

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)



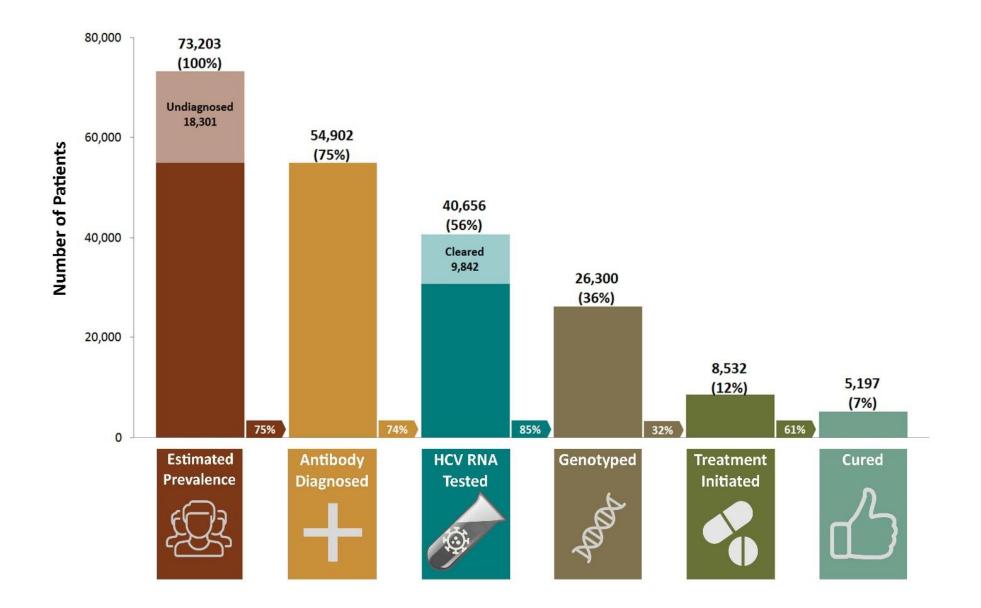
Naveed Z. Janjua DrPH^{a,b,*}, Margot Kuo MPH^a, Amanda Yu MSc^a, Maria Alvarez MSc^a, Stanley Wong MSc^a, Darrel Cook MSc^a, Jason Wong MD^{a,b}, Jason Grebely PhD^c, Zahid A. Butt PhD^{a,b}, Hasina Samji PhD^{a,b}, Alnoor Ramji MD^d, Mark Tyndall MD^{a,b}, Mel Krajden MD^{a,e}



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,¹ Sara Gianella,² Marcus J-S. Yip,¹ Wouter O. van Seggelen,¹ Robert D. Gillies,¹ Andrew L. Foster,¹ Zachary R. Barbati,¹ Davey M. Smith,^{2,3} and Daniel S. Fierer¹



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

Clin Infect Dis (2017) 64 (3): 284-288.

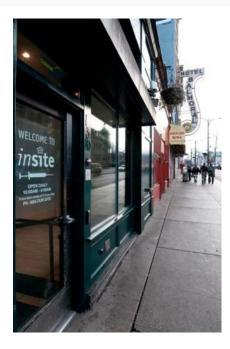


Some barriers removed for safe injection site applications

News · Canada

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

CMAJ April 24, 2017 vol. 189 no. 16 doi: 10.1503/cmaj.161521

Guideline

Recommendations on hepatitis C screening for adults

Canadian Task Force on Preventive Health Care*1



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

Liver in the News

CLF Press Releases

Public Service Announcements

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







.

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





 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 <u>www.catie.ca</u> to sign up for subsciptions!



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)

