hepc.bull

Canada's Hepatitis C News Bulletin

www.hepcbc.ca

WHAT ABOUT A VACCINE?

Wouldn't it be wonderful if, just like polio or smallpox, no one had to worry about catching Hep C ever again? Vaccines do that. Unfortunately, there is no vaccine against Hep C, but researchers keep trying... and it looks like they may be getting very close!

"Treatment will form part of the control of the disease; however, successful treatment of an infection has never led to eradication. The search for an effective prophylactic vaccine should continue, and advances in molecular vaccinology will enable progress in the coming years."

(LANCET Seminar, Hepatitis C, Webster, Dr Daniel P, et al. 13 February 2015)

What type of vaccine would work best for the Hep C virus? Ideally, it would be a vaccine that would prevent initial infection (prophylactic vaccine), AND it would prevent the infection from becoming chronic, curing the disease in those already infected (therapeutic vaccine). The problem is that the virus has many strains and mutates easily. Other problems include developing a vaccine that gives people lasting protection, and finding good models to use for testing.

The search for a vaccine suffered a big setback back in 2007. It was hoped that a "therapeutic" vaccine, one that also cured those already infected, could be found. Therapeutic antibody treatments for hepatitis C weren't working. Then researchers found out why: Usually a virus replicates inside a cell, and large numbers of the virus burst out and start over again. Some viruses don't have to leave the cell. They can infect it by travelling directly from cell to cell, and this is the case with HCV. HCV uses both methods, so the virus does not need to be released by a cell before it infects another cell. It can travel directly to the next cell, avoiding the body's neutralizing antibodies and medical treatments. That may be why HCV antibodies don't control the virus. The cell-to-cell transfer, a faster "route" to infect new cells, could explain HCV's dramatic spread in acute cases.

http://news.bbc.co.uk/2/hi/health/7075569.stm and www.natap.org Nov 2, 2007

(Continued on page 3)

WORLD HEPATITIS DAY COMING TO YOUR COMMUNITY??

World Hepatitis Day (WHD), always on or close to July $28^{th_{*}}$, is a great excuse to bring hepatitis C (and B) issues to the attention of your friends and community members. It's a great time to have an info table at your local mall, to show the movie DEAL WITH IT at your church or service club, to have speeches along with a community barbecue or concert, to ask the mayor for a proclamation, or to work with nurses to do a free on-site testing day. Groups in the east have had Niagara Falls lit up in red and yellow lights. Use your imagination!

HepCBC does four main activities every year:

First, we have a big ad campaign about a week before WHD in the 3 major BC newspapers, showcasing people from immigrant, aboriginal, and baby boomer communities, giving basic facts about HCV and publicizing the WHD activities we know about, all over the province.

Second, HepCBC volunteers serve on the Vancouver World Hepatitis Day Planning Committee (meeting monthly from August through to mid-July).

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ASSERTIVE INTERDISCIPLINARY DIALOGUE: ADVOCACY

As a charitable organization, HepCBC must strictly limit the amount and type of advocacy it provides to elected officials. However as our main office is located in the provincial capital within walking distance of parliament, we are easily available to talk with MLAs about hepatitis C in our province. We want to make sure they have the most current and accurate information so they will be able to make the right decisions about this important disease. We spoke with a group of MLAs from the governing party a few months back at an event organized by the Pacific Hepatitis C Network, and next month we'll be speaking with a group of seven MLAs from the opposition. Coverage by PharmaCare of the new hepatitis C direct -acting antiviral (DAA) therapies is a very critical issue at this point in time.

But we are interested in federal-level as well as provincial-level decisions and decision makers. To that end, one of our members wrote a letter to the federal Minister of Health, Rona Ambrose, urging her to release the upcoming hepatitis C testing guidelines which are widely expected to contain a provision for "cohort" (age group) testing of baby-boomers. She brought it to our Board and we agreed to sign it on behalf of HepCBC. Then she took the letter to a Meet and Greet with two MPs, one of whom is the opposition Health Critic. They will make sure Rona Ambrose gets the letter, which you can see published on page 4 in this newsletter. The opposition Health Critic has also invited HepCBC to make a one-hour presentation to him in early April.

We urge people all over this province to talk about hepatitis C testing and treatment to their own representatives, at all levels, at any opportunity they have. Politicians generally want to help people, especially voters!

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ORDER OR DONATION FORM

NOTE: Ordering (or donating) via Credit Card or PayPal is available online at www.hepcbc.ca/hepcbc-order-form/ OR...

Fill out form below with a cheque made out to "HepCBC" - Send to our NEW address:

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TOTAL ENCLOSED.....\$ *Only name and email address required for emailed bulletin.

Membership also requires a postal address.

We will mail you a member package with pamphlets, yellow and red ribbon pins, information about volunteering opportunities, and how to participate in our annual general meeting, plus other ways to make your voice heard.

(Note: Nothing mailed to you from HepCBC will have ANY reference to hepatitis on the envelope.)

Registered Canadian charitable organization since 2001. No. 86800-4979-RR00001.

**Download the *hepc.bull* free (since 2001) at www.hepcbc.ca/hepc-bull-monthly-newsletter/

SUBMISSIONS: The deadline for any contributions to the hepc.bull[©] is the 15th of each month. Please contact the editors at jking2005@shaw.ca, (250) 595-3892. The editors reserve the right to edit and cut articles in the interest of space.

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LETTERS TO THE EDITOR

The *hepc.bull* welcomes and encourages letters to the editor. When writing to us, please let us know if you do not want your letter and/ or name to appear in the bulletin.

IANKSII

HepCBC thanks the following institutions and individuals for their generosity: The late John Crooks, Allison Crowe, Billie Wood and Adrian, Community Living Victoria, Victoria Positive Living Centre, Provincial Employees Community Services Fund, the Victoria Foundation, Dr. C. D. Mazoff, Judith Fry, and the newsletter team: Beverly Atlas, Diana Ludgate, Alp, Cheryl, Anamaria, and S.J.

Please patronize these businesses that have helped us: Top Shelf Bookkeeping, Merck Canada, Bristol-Myers Squibb, Roche Canada, Vertex, Gilead, Janssen, Boerhinger-Ingelheim, AbbVie, Rx&D, VanCity, Country Grocer, and Thrifty Foods.

