World Hepatitis Day Webinar

Hepatitis C in 2017: Developments, improved treatment access and frontline realities

Suzanne Fish, HCV Knowledge Broker
CATIE
July 26th, 2017
Overview

1. **HCV Developments in 2017**
   - Scott Anderson, Hepatitis C Researcher/Writer, CATIE

2. **Treatment Access Changes and Frontline Realities**
   - Dr. Alexandra King, Physician/Researcher, Lu’ma Medical Centre, Vancouver, B.C.
   - Dr. Lisa Barrett, Physician/Researcher, Dalhousie University, Halifax, N.S.
   - Tara Zeagman, Clinical Nurse, Centre SIDA Amitié, St. Jerome, Que

3. **Discussion**

4. **Questions**
Key developments in 2017: hepatitis C research and policy

Scott Anderson, hepatitis C researcher/writer, CATIE
July 26th, 2017.
Seven new hepatitis C research and policy developments

1. Hepatitis C cascade of care (B.C.)
2. Sexual transmission of hepatitis C
3. Requirements for safe injection sites
4. Health Canada approved point-of-care antibody test
5. Recommendations on hepatitis C screening for adults
6. Treatment discontinuation and new treatments
7. Pan-Canadian Pharmaceutical Alliance
Hepatitis C cascade of care

GLOBAL HEALTH SECTOR STRATEGY ON
VIRAL HEPATITIS
2016–2021
TOWARDS ENDING VIRAL HEPATITIS

Research Paper
The Population Level Cascade of Care for Hepatitis C in British Columbia, Canada: The BC Hepatitis Testers Cohort (BC-HTC)

Naveed Z. Janjua DrPH\textsuperscript{a,b,*}, Margot Kuo MPH\textsuperscript{a}, Amanda Yu MSc\textsuperscript{a}, Maria Alvarez MSc\textsuperscript{a}, Stanley Wong MSc\textsuperscript{a}, Darrel Cook MSc\textsuperscript{a}, Jason Wong MD\textsuperscript{a,b}, Jason Grebely PhD\textsuperscript{c}, Zahid A. Butt PhD\textsuperscript{a,b}, Hasina Samji PhD\textsuperscript{a,b}, Alnoor Ramji MD\textsuperscript{d}, Mark Tyndall MD\textsuperscript{a,b}, Mel Krajden MD\textsuperscript{a,e}
New HCV cascade of care research

- BC Hepatitis C Testers Cohort (BC-HTC)
- 1.5 million people tested for or reported to have hepatitis B, hepatitis C, HIV, TB
- From 1990 to 2013
Prevention

- Biology of sexual transmission of hepatitis C
- Changes to requirements for safe injection site applications
Sexual transmission of HCV

• Very low risk of sexual transmission in monogamous HCV sero-discordant heterosexual couples
• Sexual transmission occurring amongst some HIV-positive MSM
  • Blood-to-blood transmission
Hepatitis C in semen

- One-third (11/33) of HIV-positive men with HCV shed HCV in their semen

Open Forum Infectious Diseases
MAJOR ARTICLE

Shedding of Hepatitis C Virus in Semen of Human Immunodeficiency Virus-Infected Men

Samuel S. Turner, Sara Gianella, Marcus J-S. Yip, Wouter O. van Sengelen, Robert D. Gillies, Andrew L. Foster, Zachary R. Barbati, Davey M. Smith, and Daniel S. Fierro
Hepatitis C in rectal fluid

- HCV found in rectal fluid of 47% (20/43) of HIV-positive men with HCV in the study

**Shedding of Hepatitis C Virus Into the Rectum of HIV-infected Men Who Have Sex With Men**

Andrew L. Foster, Michael M. Gaisa, Rosanne M. Hijdra, Samuel S. Turner, Tristan J. Morey, Karen B. Jacobson, Daniel S. Fierer

Some barriers removed for safe injection site applications

Bill to make it easier to create safe injection sites becomes law

Liberal government legislation that includes measures to remove 26 strict requirements for new supervised injection sites has received royal assent to become law.
Hepatitis C testing

- Point-of-care antibody test
- Recommendations on hepatitis C screening for adults
Health Canada approved point-of-care hepatitis C antibody test

- OraQuick HCV Rapid Antibody Test
- Test uses a drop of blood
- Results in 20 minutes
Recommendations on hepatitis C screening for adults