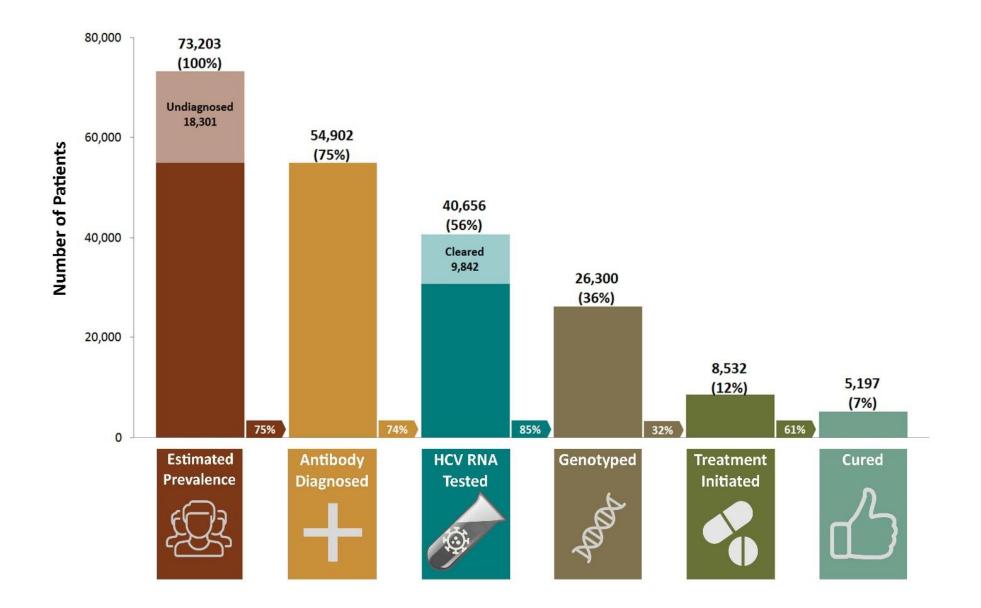


Commitments by Canada

- 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

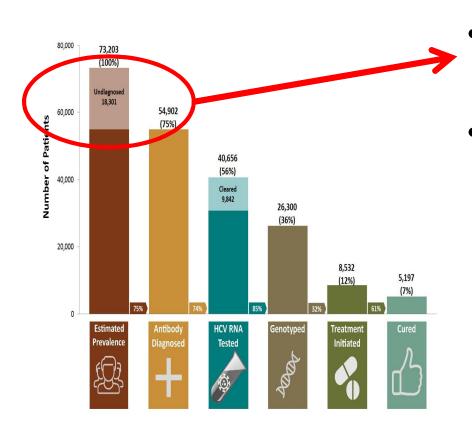
- Establish measurable goals to identify and close the gaps in health outcomes between Aboriginal and non-Aboriginal communities
 - Truth and Reconciliation Commission Calls to Action





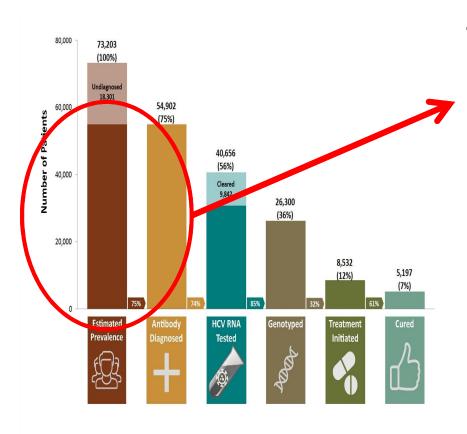
Screening/diagnosis

XCATIE 2



- Est. 44-70% undiagnosed nationally
- Likely non-random
 - \uparrow rural/remote
 - 一个 Indigenous
 - − ↑ New Canadians
 - 个 Birth cohort
 - Who else ...?