(World Hepatitis Day—Cont'd from page 1) Third, HepCBC participates in various events in Vancouver, Surrey, Abbotsford, Victoria, etc.

Fourth. and this is where YOU come in, HepCBC offers \$500 to the four communities who have the best ideas of what to do for World Hepatitis Day. Preference will be given to rural, remote, and First Nations communities. Please submit your ideas and plans to us prior to May 15th.

*the birthday of Dr. Baruch Blumber, the person who discovered the hepatitis B virus...

HEPCBC SUPPORT SERVICES EXPANDING!

VANCOUVER: The new office in Vancouver is getting set up during the month of March. Watch our website calendar for the Grand Opening! The office needs volunteers to keep the doors open as many hours a week as possible. If you think you have the time and the right personality to contribute a few hours a week on a regular basis, please phone the office and let Anita York, our Vancouver Coordinator of Volunteers, know!

ADDRESS: Room 206A, 938 Howe Street, Vancouver, BC - V6Z 1N9 **OFFICE PHONE: 1-604-259-0500** LOWER MAINLAND SUPPORT LINE: 1-604-259-0501

VICTORIA OFFICE: The new office in Victoria is set up and humming along now. Watch the website Contacts page for expanded office hours coming soon.

ADDRESS: Room 20, 1139 Yates Street. Victoria, BC V8V 3N2 **OFFICE PHONE: 1-250-595-3892** "EVERYWHERE EXCEPT LOWER MAINLAND" SUPPORT LINE: Watch our website Contacts page for this new number. Meanwhile, please use the Office Phone number above. We look forward to your visit soon!

2015 CASL CONSENSUS GUIDELINES

There is an update on how hepatitis C should be managed.in Canada. It's called The 2015 Consensus Guidelines from the Canadian Association for the Study of the Liver, and it has been compiled by the eminent doctors R.P. Myers, H. Shah, K.W. Burak, C. Cooper, and J.J. Feld.

Hepatitis C, a substantial medical and economic burden in Canada, both medically and economically, affects almost 1% of its population. Serious advances have been made, since the previous Canadian consensus conference, that deserve a review of the previously recommended treatment of these patients. The new direct-acting antiviral (DAA) agents have greatly improved rates of sustained viral responses (SVRs) compared to previous standard therapy, and interferon-free, all-oral antiviral regimens have been recently approved.

Because of these new treatments, the 2012 Canadian Association for the Study of the Liver "Consensus Guidelines on the Management of Hepatitis C" has been updated. The new document discusses the epidemiology of Hep C in Canada, the recommend-

ed diagnostic approaches, and the recommendations for treatment using the new DAAs of those chronically infected. The recommendations include non-responders to PegIFN/RBV -based treatment. It also includes recommendations on how to reduce the effects of Hep C in Canada. Select, copy and paste complete link, or click on Full-Text PDF for open access to file:

www.pulsus.com/journals/abstract.jsp? sCurrPg=journal&jnlKy=2&atlKy=13233&isuK y=1176&spage=1&isArt=t&fold=Abstract

(ADVOCACY—Continued from page 1)

So don't be shy or cynical. Give democracy a try, and speak your truth to power!

HepCBC remains independent of any political party affiliation or preference, and independent of the influence of any pharmaceutical company. We are strictly dedicated only to the interests of people affected by hepatitis C, with the goal of eliminating this terrible disease from the face of the earth, starting in British Columbia.

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(VACCINE —Cont'd from page 1)

What important information! It showed scientists where to look to find new targets for antiviral therapy. An HCV vaccine is now looking more possible. What is even more promising is that researchers are generously sharing their information and building upon each other's work. Part of this collaboration has come from the researchers deciding to unite and pool their knowledge to rid the world of Ebola--and the technologies they have developed should work with HCV, too. Below, you will see several types of possible vaccines. Some are prophylactic, and some are therapeutic, like DAAs. The vaccines seem to target and inhibit many reproductive parts of the virus, not just one, and are effective against many genotypes. More interesting is that the researchers are combining the kinds of vaccines, first building up the patient's immune system-priming it, so to speak-and then aiming at the virus itself, using one or even more of the following vaccine types. Some of these new vaccines aren't even numbered yet! It's hard to organize them into categories, since many now combine one or more of these techniques:

TYPES OF POSSIBLE VACCINES:

Passive Immunization: One would think that having HCV antibodies would cure the disease and protect a person against reinfection, but it doesn't work that way with the hepatitis C virus. Attempts at using this method on chimpanzees seem to have failed, however, a study from 2013 tested this method on some chimeric ("humanized") mice, and researchers found they produced antibodies against HCV envelope proteins which inhibited genotypes 1a, 1b and 2a. Those antibodies protected the mice against infection and "might be used in the development of a prophylactic vaccine."

(<u>www.ncbi.nlm.nih.gov/pubmed/23673355?</u> <u>dopt=Abstract&holding=npg</u>)

Envelope Glycoprotein Vaccines: This type of vaccine causes the body to make antibodies to parts of the virus' outer coating, called E1 and E2. This vaccine seems to be showing promise in chimpanzees. The structure of E2 envelope glycoprotein, possibly the protein that HCV uses to invade liver cells, was clarified by researchers from The Scripps Research Institute (TSRI) in November 2013. This discovery may make it easier to design a vaccine which will be effective against several virus strains. (<u>http://en.wikipedia.org/wiki/Hepatitis C vaccine</u>)

Epitope Based Vaccines: An epitope is the part of a protein that is recognized by the immune system—by antibodies, B cells or C cells. This type of computer-generated vaccine is designed to make the body produce a strong immune response (CD4+ and CD8+) using T-cell epitopes. It is hoped that this

technology won't allow mutations to escape, and that it will cover several genotypes, not just one. The disadvantages are that the technology requires large computer databases, and an effective vaccine would probably have to include some protein from actual HCV. (<u>www.brown.edu/Courses/Bio 160/</u> <u>Projects2000/HepatitisC/hcvvaccines.html</u>)

In spite of this, great progress has been made: Scientists have collected a set of 245 HCV-specific CD8 T-cell epitopes, of which they chose 17 promising ones...and shared their work! Eventually, after many series of procedures, they were able to select 6 epitopes that they predicted to produce the best T-cell response in any patient, in spite of his/her genetic makeup. This information is available for public use.

