems I never came out of the severe brain fog I had on the meds. I feel like I'm brain damaged. My critical thinking skills, analytical skills and memory have been affected. Someone close to me observed that I am "different" from before...I am willing to put up with some temporary side effects that make me feel worse temporarily, but I do not ever want to take a drug that will affect my brain again. Life matters, but so does quality of life."

"(After 4 unsuccessful treatments using interferon)...I discovered I have the IL28b TT allele, the most difficult to treat." Testing for this is critical in determining chance of interferon success.

"I am now at stage 4, hoping to try the new oral medications that have just been approved...I need the medication, and soon! I really want to enjoy a healthy life with my family and friends, I want to live, I want to see my grandchildren and desperately want to be HCV- free!"

## 2.4 Impact on Caregivers

"What you are left with is a caregiver that can have an increased financial burden, a desire to be home more often in order to care for their loved one and a feeling of helplessness while they watch their loved one go through a difficult treatment. I think they should be given wings."

"...I think that an asymptomatic individual on an interferon-free regime would need no care. "

"All of my wonderful caregiving family and friends are aging and the more senior caregivers are beginning to falter, thus putting more pressure on the rest of my caregivers. This in turn puts greater pressure on scanty public resources."

"My wife has voiced to me on numerous occasions that she really wonders if it was a good thing that I was diagnosed with Hep C as the treatment has not cleared me of Hep C, but it has left me with long-term effects that have had a huge negative impact on my life and hers. She hopes that one of the newer drugs might give me an opportunity to clear the Hep C. The situation right now is one of limbo for her and for me. The stigma of Hep C also made it difficult for my wife to talk to co-workers and ask for support. This has made her feel sometimes as isolated as I felt."

## Section 3 — Information about New Drugs

### 3.1 Information Gathering

Same as 2.1 above with following additional information about attributes of the 21 individuals who submitted:

GENDER: 12 males, 9 females; AGE: Range 39 – 69. Average 57.3 yrs. Median 58.5 yrs.

PROVINCE: 2-Alberta, 1-Manitoba, 1-Ontario, 17-British Columbia

GENOTYPE: Individuals identifying as GT1a=11, GT1b=4, and simply "GT1"=6.

CO-INFECTIONS: One individual identified as co-infected with HIV (& HBV though 'inactive')

TREATMENT HISTORY (some respondents fit in more than one category as they've taken treatment more than one time):

Treatment naive: 2 total

Recent DAA trials:

- 0-Simeprevir or Sofosbuvir
- 1-AbbVie trial (ABT-450/r/ABT-267) and ABT-333 coadministered With RIBA) now SVR8
- 3-BMS ASUNAPREVIR-DACLATASVIR trial, 2-now SVR1year+, 1-SVR16
- 1-B-I FALDAPREVIR trial (BI 201335 + INF+RIBA) – Patient was pulled off as non-responder but says it's possible he could have been on the placebo.
- 2-Merck DAA trial, 1-now SVR12, 1-pulled off due to heart atrial fibrillation

Older (2008) trial:

- 1-INF+RIBA+"polymerase inhibitor" trial - relapser

SOC, pre-triple therapy:

- 1-Rebitron non-responder
- 1-INF/RIBA/Glycol SVR since 2003!
- 13-INF+RIBA non-responders

SOC Triple therapy:

- 4-SVR with boceprevir
- 2-Non-responders with telaprevir
- 1-Non-responder with boceprevir

### 3.2 What Are the Expectations for New Drugs or What Experiences Have Patients Had to Date With New Drugs?

a) *Based on no experience using new drug(s):*

"If I did not have to worry about the virus damaging my liver, causing liver cancer and all of the other devastating effects that it has on my body, life would be very good!! An all oral drug therapy would be fantastic for many of us who are not able to tolerate interferon and ribavirin and who have to face all of the debilitating side effects."

"My life would dramatically change should I clear this virus from my body. To just imagine a life without the ongoing symptoms of hep C...I might return to work, develop new relationships, and most importantly end the progression of this disease which is slowly killing me by destroying my liver and other organs."

"Due to the side effects that are still occurring my doctor does not recommend I go on interferon again - so I wait until a new regimen of drugs, interferon free, is approved for Manitoba. The waiting is the hardest."

"HCV/HIV coinfecting person: In 2013, I had 5 visits to Emergency Wards and spent a month in hospital as a result of poor and incomplete diagnosis of my infections. New drugs would make hospital visits much less common. I would be a smaller burden on the system."