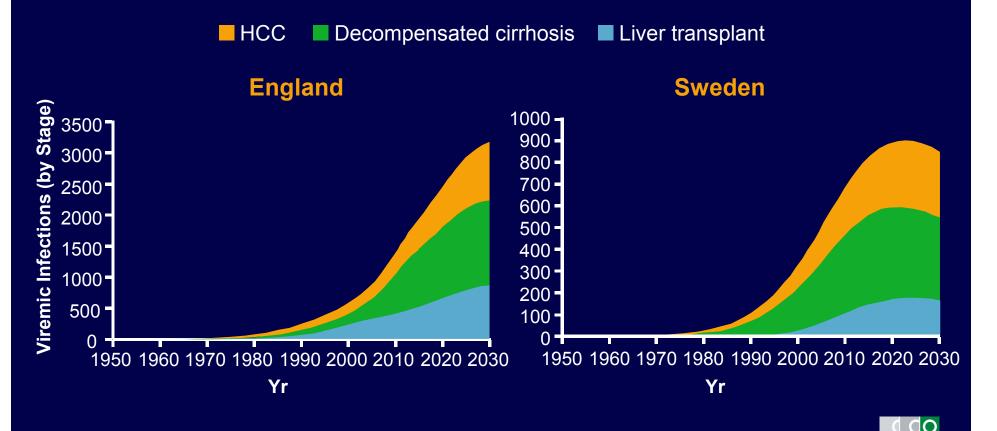
Screening/diagnosis



- 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



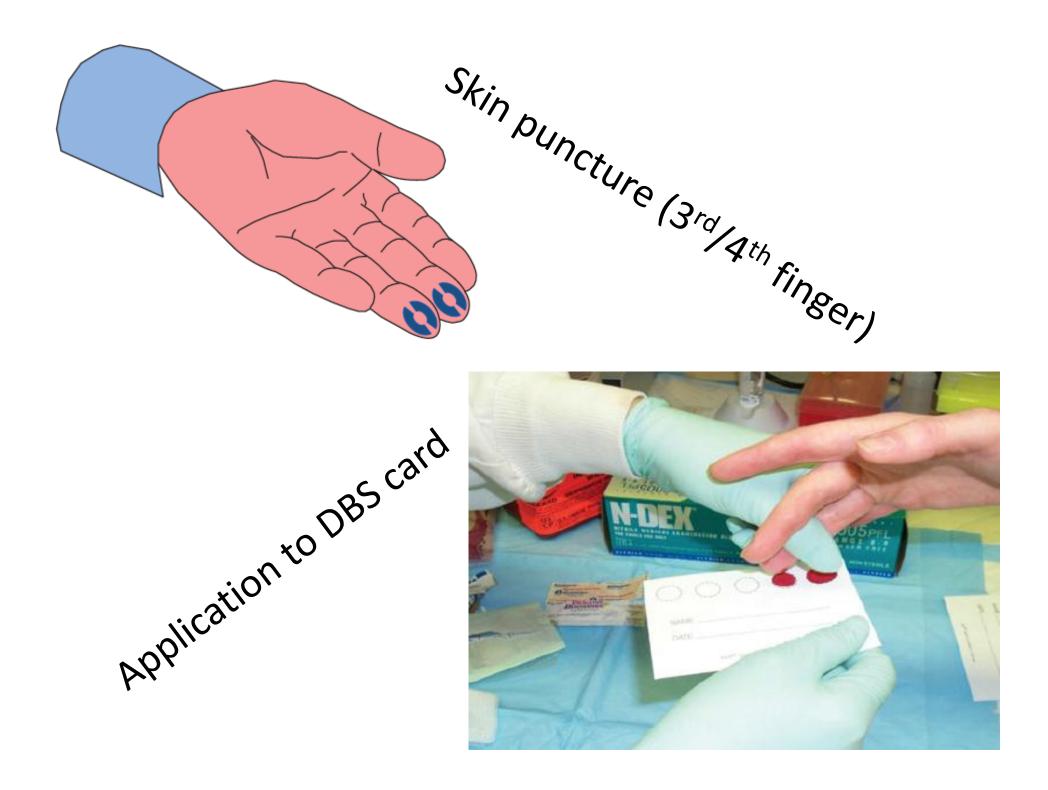
Razavi H, et al. J Viral Hepat. 2014;21(suppl 1):34-59.