(www.hindawi.com/journals/jir/2013/601943/)

<u>Naked DNA Vaccines:</u> "Naked" DNA means DNA that isn't associated with a virus, so it can't infect the patient with any-thing. Therapeutic DNA is introduced into a virus to deliver it to the body. The "C" gene of the hepatitis C virus is often used in these experiments, because it is similar in all the genotypes. Side effects of a vaccine of this type may be a problem, and safety may be an issue, although some researchers say there are no viral parts to cause unwanted immune responses, infections, or permanent changes in the cell's genetic makeup.

(<u>www.brown.edu/Courses/Bio_160/</u> <u>Projects2000/HepatitisC/hcvvaccines.html</u>) Techniques are being developed to overcome the problems with DNA vaccines:

*Alphaviral Particle (promising results in mice.

***Polytopic Vaccines** (comprised of one E2 protein and two E1 and core proteins.) ***Bacillus Calmete Gurein** (BCG) used as a vector with HCV epitope delivery.

***NS Genes-based DNA Vaccines** (Nonstructural genes are also good candidates, like the NS5a or the NS2.)

*Glycoprotein-based DNA vaccines (E1 and E2 are good targets, inducing a polyclonal humoral response desirable in an HCV vaccine.) Human clinical trials have begun. (eg., ChronVac-C, CIGB-230, Novartis-Okairos-Chiron's Vaccine and Adelaide University's DNA Vaccine)

<u>Viral Vector Vaccines</u>: These vaccines, like naked DNA vaccines, are designed to place foreign DNA into a cell to stimulate the immune system. Viral <u>vector</u> vaccines have an advantage because they allow specific host cells to be targeted, so that the vector will not enter the genetic material of the cell. Few vaccines like this have been tried, so little is known about how effective they are.

(www.brown.edu/Courses/Bio 160/ Projects2000/HepatitisC/hcvvaccines.html) Recombinant viruses can be used to deliver DNA efficiently. Experiments in animals have induced protective immunity to many viruses, and some are being tested for HCV vaccines. A favorite virus is the defective adenovirus (a virus that causes colds) because its natural "habitat" is the liver. However, the tragedy of a death in a gene therapy trial using adenovirus has severely dampened the enthusiasm for the use of this viral vector in humans.

(www.medscape.com/viewarticle/410848_6) There is an adenovirus vector called BID (BH3-interacting domain death agonist), designed to cause cells infected with HCV NS3/NS4A protease to commit suicide (aptosis), stopping the progression of the disease. Studies done with chimeric mice at the Ontario Cancer Institute, and reported in the May 2003 issue of Nature Biotechnology, showed the treatment to be effective, and nontoxic to healthy neighboring cells. "A targeted therapeutic approach using modified BID may be useful as a prophylactic against accidental virus exposure, in the early stages of hepatitis, during limited infection of the liver, or for ex vivo therapy of hepatocytes. It may also reduce virus loads in chronically infected patients, and in conjunction with interferon and ribavirin therapy, might eradicate HCV from the infected host," say the researchers (Reuters Health 05/01/03).

Peptide Vaccines: Researchers think this kind of HCV vaccine can work because helper T-cells (some of our immune system's "soldiers") recognize antigens (invaders) that they should attack, because of peptide fragments bound to molecules on the surface of the cells that carry the antigen (in this case, the HCV polyprotein). Peptides containing epitopes from the core regions of the virus have induced strong immune responses in mice. A peptide called HVR1 contains a neutralizing epitope, so it is a good target for a vaccine. This strategy has seemed to work in trials with chimpanzees. Unfortunately, this peptide is subject to mutations.

(<u>www.medscape.com/viewarticle/410848_7</u>)

Recombinant Protein Subunit Vaccines:

The first attempt to develop an HCV vaccine was by generating a recombinant protein subunit vaccine. Chiron used recombinant HCV E1 and E2 proteins in early vaccination studies. Results of these experiments showed that the vaccine did not protect any of the chimpanzees when challenged with the virus, but self-limited infection occurred more frequently than in nonvaccinated animals. The results show that even though no sterilizing immunity was achieved, chronic infection might be prevented.

(Excerpt from the NEW Peppermint Patti's FAQ, version 10, soon to be released.)



HepCBC Hepatitis C Education & Prevention Societywww.hepcbc.cainfo@hepcbc.ca1-250-595-3892

HepCBC Victoria MAIN Office #20 -1139 Yates Street, Victoria, British Columbia, V8V 3N2

HepCBC Vancouver Office #206A – 938 Howe Street, Vancouver, BC V6Z 1N9

February 12, 2015

Dear Minister Ambrose:

I am writing to respectfully request the release of the Public Health Agency of Canada's new guidelines recommending increased hepatitis C screening for baby boomers. These guidelines, long-requested by organizations like HepCBC and the Canadian Liver Foundation, are long overdue.

Hepatitis C is a significant public health issue in Canada. The Public Health Agency of Canada indicates 44% of people living with hepatitis C do not know they are infected, and as a result, cannot receive medical care for their illness, and may even inadvertently pass it on to others. Untreated hepatitis C causes negative health outcomes for individuals living with the disease, as well as unnecessary costs to the health system.

The longer a person lives with hepatitis C - *especially when undiagnosed* - the more liver damage they suffer. Between 20 and 40% of all people with hepatitis C are expected to develop severe liver fibrosis or cirrhosis which often requires hospitalization. Total life-time costs to manage untreated hepatitis C therapy range from \$100 589 for a person with severe fibrosis (F3), \$133 575 for a person with compensated cirrhosis (F4), and \$327 068 for a person requiring liver transplantation.

The majority of liver transplants in Canada are due to hepatitis C. In 2012, 62 people died waiting for a liver transplant, while 492 people remained on the waiting list.

New treatments for hepatitis C approved by Health Canada in 2014 have very high cure rates (97%) with few side effects. Now is the time for federal leadership in promoting hepatitis C screening, to ensure baby boomers living with hepatitis C can cure the disease now - and remain healthy well into their senior years.

In the interest of better health outcomes and stronger health care for people who are living with hepatitis C but do not yet know it, I urge you to release the Public Health Agency of Canada's new hepatitis C screening guidelines immediately.