Guideline

Recommendations on hepatitis C screening for adults

Canadian Task Force on Preventive Health Care
Hepatitis C screening guidelines

• Recommended against age cohort screening for older adults
  • Reasons in report:
    • Lack of accuracy of hepatitis C tests
    • Cost of treating people who test positive
    • People will experience harm if they are test positive for hepatitis C but cannot access treatment
  • Recommend continuation of risk-based screening
Great disappointment: Canadian HCV screening guidelines ignore data and contemporary HCV drug access

Lisa Barrett, Clinician Scientist Jordan Feld, Harry Janssen, Hemant Shah, Morris Sherman
Dalhousie University

Canadian HCV Screening Guidelines: A Disconnect Between Evidence and Recommendations

Alex Haines, Health Economist William WL Wong, Murray Krahn
Toronto Health Economics and Technology Assessment collaborative

Hepatitis C testing in Canada: Don't leave baby boomers behind

Lianping Ti, Research Scientist Julio Montaner, Viviane Lima, Mark Hull, Mel Krajden, Richard Harrigan, Bohdan Nosyk, Jeffrey Joy, Thomas Kerr, Kate Shannon, Evan Wood, Jean Shoveller, Alnoor Ramji, Hin Hin Ko, Eric Yoshida, David Hall, and Rolando Barrios
Seek and Treat for Optimal Prevention of Hepatitis C Virus in British Columbia Team

New hepatitis C screening guidelines will lead to avoidable deaths and soaring costs to health care system
Criticisms of recommendations

- Risk-based screening is not effective
- Hepatitis C screening tests are highly effective
- Birth cohort screening of older adults reflects Canadian epidemiology data
- Access to treatment is improving so it doesn’t make sense to restrict testing
New developments in hepatitis C treatment

- Peg-interferon is no longer used to treat hepatitis C!!
- New treatments that are effective against all genotypes
- More highly effective treatments likely to be approved this year
DAA’s and liver cancer

- Some evidence linking DAA’s to higher liver cancer risk
- Large meta-analysis of 31 studies looking at liver cancer occurrence or recurrence after DAA treatment
  - Found no increased risk

**NO!**
Pan-Canadian Pharmaceutical Alliance and improved access to hepatitis C treatment
Drug formulary coverage

- Pan-Canadian pharmaceutical alliance
  - asunaprevir, daclatasvir, Epclusa and Zepatier
  - Lowered prices for Harvoni and sofosbuvir
Drug formulary coverage

- Yukon, B.C., Alberta, Saskatchewan, Manitoba, Ontario, Quebec, Nova Scotia and New Brunswick have improved access to Hep C meds
- Still require F2 eligibility but long list of exceptions!
Drug formulary list of exceptions

- People who want to get pregnant in the next year
- HIV
- HBV
- Serious chronic kidney disease
- Diabetes that is being treated
- Any organ transplant
- Fatty liver disease
- Extra-hepatitis manifestations
Big news!

- BC and ON- will cover these hepatitis C medications regardless of liver fibrosis level in 2018
Looking for more information?

- HepCinfo updates
- CATIE News
- TreatmentUpdate

Visit [www.catie.ca](http://www.catie.ca) to sign up for subscriptions!
CATIE – World Hepatitis Day
Building on HCV developments in 2017

July 26, 2017

Alexandra King, MD, FRCPC
Nipissing First Nation
Lu’ma Medical Centre (Vancouver)
Commitments by Canada

• The elimination of hepatitis B and C by 2030
  – *Global Strategy on Viral Hepatitis, WHO*

• Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health.
  – *United Declaration on the Rights of Indigenous Peoples*

• Establish measurable goals to identify and close the gaps in health outcomes between Aboriginal and non-Aboriginal communities
  – *Truth and Reconciliation Commission Calls to Action*
Screening/diagnosis

- Est. 44-70% undiagnosed nationally
- Likely non-random
  - ↑ rural/remote
  - ↑ Indigenous
  - ↑ New Canadians
  - ↑ Birth cohort
  - Who else ...?
Screening/diagnosis

- High likelihood of loss to follow-up
  - “In remission”
  - “Antibodies are protective, like with hep B”
  - Forgotten diagnosis
  - Stigmatized disease
  - Unaware of new DAAs
  - Unaware of potential consequences
Impact of HCV: What Happens If We Do Nothing?