Slide credit: clinicaloptions.com

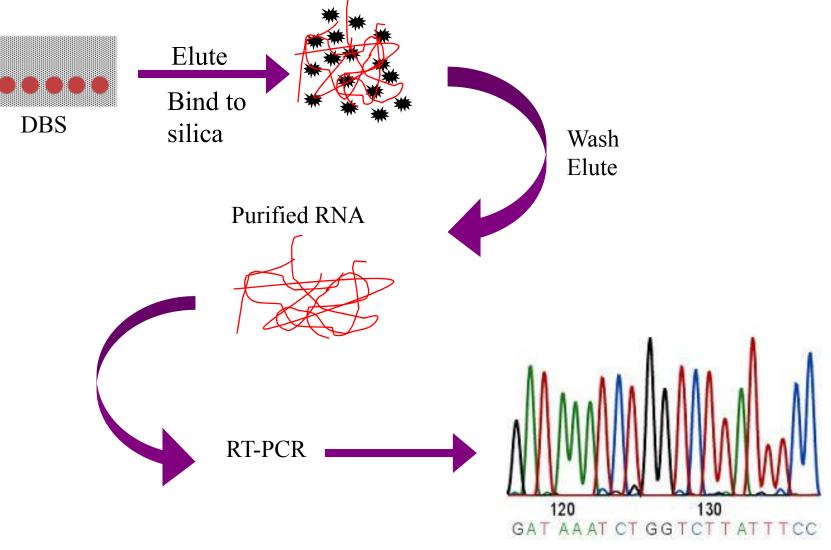
Hepatitis C screening guidelines

- creening Recommended against age cohe ng for older adults
 - Reasons in report;
 - Lack of accur>
 - Cost of + st positive
 - arm if they are test • Per C but cannot access
- continuation of risk-based Rec scree





DBS - Molecular Analysis



DBS Validation –HCV antibody (2011)

Ortho HCV

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

FINAL Sensitivity / Specificity = >96% />95%

Patient samples x 54

TOTAL: 76

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

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

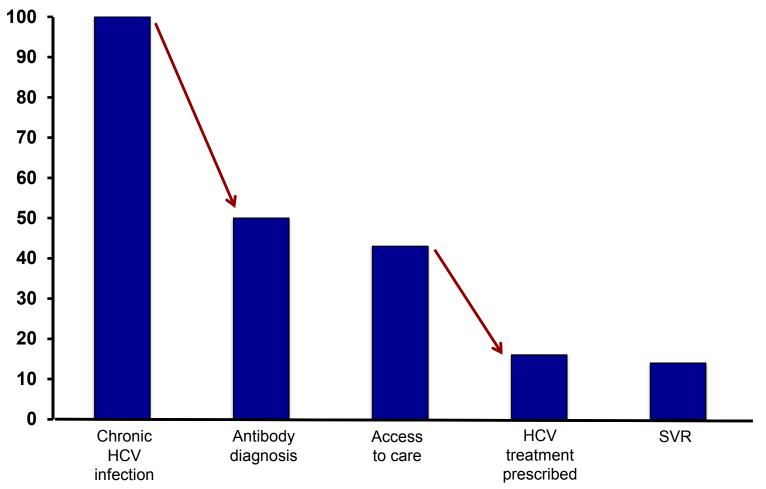
HCV: it's an infection

Infectious diseases can be eliminated

HCV elimination strategies

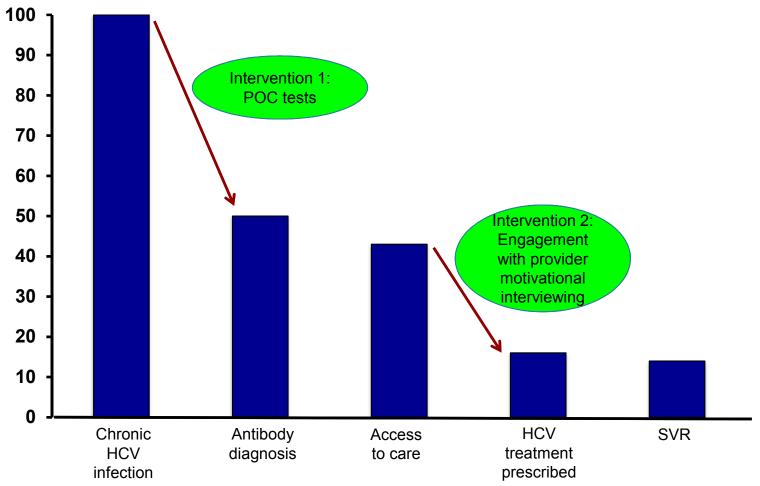
- Treat HCV infection with highly efficacious DAA therapy to increase cure rates and lower cost per cure
- Treat all individuals with chronic HCV infection
 - Prevent progression to more expensive advanced liver disease
 - Increase work productivity
 - Increase quality of life
- Treat everyone, early 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?