Sincerely yours,

Rosencerez Plummer, RN BEN President

Rosemary Plummer, RN, BSN, President HepCBC

TREATMENT SUPPORT FOR 1986-1990 PATIENTS

There are special support programs for accessing Hep C treatments through the Hepatitis C January 1, 1986 - July 1, 1990 Class Actions Settlement. More information here: <u>www.hemophilia.ca/files/HT%20March%202015.pdf</u>

If you are an approved claimant under the Hepatitis C January 1, 1986 - July 1, 1990 Class Actions Settlement, you may be eligible to be reimbursed for the cost of treatment and accepted hepatitis C (HCV) medications that are not reimbursed by any other health care plan, private or public.

Thanks to a collaborative effort between the CHS and Gilead Sciences Canada, Inc., until the claimants receive reimbursement from the 1986-1990 plan, treatment is being offered upfront to those able to physically qualify for **Sovaldi**, through the Gilead Momentum HCV Support Program. **Harvoni** (ledipasvir and sofosbuvir combined in a single tablet), approved in October 2014, is now included as well under the Gilead Momentum HCV Support Program (1-855-447-7977).

Holkira Pak (paritaprevir/ ritonavir + ombitasvir + dasabuvir) was approved for sale in December 2014, and the CHS has collaborated with AbbVie Canada to make the treatment available to 1986-90 class action claimants, as well, through the AbbVie Care Program. (1-844-471-2273).

Janssen's Galexos (simeprevir), which received Health Canada approval back in November 2013, is providing financial assistance and other support through the Galexos' BioAdvance Patient Support Program (1-855-512-3740).

These programs provide many services: reimbursement assistance, health care professionals and patients during their quest to achieve a cure. This assistance may cover the whole treatment regimen prescribed by your doctor, including drugs from other pharmaceutical companies that you might need to complete your treatment. The programs help you and your doctor see if you qualify for reimbursement through the 1986-1990 Class Actions Settlement. Once the plan issues reimbursement cheques to the patients, the patients must reimburse the pharmacy directly. To enrol in a program, ask your doctor or nurse or call the numbers above for more information.

For more information, see <u>www.hemophilia.ca/en/hcv-hiv/hcv-treatment-</u> support-for-1986-1990-claimants

P.E.I. FIRST TO COVER HOLKIRA PAK

Congratulations to Prince Edward Island, the first Canadian province to approve coverage for the new Hep C drug combo called the HOLKIRA PAK, which was approved by Health Canada in December. A \$5-million strategy was announced by the province's Health and Wellness minister on February 12. The drug is meant to cure Hep C genotype 1, the kind infecting 70-75% of PEI hepatitis C patients, and up to now, the most difficult to treat. Fortunately, the new treatments can cure 95-100% of patients, in a shorter time, with sometimes no side effects. These drugs can change people's lives. They can save people's lives.

The previous treatment, pegylated interferon, injected weekly, plus several capsules of ribavirin and a protease inhibitor daily, cures up to 70% of patients, but the treatment lasts 6 to 12 months, and it can produce uncomfortable and sometimes serious side effects. Holkira Pak is a pill taken daily for 12 weeks.

The treatment with HOLKIRA PAK takes 12 weeks with a daily pill and fewer side effects. The problem is that it is very expensive. The final price hasn't been decided yet.

About 400 residents of PEI have been diagnosed, and at least 60 have serious liver damage. Thanks to the small population of the province, these patients can be closely monitored and resources can be well-coordinated. PEI will be working with AbbVie, which is a company based in Quebec, regarding patient support, referral, education and other services. Screening for patients still not diagnosed will take place at emergency rooms, primary care centres, correctional institutions, methadone clinics and addiction services, and will offer the best treatment available to all diagnosed, to stop the spread of the disease and avoid health complications for those diagnosed.

"Dr. Morris Sherman, chairman of the Canadian Liver Foundation, said the province has 'stepped up as a role model' and he hopes that 'other provinces will soon follow their lead.""

Source

https://ca.news.yahoo.com/5m-hepatitis-c-strategyannounced-155625454.html



SVR HONOUR ROLL

Have you been undetectable for a minimum of 12 weeks after treatment?

Give others hope. Congratulations to our friends:

1. GJ - SVR Dec 1998 - IFN/RBV 52 wks - Dr. Anderson /Natalie Rock, Vancouver, BC.

2. Amberose - 2000 (GT2a/2c) - Schering IFN/RBV 24 wks

3. Jeanie Villeneuve - Oct 2000 - Schering IFN/RBV

4. Kirk Leavesley - (GT1) - 2004 - Roche

5. Darlene Morrow - (GT1 relapser) - Mar 2004 - Hyperthermia/Induction + pegIFN/RBV. 6. KG-Transfused 1987 (GT2a/2c treatment naïve) 2003-4 IFN/RBV 24 wks. Still undetectable in 2014.

7. Beverly Atlas - (GT1a) - 2005/2006 - Albuferon/RBV 44 wks

8. Steve Farmer - 2008 (Transplant Vancouver 2005) IFN/RBV 72 weeks.

9. Gloria Adams - (GT1b relapser) - Fall 2009 IFN/RBV/Telaprevir 48 wks - Drs. Erb & Yoshida, Vancouver, BC.

10. Don Crocock - (GT1 Stage II) - Dec. 2010 IFN/RBV - 48 weeks

11. Daryl Luster - (GT1a) - Feb 2011 - IFN/ RBV/RO5024048 48 wks.

12. Donna Krause - (GT1 partial responder) SVR Nov 2011- Pegasys/Copegus, Danoprevir/ Ritonavir/R05024048 24 wks. Dr. Erb, Vancouver

13. Chervl Reitz - (GT1b previous partial responder) SVR12 Mar 2013 - Asunaprevir/ Daclatasvir 24 wks - Dr. Ghesquiere, Victoria, Montaner, Salt Spring Island, BC. BC.

14. Anita Thompson - (GT1a treated 3 times) Cirrhosis - Apr 2013 - Pegasys/Boceprevir 48 wks. Dr. M. Silverman, Whitby, ON.

15. Leon Anderson - (GT2 partial responder) SVR24 May 8, 2013 - GS-7977/RBV 16 weeks -

Dr. Alenezi & Dr. Conway- VIDC - Vancouver.