- Change in the number of HCV-related liver transplants, decompensated cirrhosis cases, and HCC cases over time


Slide credit: clinicaloptions.com
Hepatitis C screening guidelines

- Recommended against age cohort screening for older adults
  - Reasons in report:
    - Lack of accuracy of hepatitis C tests
    - Cost of treating people who test positive
    - People will experience harm if they are test positive but cannot access treatment
  - Recommend continuation of risk-based screening

Need expanded screening ... and linkage to care/cure
Skin puncture (3\textsuperscript{rd}/4\textsuperscript{th} finger)

Application to DBS card
DBS - Molecular Analysis

1. DBS
2. Bind to silica
3. Elute
4. Purified RNA
5. Wash
6. Elute
7. RT-PCR
8. Sequencing (GATAATCGGTCTATTTCCT)
DBS Validation – HCV antibody (2011)

Ortho HCV

Sero Conversion Panels
PHV 901 1-10
PHV 907 1-7
PHV 917 1-5

Patient samples x 54

TOTAL: 76

FINAL Sensitivity / Specificity = >96% / >95%
Eliminating HCV Is *Everyone’s* Job

- Identify undiagnosed HCV
  - HCV rapid testing
  - Opiate replacement therapy
  - Syringe access

- Preventing infection and reinfection
  - Outreach and education
  - Safer injection counseling
  - Reinfection prevention counseling

- Treatment access and delivery
  - Linkage to HCV care
  - Access to HCV drugs
  - Primary care–based therapy
  - Methadone-based directly observed therapy
  - Access to specialty care

Slide credit: clinicaloptions.com
Change still needed ...

- Non-fibrosis-based treatment
- Provincial jails
- Re-infections
- More rapid adoption of innovations
- Ethical funding
  - Need for sustainable and robust programming
- pCPA
  - Need for increased transparency
Working towards …

- Innovative and comprehensive wise practice, evidence-based care
  - ... throughout care continuum
  - ... culturally safe and appropriate
  - ... regardless of location, regardless of service provider/funder
  - ... not subject to non-clinical constraints

- Coordinated national response which prioritizes Indigenous-led approaches, strategies, targets and accountabilities for Inuit, Métis and First Nations peoples

- Achieving health equity and wellness
Formulary changes don’t eliminate HCV….
but elimination strategies might!

Lisa Barrett MD PhD
Division of Infectious Diseases
July 26 2017
Disclosures

• **Industry:**
  – AbbVie
  – Gilead
  – Merck
  – BMS
  – ViiV

• **Academic:**
  – Affiliation with Dalhousie University and Nova Scotia Health Authority
  – HCV virology / immunology lover

• **Advocacy:**
  – HCV and HIV advocacy groups
HCV: it’s an infection

Infectious diseases can be eliminated
HCV elimination strategies

• Treat HCV infection with highly efficacious DAA therapy to increase cure rates and lower cost per cure

• Treat all individuals with chronic HCV infection
  – Prevent progression to more expensive advanced liver disease
  – Increase work productivity
  – Increase quality of life

• Treat everyone, early or late disease; high or low risk
Where are there challenges to HCV elimination?

Adapted from Yehia et al. 2014 Plos One 9(7): e101554
Where are there challenges to HCV elimination?

- Intervention 1: POC tests
- Intervention 2: Engagement with provider motivational interviewing

Adapted from Yehia et al. 2014 Plos One 9(7): e101554
PEI:
A province that is way ahead
Provincial government

Providers

Education and Evaluation

Automatic referral to provincial HCV program

Treatment timing

Centralized triage and workup

Referral to appropriate provider

HCV Care Plan

Patients

Industry partner

Identification of HCV positive
Nova Scotia: Starting to take the lead from PEI
Hepatitis C in Nova Scotia

• Approximately 1100 Nova Scotians with Hepatitis C (GI database)

• Unclear how many people are infected but unaware of status (?3000 total people?)

