What’s new in Hepatitis C?
Community Report-back from Victoria 2013

Presented by Scott Anderson and Jeff Rice
CATIE
April 16th, 2013
Introduction – Organizations & acronyms

- Canadian Association for the Study of the Liver (CASL)
- Canadian Association of Gastroenterology (CAG)
- Canadian Association of Hepatology Nurses (CAHN)
- National CIHR Research Training Program in Hepatitis C (NCRTP-HepC)
- Action Hepatitis Canada
- CATIE
Introduction - Organizations & events

- CASL & CAG – Canadian Digestive Disease Week - (February 26 – March 4)
- CAHN – Education Day(s) (February 28 – March 2)
- CASL – Annual Winter Meeting (March 1-4)
- Action Hepatitis Canada – Strategic Planning Meeting (March 2 – 3)
- CATIE – Community Info Sharing Session (March 3)
- CATIE – Learning Institute/Rapporteur Project (March 3-5)
- NCRTP-HepC – 2nd Canadian Symposium on Hepatitis C Virus (March 4)
Overview

- New Hep C treatments
- Treat or wait?
- Managing side effects
- Specific populations
  - Liver transplant
  - Pregnant people
  - People who use drugs
- Screening / testing and cost-effectiveness
- What about the ‘Baby Boomers’?
- Action Hepatitis Canada
Hepatitis C treatments

in the pipeline
Terms

- Sustained virological response (SVR)
- Treatment naïve
- Prior relapsers
- Null responders
# Current treatment

<table>
<thead>
<tr>
<th>Direct Acting Anti-viral (DAA)</th>
<th>Standard Treatment</th>
<th>Genotype</th>
<th>SVR (cure rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>telaprevir (Incivek)</td>
<td>peg-interferon ribavirin (PegIFN/RBV)</td>
<td>1</td>
<td>74% (Tx naïve)</td>
</tr>
<tr>
<td>boceprevir (Victrelis)</td>
<td>peg-interferon ribavirin (PegIFN/RBV)</td>
<td>1</td>
<td>65% (Tx naïve)</td>
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</tbody>
</table>
Why are new treatments important?

- Current treatment options are difficult
  - Interferon injections
  - High pill burden
  - Side effects
  - Length of treatment

- Increase SVR – currently 45-74% (treatment naïve G1)
What’s going on in the treatment pipeline?
Direct Acting Antivirals in Development

## Which treatments will be first?

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| peg-interferon ribavirin (PegIFN/RBV) | All | G1 45%  
G2 + G3 80% |
| telaprevir (Incivek) peg-interferon ribavirin (PegIFN/RBV) | 1 | 74% (Tx naïve) |
| boceprevir (Victrelis) peg-interferon ribavirin (PegIFN/RBV) | 1 | 65% (Tx naïve) |
| new drug(s) peg-interferon ribavirin (PegIFN/RBV) | 1a, 1b, 4,5,6 | 71-97% |
New triple therapies

- simeprevir- protease inhibitor
- faldaprevir- protease inhibitor
- daclatasvir- NS5A inhibitor
- sofosbuvir- nucleotide polymerase inhibitor

- Each drug is taken with peg-interferon and ribavirin (PegIFN/RBV)
New triple therapies

- Once daily dosing
- No food requirement with pills
- None or few side effects
- Shorter treatment length, in some cases 12 weeks
- Work for several genotypes
- SVR: 71-97%
Quad Therapy

• 2 DAA’s + PegIFN/RBV
  • daclatasvir + asunaprevir + PegIFN/RBV for 24 weeks
    • SVR 12 or 24: 90-95%
  • danoprevir + mericitabine + PegIFN/RBV for 24 weeks
    • SVR 12: 84%

• May be a good option for null responders
Interferon-free treatments

Some promising combinations...
Interferon-free treatment: Genotype 2 + 3

sofosbuvir + ribavirin

- 12 or 16 weeks of treatment
- sofosbuvir: 1 dose/day
- ribavirin: weight based dose 2x/day
- Genotype 2: 86-94% SVR
- Genotype 3: 30-61% SVR
Interferon-free treatments - Genotype 1

- faldaprevir + BI 207127 ± ribavirin
- sofosbuvir + ledipasvir ± ribavirin
- ABT-450/ritonavir, ABT-267, ABT-333 ± ribavirin
Interferon-free treatment summary