16. Joan King - (GT1b treated 5 times) June 2013 - Asunaprevir/Daclatasvir 24 wks Dr. Ramji, Vancouver, BC

17. Šandy J. (GT 1a treatment naïve) Oct 31, 2013 - IFN/RBV/Victrellis 28 wks. Fran Faulkner, RN, Vancouver Island. Now SVR24.

18. Andrew P. - (GT 1a many prev treatment attempts over 10+ years, including Incivek Jan 2014.) Sofosbuvir/Ledipasvir + RBV 24 wks

19. Diane Stoney - Transfused 3/21/79 (GT 1a treatment naïve) 2/4/2014 - 12 wks placebo, then 12 wks on ABT-450/r+ABT-267+ABT-33+RBV. Dr. Tam, Vancouver, BC

20. Coreen Kendrick - (GT 1a treatment naïve) Mar 10, 2014 MK5172/MK8742 12 weeks Dr. Ramji, Vancouver, BC.

21. Jack Swartz—(Treated 3 times) Apr 2014 IFN/RBV/Victrelis, Dr. S. Wong, WHSC.

22. Del Grimstad July 2014, 12 weeks Simeprevir/Solvaldi

23. Linda May (GT 1b transfused, treatment-naïve) 12 wks Asunaprevir/ Daclatasvir . Dr. Tam, LAIR Centre.

24. Jackie—(GT1 relapser) - SVR24 June 2013 - IFN/RBV/Boceprevir 48 wks. Dr. Keith Bovell, Guelph, ON.

25. Bob (GT1a/HIV relapser) SVR24 Nov 2014 pegIFN/RBV/Incivek 24 wks, Dr.

26. KG (GT2A/2C) IFN/RBV 24 wks, 2003-2004. Toronto. SVR confirmed 2014.

Please send your name and info to Joan at info@hepcbc.ca

PLEASE SHARE THIS VIDEO!

The Gastrointestinal Society (GI Society) has just released a video about hepatitis C to spread awareness and educate Canadians on the risk factors for this disease. The fastpaced, whiteboard-style animation also includes information on diagnosis, testing, treatment, management, symptoms, and more, so you can do your part to help stop the spread of this disease. Watch the video online in English at http://ow.ly/ICVF4 and in French at http://ow.ly/ICVQ8. Dr. Gray narrates this animation in English and Jean Bruyère narrates in French.

Gail Attara, Chief Executive Officer and co-founder of the Gastrointestinal Society, who produced the video, said, "We are grateful for the medical support of Dr. James R. Gray, Gastroenterologist and Clinical Professor, University of British Columbia, and Dr. Ed Tam, Hepatologist, of the Liver and Intestinal Research (LAIR) Centre. We are also very appreciative of the generous educational grants provided to us by AbbVie Corporation and Janssen Inc. that allowed us to produce this independent video." Here are the short links:

English: http://ow.ly/ICVF4 French: http://ow.ly/ICVQ8 Visit www.badgut.org

Watch, and share this video; it could help save someone's life.

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HEPCBC COMMENTS ON NEW THERAPEUTIC REVIEW PROPOSAL (CADTH)

Last year, the federal government's drug regulatory body CADTH completed a "Therapeutic Review" of all the therapies currently being used for hepatitis C. CADTH looked at the entire "HCV treatment landscape" from the perspective of all significant stakeholders, so that it would be able to make rational recommendations to the groups (such as provincial pharmacares) which look to CADTH for guidance. However CADTH noted in its review that its recommendations would almost be obsolete 'before the ink was dry', due to the expected upcoming approvals of several newer and significantly better hepatitis C drugs and combinations of drugs.

CADTH planned to do a second review once some of these drugs were approved for sale in Canada by Health Canada. Given several recent new DAA approvals, this time has arrived, and a "DRAFT PROPOSED PROJECT SCOPE (of) Treatment Regimens for Chronic Hepatitis C: A Therapeutic Review" was recently sent to many stakeholders, including patient groups, to comment on by February 13, 2015. The proposed new review will look at the existing regimens of pegylated interferon + ribavirin (PR), additions of boceprevir, telaprevir, simeprevir, or sofosbuvir to PR, sofosbuvir + ledipasvir, and paritaprevir/ritonavir + ombitasvir + dasabuvir. However, this review also proposes looking at the following Interferon-Free Direct-Acting Antiviral (DAA) regimens:

Genotype 1	simeprevir + sofosbuvir
	sofosbuvir + ledipasvir
	paritaprevir/ritonavir + ombitasvir + dasabuvir
	daclatasvir + asunaprevir
	daclatasvir + sofosbuvir
	grazoprevir + elbasvir
	sofosbuvir + ribavirin
	daclatasvir + asunaprevir + beclabuvir
	sofosbuvir + GS-5816
Genotype 2	sofosbuvir + ribavirin
	sofosbuvir + GS-5816
	daclatasvir + sofosbuvir
Genotype 3	sofosbuvir + ribavirin
	sofosbuvir + ledipasvir
	daclatasvir + sofosbuvir
	sofosbuvir + GS-5816
	paritaprevir/ritonavir + ABT-530
Genotype 4	sofosbuvir + ribavirin
	sofosbuvir + ledipasvir
Genotype 5	daclatasvir + sofosbuvir
	sofosbuvir + GS-5816
	grazoprevir + elbasvir
Genotype 6	sofosbuvir + ribavirin
	daclatasvir + sofosbuvir
	sofosbuvir + ledipasvir
	sofosbuvir + GS-5816
	grazoprevir + elbasvir
Dogo 6	

While HepCBC is pleased with the scope of this review, and commented that it was asking the right policy questions about reimbursement, treatment criteria, and re-treatment, we did make a few suggestions. We want CADTH to ask these additional questions:

TREATMENT CRITERIA: Upon what basis does CADTH make decisions regarding HCV treatment criteria: scientific evidence? Short-term fiscal expediency? Compare short-term cost of curing HCV and preventing chronic hepatitis C (CHC) and serious sequelae, versus long-term cost of treating patients with incurable chronic diseases such MS, diabetes, or HIV over a patient's lifetime.

REIMBURSEMENT and STAGING: Should reimbursement for DAAs for CHC (a) be given to everyone who is HCV+ upon their doctor's recommendation, or (b) should it be limited to those who can prove a minimum degree of physical damage to their bodies, even though we know the treatment works better and results in greater increase in QALYs (Quality-Adjusted Life-Years), the earlier it is treated?