• Approximately 30% of the individuals within the GI referral database have advanced liver disease
Hepatitis C in Nova Scotia, 2014-2016

North

South

Central

West

IWK

Courtesy of Todd Hatchette, Jason Leblanc, Charlie Heinstein Provincial testing lab
How does HCV care work in Nova Scotia today?
Move to one health authority great opportunity

All clinical programs are administered by the authority

All funding for clinical programs (outside drug cost) is disseminated to the health authority

Care programs that require drug may / may not be involved in the decisions around drug availability
The hepatitis C situation

- Excellent work within public health to identify and contact trace individuals newly positive for HCV

- Expert providers in multiple disciplines who want to work together
  - Good: expert treatment capacity exists

- Highly invested in:
  - HCV elimination and public health (prevention)
  - Excellent patient care
  - Equitable access to care
  - Judicious, evidence based use of new therapies
  - Assessing outcomes to guide future program decisions
REQUIRES

• **Registry** and health outcomes specialists
• Engaged providers
• Engaged communities
• Programmatic treatment procurement
• **Innovative** partnerships for treatment and care procurement, and delivery
• Commitment to **assessment and research**
GOAL: HCV elimination in Nova Scotia

HARM REDUCTION

GOAL:

HCV elimination in Nova Scotia

Centralized triage and workup

Automatic referral to provincial HCV program

Referral to providers with specific skills in care engagement

Ongoing Education and Evaluation

Identification of HCV positive

Correctional system
HARM REDUCTION

GOAL: HCV elimination in Nova Scotia

- Identification of HCV positive
- Automatic referral to provincial HCV program
- Centralized triage and workup
- Referral to providers with specific skills in care engagement
- Ongoing Education and Evaluation
- Correctional system

Gap in care
Core program in place
TREATMENT SUPPORT, EVALUATION AND EDUCATION

Science of cure research

On-treatment adherence support, advice to patient
Liver health and blood borne pathogen education to patient
Informed consent and enrollment in a provincial de-identified clinical database
Health systems outcome measurement and cost effectiveness analysis

Implementation science of elimination
Critical nodes in moving forward

- Knowing who is infected **INCOMPLETE**

- **Streamlined referral and public health engagement**
  PRELIMINARY ROLL OUT

- Highly effective and well tolerated treatments that are accessible
  **REQUIRES INTER-DEPARTMENTAL GOVERNMENT COLLABORATION IN PUBLIC PAYER SYSTEM**

- Collaborative providers  **YES AND STILL BUILDING**

- Built in evaluation and research to monitor economic, patient, and care effects are key to sustainable program improvement
  **IN PROCESS**
GOAL: HCV elimination in Nova Scotia

Automatic referral to provincial HCV program
Centralized triage and workup
Referral to providers with specific skills in care engagement
Treatment initiation
Ongoing Education and Evaluation

HARM REDUCTION
Correctional system
Identification of HCV positive

Intervention 1: Point of care HCV testing in high risk populations
GOAL:

HCV elimination in Nova Scotia

Automatic referral to provincial HCV program

Centralized triage and workup

Referral to providers with specific skills in care engagement

Ongoing Education and Evaluation

Correctional system

Identification of HCV positive

Correctional system

HARM REDUCTION

Intervention 2: Iterative motivational interviewing techniques
Next steps and challenges

• A national idea that needs provincial buy in

• Political will for elimination?
  – Ongoing education around the public and personal health impetus for treatment

• Organizational cul de sac: no organizational formalized link between clinical program admin and delivery and the people with the curative drug
The city of Saint-Jerome in Quebec has a community clinic that specializes in infectiology. It is a non-profit organisation that offers medical and social support to people living with HIV and Hepatitis C infections.
Please meet our team:
How have frontline realities shifted since the formulary changes?

• No obvious or noticeable changes have been noticed by our team since the formulary changes.
Beyond changing the formulary restrictions, what else needs to be done in order to ensure broad and equitable access in our region / for the community we serve?

• Reduction of stigmas concerning Hepatitis C through education
• Offering free and anonymous testing
• Facilitating access to testing
• Introducing initiation to STD testing in schools (sex-ed class)
• Informing population to get tested for Hepatitis C
• Medical teams can visit workplaces and therapy centers around the province
What other aspects of the continuum of care require attention and changes in our region / for the community we serve?

• Treating patients despite ongoing consumption of illicit drugs
• Broader harm reduction services
• Easier access to substitution/maintenance therapy (ie: Methadone)
• Linking patients to a medical practitioner
• Offering follow-ups for ``fibrotest`` post treatment (q 6 months)
Questions?
Suzanne Fish
Knowledge Broker, Hepatitis C
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Please evaluate this webinar.
Thank you!