"I would rather die than go through this again."

"Ideal new drug expectations: 100% effective, no (or minor) side effects, short drug treatment timeline, easy to take, one pill once a day, easily accessible and **affordable** to all effected"

"I would like to have my energy back. I would like to be able to know that I am Hep C free, that my liver is not going to deteriorate and cause larger problems for me health wise.

Basically I now live with the knowledge that I cannot return to work due to my ongoing issues with fatigue and various side effects of being on interferon. I wait, hoping that a new drug becomes available and approved so that I can afford it."

b) *Based on patients' experiences with new drug(s) as part of a clinical trial or through a manufacturer's compassionate supply:*

"After week two of a 24 week (AbbVie trial) program the virus was completely gone...The drugs have very little side effects but the Ribavirin does take its toll with headaches and extreme mood swing...And it has taken a while to get my WBC and RBC back to normal levels. The new drugs also allowed me to work, but I also continued to golf and play baseball during my whole time on the drugs and I am 58 years old."

**(BMS trial for 1b only, with asunaprevir and daclatasvir):**

PATIENT# 1: "No interferon, no ribavirin, no needles, no special dietary requirements, and **no side effects**. I even walked the half marathon 4 months into treatment. I could have worked while on this treatment, but I'd already retired. 13 months post treatment I remain SVR, though my platelets are somewhat low. My pre-treatment Fibroscan was 49.6 kPa; 12 months post-treatment it has dropped dramatically to 18.0 kPa."

PATIENT #2: "I had **no side effects** from this treatment, unlike the previous ones. According to my Fibroscan, my fibrosis has decreased, and my energy is returning. My memory seems to be improving. My retinas did not detach with this latest treatment, as they did with previous treatment. I can't begin to explain the pure joy I feel at not having the virus anymore! This is so amazing to me that I still have trouble believing it, but the truth is that I haven't felt this good in decades. I have more energy. I have no stomach pain. Most of my joint/arthritis pain is gone."

"The (MERCK trial) DAA Interferon-free combo was WONDERFUL. After 2 days I felt so different I didn't recognize myself. My fibromyalgia and brain fog were gone!!!!!!!!!! There were only a few minimal queasy type feelings on the first day. So basically **no side effects**."

"Because of the new (INF-free AbbVie trial) drugs I took I was able to function on my own and the only issue I had was with the moods swings from the RIBA...But I hear that the new regimens may not need to use that drug; please, let's get these new drugs approved and give people a chance to clear this virus without frying their brain with the old drugs."

## Section 4 — Additional Information

Each GP, liver specialist, nurse, & hep C support professional should be given a set of guidelines to follow when dealing with Hep C patients such as

- protocol for regular diagnostic follow-up (pre- and post-treatment): Fibroscans, ultrasounds, blood tests for cancer markers & thyroid production, blood panel, and ensuring that Hep A & B shots still working. This to make sure patients get referred to treatment at the ideal time, to identify treatable co-morbidities, to save lives by early detection of liver cancer and liver failure, and to help prevent the need for liver transplant.
- add to patient questionnaires often-discounted symptoms of Hep C such as chronic fatigue, brain fog, depression, joint pain, dry eyes, restless legs, thyroid imbalance, metabolic syndrome, or bowel disease. This will help locate patients who don't know they are HCV+.
- list of at-risk populations other than those with addictions ie: baby boomers, men who have sex with men, Rh-neg mothers who had RhoGam shots, soldiers who had mass immunizations with shared equipment, those who got Gamma (Immune) globulin and other blood products before the blood supply was safe, immigrants from certain countries, those who have non-professional tattoos or piercings, present/former prisoners and sex workers, healthcare workers at risk of stick injury, etc.

"Get rid of interferon and ribavirin asap. Get rid of liver damage requirements so patients can get treated sooner, when treatment will be more effective (and its benefits last longer!)."

"Insist that treatment be affordable...If 170 million of us worldwide were cured, plus the many more that do not know they have the disease yet, the reduced cost to the health system and governments would be enormous...I think the price of sofosbuvir is prohibitive for many patients, the world over...I think it is very sad that sofosbuvir has been labelled the "game changer" but it is going to be out of the reach of most, at least for the next few years. Many HepC sufferers are in their 50s and beyond. How much time do they have left to finally get rid of HepC?"

"Please approve the HCV treatments that work without interferon...There are so many that can be saved from these and it's your duty to MAKE THIS HAPPEN NOW!"