(i) If we choose the exclusiveness of (b) over the inclusiveness of (a), what place does fibrosis staging have in determining the degree of physical damage? In other words, are there other factors we should be looking at as well, such as autoimmune responses, mental health, or extrahepatic manifestations?

ceprevir, telaprevir, simeprevir, or sofosbuvir to PR, sofosbuvir + ledipasvir, and paritaprevir/ritonavir + ombitasvir + dasabuvir. However, this review also proposes looking at the F2?

(iii) If fibrosis staging has a place, how accurate are the various means of determining fibrosis score and how cost-effective are they?

ADVANCED DISEASE: (a) What recommendations, if any, do we want to make to limit the reimbursement of the DAAs for CHC in those with various degrees of liver de-compensation?

(b) Should we reimburse for drugs or treatments used to enable a patient approaching de-compensation to qualify for DAA treatment, or to enable any patient to remain on treatment? These could include drugs to control or reverse conditions such as hepatic encephalopathy, low platelets, anemia, or fluid retention which now preclude patients from going on to treatment, or which can result in patients having to stop treatment.

REVIEW PROTOCOL: (a) How can CADTH/CDR streamline future reviews of regimens for which all of its components are already approved in other regimens, rather than doing an entirely new review? (b) Is CADTH/CDR doing all it can to ensure equitable pricing and access? In some cases it has called for lower prices, but there does not seem to be a clear pattern of when this call is made, and in those cases where it is, spe-cific target pricing or pricing structures are not defined. It would be helpful to all stakeholders if CADTH/CDR would take leadership on this issue, possibly even mandating a particular equitable pricing structure or formula.

FINAL RECOMMENDATION FROM HepCBC: As a patient group

whose members collectively possess broad, longtime and extensive experience in treatment with interferon, ribavirin, telaprevir, and boceprevir, we strongly protest any of these harsh and often debilitating drugs being prescribed instead of the next generation DAAs for short-term fiscal expedience. The very side-effects common of these drugs (experienced by most who take them) are within the realm of "cruel and unusual punishment", and unless their use is of proven scientific value in a particular case, they should be struck from the provincial formularies.



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ABBVIE CARE

MERCK CARETM

With the approval of HOLKIRA[™] PAK, AbbVie is launching AbbVie Care, which is a program that will provide best-in-class solutions to improve outcomes for people living with hepatitis C.

Canadians prescribed HOLKIRA PAK will have the opportunity to request to be enrolled in AbbVie Care. The signature care program is designed to provide a wide range of customized services including reimbursement assistance, education and ongoing disease management support. AbbVie Care will not only support health care professionals but people living with genotype 1 hepatitis C throughout their treatment journey to achieve high cure rates in the real world. For enquiries: 1-844-471-2273.

MerckCareTM is a program to help people who have been prescribed PEGETRONTM, VICTRELISTM or VICTRELIS TRIPLETM. The program provides:

•assistance with reimbursement and/or insurance claims.

financial assistance for co-pay/

deductible for people who qualify.

- •24/7 nursing support by phone.
- •multilingual assistance.

•home delivery of medication.

MerckCareTM provides all of these services free of charge.

To enroll in MerckCareTM, you can call 1-866-872-5773 or your doctor or nurse can submit an enrollment form for you. Reimbursement specialists are available from 8:00 a.m. to 8:00 p.m. EST Monday to Friday, excluding statutory holidays.

MOMENTUMTM SUPPORT

PEGASSIST

To learn more about SOVALDITM or the Momentum ProgramTM in Canada, the patient should speak to his/her doctor or nurse or call the Gilead Sciences Canada medical information line at 1-866-207-4267. Eligible patients may receive an integrated offering of support services for patients and healthcare providers throughout the entire treatment journey, including:

•Access to dedicated case managers/ reimbursement navigators to help patients and their providers with insurance-related needs, including identifying alternative coverage options through private, federal and provincially-insured programs.

•The SOVALDITM Co-pay assistance program, which will provide financial assistance for eligible patients who need help paying for out-of-pocket medication costs.

Medication delivery services.

•Compliance and adherence programs.

NEUPOGEN

Amgen has a program for patients who have been prescribed Neupogen. Dependent on specific criteria, some patients may be able to obtain Neupogen on a compassionate basis free of charge as long as it is prescribed and dosed in accordance with the approved product monograph. This service is accessed through the Victory Program:

1-888-706-4717.

PLEASE TRY TO GET **ONE PERSON TESTED THIS MONTH!**

The PegAssist Reimbursement Assistance Program provides reimbursement coordination assistance for patients who have been prescribed Pegasys or Pegasys RBV. The program will assist in securing funding for patients to ensure that they can start, stay on, and complete their treatment successfully. PegAssist Reimbursement Specialists are available (Monday to Friday, 10 AM - 6 PM EST) by calling: 1-877-PEGASYS or 1-877 -734-2797. Patients can also obtain a program enrollment form from their nurse/physician to gain access to the program.

The program provides financial aid to qualified patients, alleviating financial barriers which may prevent patients from starting treatment, i.e., deductibles and/or copayments. In partnership with CALEA Pharmacy, the program can conveniently deliver the medication directly to patients' homes or to the clinics.

INCIVEK CARE

Vertex's Incivek Care Patient Assistance Program supports patients with the reimbursement process for Incivek (telaprevir) treatment (Incivek, pegIFN, ribavirin). It will give you an efficient assessment of your options and eligibility. You may qualify to receive co-payment and other financial Administrator 1-877-434-0944 assistance to supplement your private and www.hepc8690.com provincial drug program coverage. The program also provides dispensing and home Pre-86/Post-90 delivery options, and expert treatment advice. Call the Support Line at 1-877-574-4298. (Select option 2 for English, then 2 for Incivek Care.)

Pendopharm has established the IBAVYRTM Patient Support Program. The program will assist patients who have been prescribed IBAVYRTM (ribavirin tablets) with reimbursement navigation, financial assistance and pharmacy services. Case managers will support patients with insurance-related matters and assess eligibility for financial support. Pharmacy services include adherence support, medication delivery and counselling.

To enquire or to enroll, you may call 1-844-602-6858 Monday-Friday 7am to 11pm EST.