- Multiple options for interferon-free treatment
- 12 weeks or less
- 1-2 doses/day + ribavirin
- Cure rates of 90% and up (G1,2,4,5,6)
- High cure rates even for people who did not previously respond to treatment
- Few serious side effects

J. Feld NCRTP-HCV 2013
When will these treatments emerge from the pipeline?

• Predictions by Dr. S. Shafran:
• 2014
  • simeprevir triple therapy
  • sofosbuvir triple therapy
  • sofosbuvir + ribavirin for G 2 + 3
  • Maybe faldaprevir triple therapy
• 2015 or 2016
  • Interferon-free treatment will be approved
Is this the end of Hep C?  
Not quite yet. Here’s why…

Some questions about the new treatments

• Will the treatment options work for people with severe liver damage?
• Will the treatment options work for people who have other illnesses (HIV, chronic kidney disease)?
• What will be the cost of the new drugs?
• Will treatment options be developed for people with genotype 3?

J. Feld NCRTP-HCV 2013
So now what?: Treat or Wait?

- Considerations:
  - Amount of liver damage
  - Previous response to treatment?
  - Age
  - Situation of person with Hep C: motivation, drug coverage, family planning, support, able to manage treatment

J. Feld CASL 2013
S. Shafran, CAHN 2013
Managing side effects of current treatments

- Mental Health Issues
  - Depression, anxiety, fatigue, cognitive problems are common
  - 10% suicidal thoughts
- Citalopram (anti-depressant) first line of treatment for depression
- Mood assessment and sleep assessment considered best practise

*Hepatitis C infection, antiviral treatment and mental health: a European expert consensus statement.*
Beyond medications: What do we need to do to end Hep C?

- Increase testing for Hep C
- Need to have needle exchange programs and opiate substitution programs AND Hep C treatment
- Address barriers to health care for people who use injection drugs
- Need infrastructure to deliver care to marginalized groups

J. Feld NCRTP-HCV 2013
G. Dore NCRTP-HCV 2013
Specific populations

- Post-liver transplant
- Pregnant people
- People who use drugs
Hep C treatment post-liver transplant

Case study of a young woman with Hep C who had a liver transplant


J. Ford CAHN 2013
Hep C and Pregnancy

- Person who is pregnant to child transmission of hep C accounts for 10% of Hep C cases.
- Higher number of Hep C variants transmitted when the person who is pregnant is also co-infected with HIV-1 (4-fold risk of transmission to child).
- Those who are pregnant must be screened for Hep C.
Hep C and people who use drugs

- People who use drugs are just as treatment adherent as those who don’t use drugs
- Information, education and support is needed
- Patient ‘citizenship’ (agency) is needed and can be developed with assistance from peers and front-line workers
- Multi-disciplinary approach to care, treatment and support is essential
Hep C and people who use drugs

- East Toronto Hepatitis C Program is one model of a multi-disciplinary approach
- Client / Patient, caregiver alliance
- People who have been marginalized often crave a sense of ‘community’
- One-stop shop provides: screening/testing, peer workers, treating physicians, nurses/nurse practitioners, social workers, counsellors, psychiatrist, support group, engaging activities (meals, discussions), all working together with the client/patient as the focus.
Hep C and people who use drugs

- There is ‘memory’ in terms of successful immune response following Hep C infection and this is protective
- Encouraging news for anyone who becomes re-infected, including people who use drugs, as some people, including drug users, have resolved two successive infections
Screening / Testing and cost-effectiveness

• Several ways to screen for the Hep C virus
  
  • Risk-based approach (Example - testing all people who inject drugs)
  
  • Population-based approach (Example - testing all people of a certain age or people from a country where Hep C is endemic)
  
  • Using clinical results such as ALT levels (Alanine transaminase)

Dr. Bryce Smith (CDCP) – *Population-based Strategies for HCV Testing*
Screening / Testing and cost-effectiveness

• Cost-effectiveness of population-based screening

• Directly related to higher prevalence and burden of disease

• In the U.S., persons in 1945-1965 birth cohort are 5X more likely to test positive for antibodies to Hep C (anti-Hep C) than other cohorts - prevalence 3.25%

Dr. Murray Krahn (UHN) – Hepatitis C Treatment Cost Effectiveness: A Synthesis of Available Data
Maxim Trubnikov (PHAC) – Increased Reported Rates of HCV in Canadian “Baby Boomers”: Results of a 20 Year Cohort Analysis of Nationally Reported Data
Screening / Testing and cost-effectiveness

• In the U.S., the Centre for Disease Control (CDC) suggested that one-time only testing of this birth cohort would diagnose many new cases, substantially reducing burden of disease.