Adapted from Yehia et al. 2014 Plos One 9(7): e101554

PEI: A province that is way ahead



PEI model

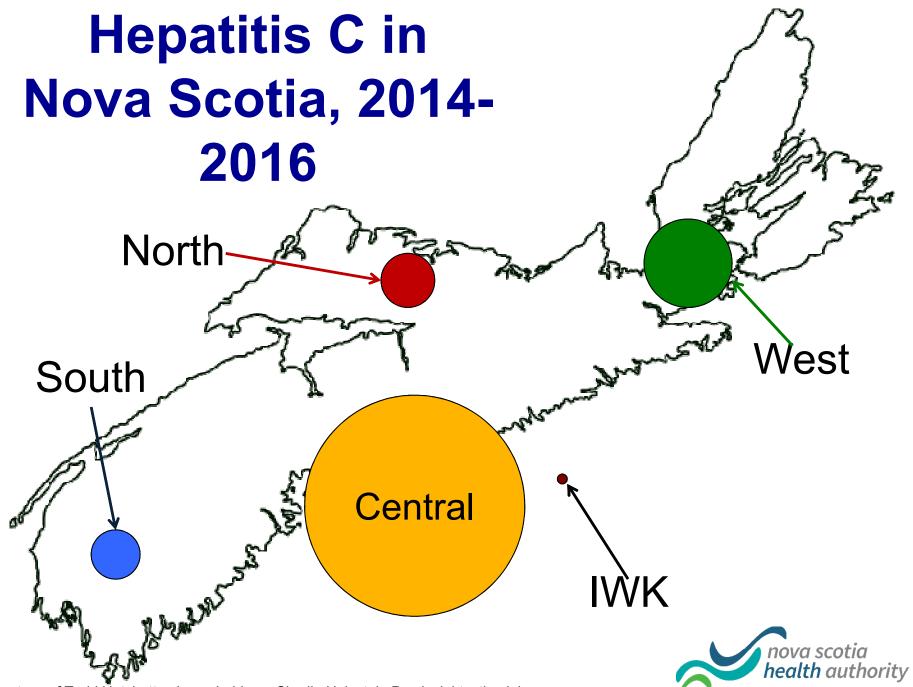


Nova Scotia: Starting to take the lead from PEI



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



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

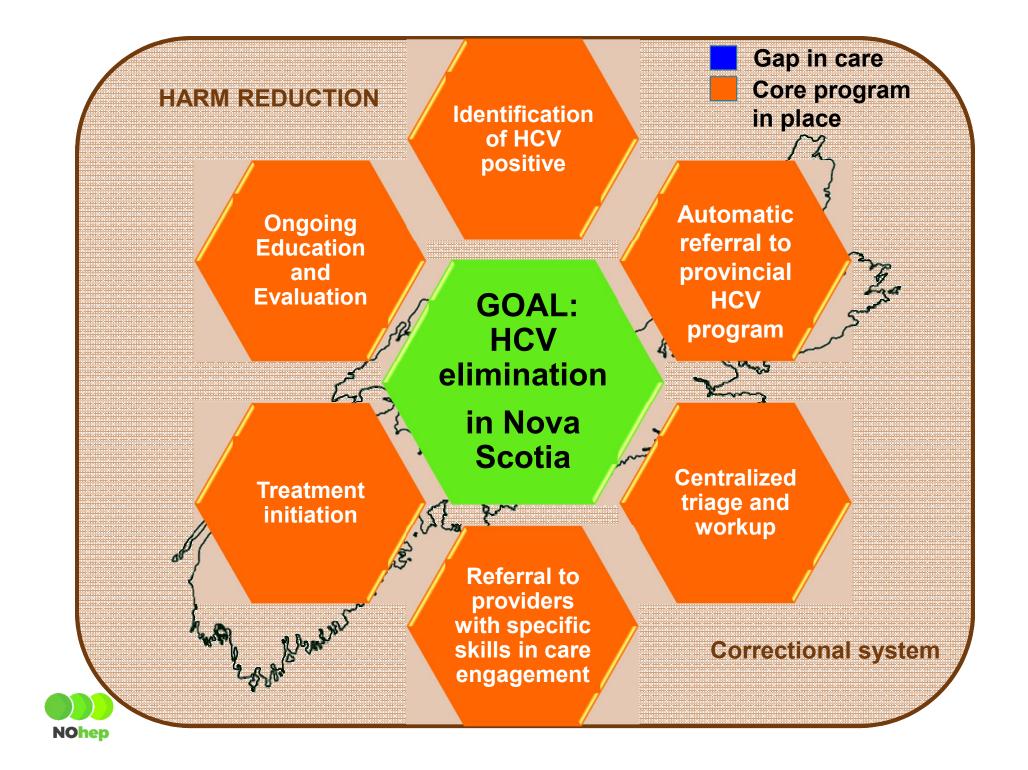
Care programs that require drug may / may not be involved in the decisions around drug availability