BIOADVANCE®

JANSSEN's GALEXOSTM: BioAdvance® program can assist you in many ways during your treatment. This includes compiling and submitting, on your behalf, all the forms and documents required by your insurance company to request coverage of GALEXOSTM, and following up with your insurer to get you the best coverage possible. If you don't have private insurance, the GALEXOSTM: BioAdvance® program will investigate public assistance programs that can help pay for your treatment. Whichever type of coverage you have, if your insurance does not fully cover the cost of treatment, the GALEX-OS[™]: BioAdvance[®] program can usually coordinate and provide financial assistance to help you get treated. Finally, the program can offer many other types of support and your doctor and members of your healthcare team will work with the GALEXOSTM: Bio-Advance[®] Program to develop a customized approach to best support you throughout the course of your treatment. Contact: 1-855-512-3740

COMPENSATION

Class Action Suit Hotline: 1-800-229-5323 ext. 8296 Health Canada Compensation Line: 1-888-780-1111 Red Cross Compensation pre-86/post-90 Registration: 1-888-840-5764 HepatitisC@kpmg.ca Ontario Compensation: 1-877-222-4977 Quebec Compensation: 1-888-840-5764

CLAIMS ADMINISTRATOR 1986-1990

Claimants may be reimbursed for costs of treatments and accepted hepatitis C medications not covered by public or private healthcare plan while they wait for reimbursement from the 1986-1990 plan.

info@hepc8690.com

Administrator 1-866-334-3361 preposthepc@crawco.ca www.pre86post90settlement.ca

Settlement Agreement: www.pre86post90settlement.ca/PDFs/SA/

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IBAVYRTM

SUPPORT BC/YUKON

Armstrong HepCURE Phone support 1-888-437-2873

AIDS Vancouver Island The following groups provide info, harm reduction, support, education and more:

· Campbell River: Drop in, harm reduction, needle exchange, advocacy. 1371 C - Cedar St.

Contact leanne.wingert@avi.org 250-830-0787

• **Comox Valley** Harm reduction, counselling, advocacy. 355 6th St., Courtenay. Contact Sarah sarah.sullivan@avi.org 250-338-7400

• Nanaimo AVI Health Centre. Counseling, advocacy. NEW: 102-55 Victoria Rd Contact Anita for details. 250-753-2437

anital.rosewall@avi.org

· Port Hardy (Port McNeil, Alert Bay, Port Hardy, Sayward, Sointula and Woss) Drop-in kitchen. 7070 Shorncliffe Rd. Contact Shane, 250-949-0432 shane.thomas@avi.org

•Victoria Access Health Centre, drop in, disability applications, peer training. Support group Tues 12:30 PM, 713 Johnson St., 3rd floor, 250-384-2366 Hermione.jefferis@avi.org

ANKORS Hepatitis C Project

Hep C Info, support for prevention, testing, treatment and living well with Hep C. •Boundary, Nelson, West Kootenay Wom-

en's gathering monthly. 101 Baker St, Nelson. Contact Laura 1-800-421-2437 250-505-5506 <u>ankorshepc@ankors.bc.ca</u> • East Kootney 209 16th Ave N, Cranbrook,

Contact Michelle 250-426-3383 1-800-421-2437 ankorshcv@gmail.com

Castlegar Contact Robin 250-365-6137 eor@shaw.ca

Chilliwack PCRS Hep C Prevention, harm reduction. 45904 Victoria Avenue, Chilliwack. Contact Kim Lloyd 604-798-1416. lbirdsall@pcrs.ca www.pcrs.ca

Comox Valley Positive Wellness North Island Treatment/Pre & Post-treatment Support Group 2nd & 4th Wed., 615-10th St, Courtenay. Lunch. Contact Cheryl 250-331-8524. Cheryl.taylor@viha.ca

CoolAid Community Health Centre, Victoria. Meetings each Wed 10 AM and Thu 1:30 PM. 713 Johnson St. Support for all stages of treatment (deciding, during, after). Contact Roz rmilne@coolaid.org for treatment or group info.

Courtenay HCV Peer Support and Education. Contact Del 250-703-0231 dggrimstad@shaw.ca

Cowichan Valley HCV Support Contact Leah 250-748-3432 r-l-attig@shaw.ca

Haida Gwaii support. Contact Wendy wendy@wendyswellness.ca www.wendyswellness.ca

HepCBC info@hepcbc.ca, www.hepcbc.ca Call for office hours.

•Victoria Peer Support: 4th Tues. monthly 7-8:30 PM, Victoria Health Unit, 1947 Cook St. Contact 250-595-3892 Phone support 9 AM-10 PM. •Fraser Valley Support/Info: 604-576-2022

Kamloops ASK Wellness Centre. Chronic illness health navigation/support.

info@askwellness.ca 250-376-7558 1-800-661-7541 ext 232 or Merritt health housing & counseling 250-315-0098

www.askwellness.ca

Kamloops Hep C support group, 2^{nd} and $4^{th}\ Wed$ monthly, 10-1 PM, Interior Indian Friendship Society, 125 Palm St. Kamloops. Contact Cherri 250-376-1296 Fax 250-376-2275

Kelowna Hepkop: Phone support, meeting info. Contact Lisa 1-866-637-5144 limortell@shaw.ca

Nanaimo - Central Island Hepatitis Service: Nurses & doctors available for info, support, treatment. Clinic located in Nanaimo. Doctor or self-referral. Contact 1-855-740-2607, sarah.hughes@viha.ca or shelby.munk@viha.ca

New Westminster Stride with Purpose "HepC" Support Group 1st&3rd Fri monthly 10:30-11:30. BBP Nursing Team, refresh-ments/lunch. Contact: Stride Workers 604-526-2522, mail@purposesocietv.org

Positive Wellness North Island-North Island Liver Service Info, support, treatment/pre-post treatment groups. Doctor or self-referral. 1-877 -215-7005 250-850-2605.

•Courtenay: 2nd Fri monthly 1PM, Drop-in, Comox Valley Nursing Centre (nurse)

•Campbell River: Treatment/pre&posttreatment support group 1st&3rd Thu monthly 10-11pm, Discovery Room, Sunshine Wellness Centre, Campbell River Hospital. Jody Crombie at 850-2620, jody.crombie@viha.ca

Penticton & District Community Resources Society, Harm Reduction Program, Meetings every 2nd Tues, 12:30-1:30 PM. 330 Ellis Street. Contact Melanie: 250-488-1376 or 250-492-5814

Positive Haven Info, harm reduction, support, drop in, clinic. 10697 135A St. Surrey. Contact Monika 604-589-9004.