• In the U.S., immigrant populations could also benefit from one-time testing.
Screening / Testing and cost-effectiveness

- Some cost-effectiveness studies of Hep C testing and treatment have over-estimated the benefits.
- Boceprevir and telaprevir both cost-effective, however boceprevir more-so that telaprevir.
- Most pronounced health outcomes are found in those who are midway through Hep C disease progression, much lesser benefits later.
Fibroscan testing

- Greater access to fibroscan testing
- Better clinical guidelines for fibroscanning
- Better reimbursement policies through government formularies, across the country
The Debate: Baby boomer testing

• Testing and Screening for Hepatitis C Virus Infection: Should we screen everyone born between 1945-1965?
The Debate: Baby boomer testing (Pro)

Dr. Bryce Smith

• Catch more Hep C positive results in a cohort vs risk-based testing
• Cost-effective when compared to other diseases
• Other benefits include Hep A and B vaccinations, behaviour change in alcohol consumption
The Debate: Baby boomer testing (Con)

Dr. Greg Dore (Con)

- Current surveillance data in U.S. is flawed
- Access to treatment for boomers will be problematic
Action Hepatitis Canada

• New name!

Action Hepatitis Canada / Action hépatites Canada

• New tagline:

Ensuring an equitable response to hepatitis B & C / Assurer une réponse equitable à l’hépatite B et C.
Action Hepatitis Canada

Back (L-R): Annika Ollner (PASAN), Billie Potkonjak (CLF), Deb Schmitz (Pacific Hep C Network), Colin Green (Hep NS), Patricia Bacon (Blood Ties), Paul Sutton (CTAC). Front (L-R): Jeff Rice (CATIE), Alexandre Laporte (Hépatites Ressources), Cheryl Reitz (Hep C BC), Douglas Laird. Missing: Danny Sung (SFU), Michel Long (CHS), Karyne Giguère (CAPAHC)
Community Rapporteurs

L-R: Billie Potkonjak (CLF), Jeff Rice (CATIE), Paul Sutton (CTAC) Deb Schmitz (Pacific Hep C Network), Colin Green (Hep NS), Patricia Bacon (Blood Ties), Hywel Tuscano (CATIE), Scott Anderson (CATIE), Annika Ollner (PASAN), Cheryl Reitz (Hep C BC), Lara Barker (CATIE). Missing: Alexandre Laporte (Hépatites Ressources), Danny Sung (SFU).
Thank you

- Dr. Jordan Feld
- Dr. Stephen Shafran
- Colina Yim
Future CATIE webinar

New Developments in HCV Research and their implications for front-line practice

Dr. Curtis Cooper, Ottawa Hospital Research Institute
Monday, June 17  English webinar
Date of French webinar TBA

Topics include: new HCV treatments in pipeline, HCV-HCV coinfection, sexual transmission of HCV, new multidisciplinary service delivery model, and others
Organization Links

- Canadian Association for the Study of the Liver (CASL) - http://www.hepatology.ca/
- Canadian Association of Gastroenterology (CAG) - http://www.cag-acg.org/
- Canadian Association of Hepatology Nurses (CAHN) - http://www.livernurses.org/
- National CIHR Research Training Program in Hepatitis C (NCRTTP-HepC) - http://www.ncrtp-hepc.ca/
- Action Hepatitis Canada - http://www.canadianhepatitiscoalition.ca/
Resources

• Management of chronic hepatitis B: Canadian Association for the Study of the Liver consensus guidelines
• Management of chronic hepatitis C: Canadian Association for the Study of the Liver consensus guidelines
• Available at www.hepatology.ca
• Hepatitis C infection, antiviral treatment and mental health: a European expert consensus statement. www.elpa-info.org
Contact information

• Jeff Rice – Hepatitis C Coordinator
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• Scott Anderson – Hepatitis C Researcher/Writer
  sanderson@catie.ca

Catie.ca
Hepcinfo.ca
CATIE is now on Facebook and Twitter

We tweet, inform and engage with you through our online Twitter account @CATIEInfo and our Facebook Page CATIEInfo.

Keep in-touch with us, find out what’s new from CATIE, and stay in the loop on the newest HIV and HCV treatment and prevention information.

Join in the conversation!
Join us on Twitter and Facebook!