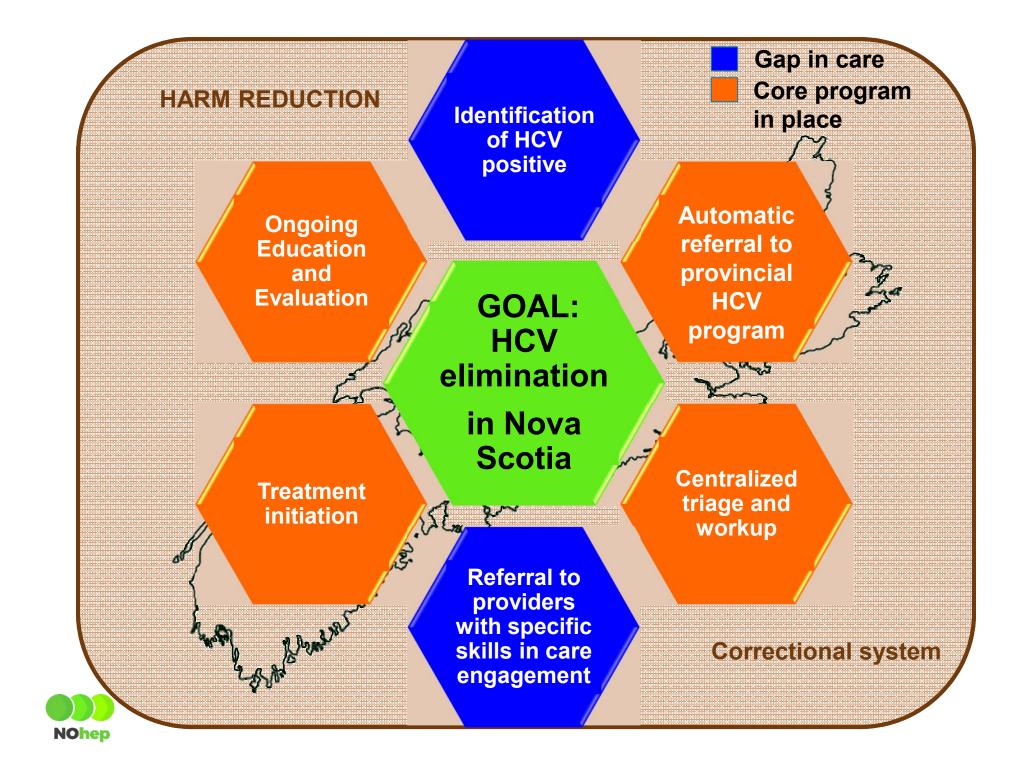
The hepatitis C situation

- 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



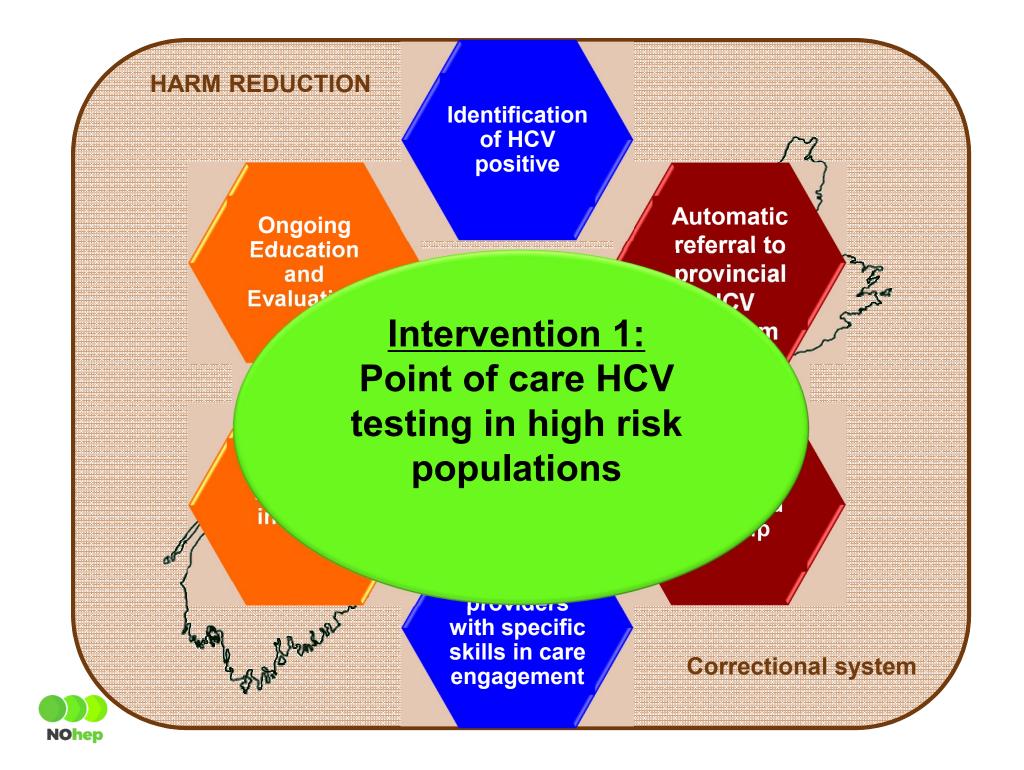


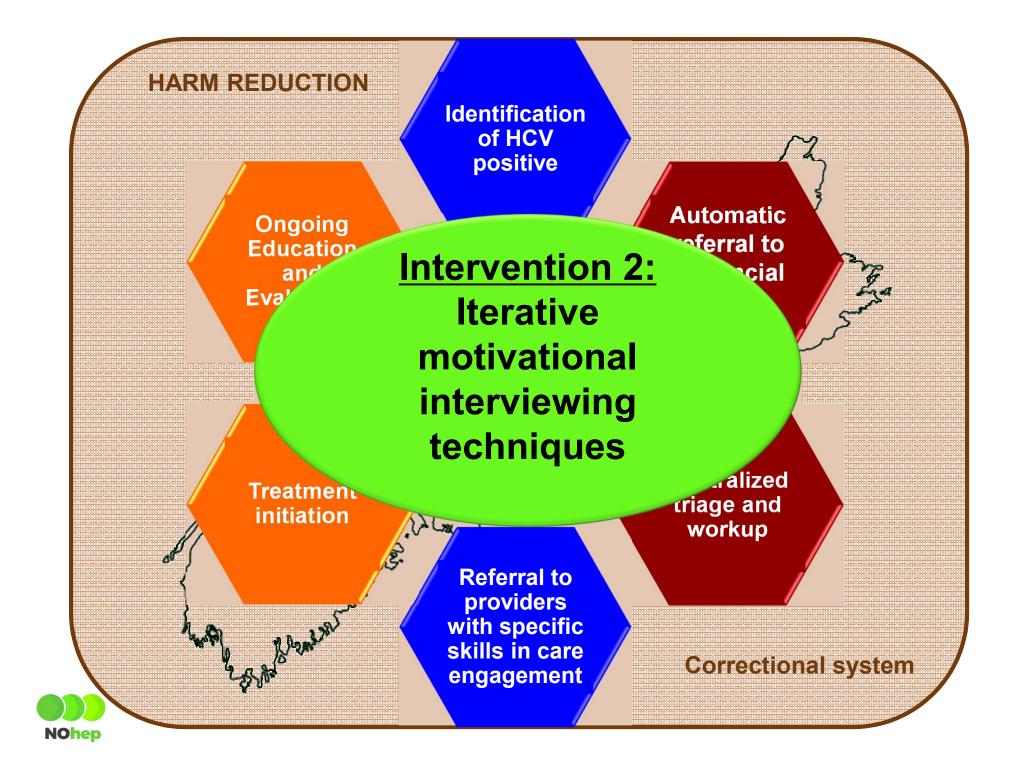
TREATMENT SUPPORT, EVALUATION AND EDUCATION

Science of cure research Liver health and blood borne **On-treatment adherence** pathogen education to patient support, advice to patient Informed consent and Health systems outcome enrollment in a provincial demeasurement and cost identified clinical database 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





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 sfish@catie.ca

Please evaluate this webinar. Thank you!