Positive Living Fraser Valley (Abbotsford) http://hepcnetwork.net Hep C support, Drop-in centre #108-32883 S. Fraser Way, M-F 10:30 AM-4:30PM. Info, support worker, rides to appointments in surrounding areas. Contact 604-854-1101 or plfvcentre@plfv.org

Powell River Hepatology Service Powell River Community Health, 3rd Floor–5000 Joyce Ave. Contact Melinda 604-485-3310 Melinda.herceg@vch.ca

Prince George Hep C Support Contact Ilse ilse.kuepper@northernhealth.ca

Sunshine Coast-Sechelt Healthy Livers Support Group Information/resources Contact Catriona 604-886-5613 catriona.hardwick@vch.ca or Brent 604-740-9042 brent.fitzsimmons@vch.ca

VANDU The Vancouver Area Network of Drug Users. 380 E Hastings St. M-F 10-4 Contact 604-683-6061 vandu@vandu.org www.vandu.org

Vancouver HCV Support Contact Beverly 604-435-3717 batlas@telus.net

Vancouver Hepatitis C Support Group Contact 604-454-1347 or 778-898-7211, or call 604 -522-1714 (Shelley), 604-454-1347 (Terry), to talk or meet for coffee.

Vernon telephone buddy, M-F 10-6 Contact Peter, pvanbo@gmail.com Tel. 250-309-1358.

YouthCO HIV and Hep C Society of BC. Call for appts or drop in M-F 10-6. 205-568 Seymour St,

Vancouver 604-688-1441, 1-855-YOUTHCO Stewart info@youthco.org, www.youthco.org

Whitehorse, Yukon-Blood Ties Four Directions 376-9420 Ext. 1257, Contact 867-633-2437 1-877-333-2437 admin@bloodties.ca



OTHER PROVINCES

ONTARIO:

Barrie Hepatitis Support Contact Jeanie for info/ appointment jeanievilleneuve@hotmail.com

Hamilton Hepatitis C Support Group 1st Thurs. monthly, 6-7 PM, Hamilton Urban Core Community Health Centre, 71 Rebecca St, Hamilton. Contact Maciej Kowalski, Health Promoter 905-522-3233 mkowalski@hucchc.com

Hep C Team, AIDS Committee of North Bay & Area. Education, outreach, treatment, individual & group support, harm reduction, needle ex-change. 269 Main St. W, Suite 201, North Bay. Contact 705-497-3560, 1-800-387-3701 or <u>hepccommcoord@gmail.com,</u> www.aidsnorthbay.com

Hepatitis C Network of Windsor & Essex County Last Thurs. monthly, 7 PM, Teen Health Centre-Street Health Program Office, 711 Pelissier St., Suite 4, Windsor. Contact Andrea Monkman 519-967-0490 or hepcnetwork@gmail.com.

Kingston Hep C Info HIV/ AIDS Regional Service. Contact 613-545-3698, 1-800-565-2209 hars@kingston.net www.hars.ca

London Hepatitis Hep C Support 186 King St, London. For those infected as well as affected by Hep C. Contact: Hepatitis Outreach Society 519-434-1601. 1-866-920-1601

www.hivaidsconnection.com

Niagara Health System Hepatitis C Care Clinic (HCCC) Clinics:

New Port Centre-Port Colborne, 4 Adams Street - St Catharines, Niagara Falls Hospital. Education, counseling, individual/group support, treatment, outreach, and harm reduction. Contact 905-378-32554 4647 ext and HCCC@niagarahealth.on.ca www.niagarahealth.on.ca/ services/hepatitis-c-care

Oshawa Community Health Centre Hepatitis C Team Drop-in, lunch provided each Thurs. 12-1 PM, 79 McMillan St. www.ochc.ca Contact 1-855-808-6242

Owen Sound Info, support. Contact Debby Minielly dminiel-

ly@publichealthgreybruce.on.ca 1-800-263-3456 Ext. 1257, 519-

www.publichealthgreybruce.on.ca Peel Region (Brampton, Mississauga, Caledon) 905-799-7700

healthlinepeel@peelregion.ca

St. Catharines Contact Joe 905-682-6194

Toronto CLF 1st Mon. monthly Oct.—June, 7:30 PM, North York Civic Centre, 5100 Yonge Street. Contact Billie 416-491-3353, ext. 4932. <u>bpotkonjak@liver.</u>ca <u>www.liver.ca</u>

Thunder Bay Hep C support. Contact Sarah Tycholiz 807-345-1516 (or for 807 area only 1-800-488-5840)

Unified Networkers of **Drug Users Nationally** undun@sympatico.ca

York Region Hepatitis C Education Group 3rd Wed. monthly, 7:30 PM, York Region Health Services, 4261 Hwy 7 East, B6-9, Unionville. Contact 905-940-1333, 1-800-361-5653 info@hepcyorkregion.org www.hepcyorkregion.org

OUEBEC:

Ouebec City Region Contact Renée Daurio 418-836-2307 <u>reneedaurio@hotmail.com</u>

CAPAHC support group meetings 3rd Thurs. monthly 6-8PM, 5055 Rivard St., Montreal) Contact 514-521-0444 or 1-866-522-0444

ATLANTIC PROVINCES

of NS. Info and support line for the entire province. Call 1-800-521-0572, 902-420-1767 Online Peer Support: info@hepns.ca www.hepns.ca

PRAIRIE PROVINCES:

Manitoba Hepatitis phone and email support and outreach. Contact Kirk at info@mbhepc.org. Direct line: 1-204-231-1437

Manitoba CLF each Thu 1:30-3. 375 York Avenue, Suite 210, Winnipeg, Con-tact Bianca 204-831-6231 bpengelly@liver.ca

Medicine Hat, AB Hep C Support Group 1st & 3rd Wed. monthly, 6:30 PM, HIV/ AIDS Network of S.E AB Assoc, 550 Allowance Ave. Contact 403-527-7099 bettyc2@hivnetwork.ca

To list Canadian groups here, please send details to <u>info@hepcbc.ca</u> by the 15th of the month. It's free!

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