The micro-elimination of hepatitis C virus (HCV) among people in provincial prisons: What will it take?

Nadine Kronfli
March 27, 2018
Conflicts of interest – Disclosure

• Consulting fees from ViiV Healthcare, Merck and Gilead Sciences; lecture fees from Gilead Sciences; and grants from ViiV Healthcare and Gilead Sciences.

• Canadian HIV Trials Network Postdoctoral Fellow.
Objectives

1. To review the epidemiology of HCV in Canadian correctional facilities.
2. To understand the unique challenges of HCV screening and treatment in provincial prisons.
3. To evaluate interventions to increase engagement along the HCV care cascade among people in prison.
4. To propose a model of care that may expedite micro-elimination of HCV among people in provincial prisons.
Multiple choice

1. Which groups of people in Canada have NOT failed to access hepatitis C treatment in recent years?
   a. People in prison
   b. Men who have sex with men (MSM)
   c. Indigenous people
   d. Active injection drug users
Multiple choice

2. What evidence-based intervention has increased linkage to HCV care following release for people in prison?
   a. Escort to first appointment
   b. Scheduling of first appointment
   c. Peer navigator-based intervention
   d. Dried blood spot (DBS) testing
Natural history of HCV

Acute hepatitis
- HCV infection
- Hepatic artery
- IFNα expression
- Vira tolerance in 70% of infected individuals
- HCV elimination in 30% of infected individuals
- Viral replication

Acute infection often remains undetected

Chronic hepatitis C
- Infected hepatocyte
- Necrotic hepatocyte
- ISG expression in 50% of patients with CHC

The majority (75%) of patients develop chronic HCV

Liver cirrhosis
- Hyperplastic or dysplastic liver nodule
- Cirrhotic liver nodules
- 15-25% of patients with CHC

15-25% develop cirrhosis, of which 3% develop HCC

Historical look at HCV treatment

1989
RCTs carried out using IFNα to treat CHC

1991
Ribavirin tested for CHC

1998
First RCT looking at combo therapy with IFNα + ribavirin

2001
Pegalated IFNα + ribavirin combination therapy is trialed

Long durations (6-12 m) and low SVR rates (10-20%)

Combination therapy resulted in significantly higher SVRs compared with monotherapy at 12 months (40%)

SVR rates increased to 55% with Peg-IFNα.

Hepatology; 1996 24(4):778-89
NEJM 1998; 339:1485-92
Lancet 2001; 358: 958–65
Side effects were common!

- From 2001-2011, the standard of care for chronic HCV was pegIFN + ribavirin x 24-48 weeks
  - Overall SVR 55%
  - Significant side effects!
    - Interferon: cytopenia, influenza-like syndrome, neuropsychiatric issues
    - Ribavirin: anemia (hemolytic), fatigue, rash
A Decade Later... Direct-acting antivirals (DAAs)

1st generation protease inhibitors  
2011

Boceprevir

Telaprevir
SVR rates in G1

*SVR12 rate of 90% among GT 1 patients in the Phase 3 NEUTRINO trial (12 weeks of SOF+PEG-IFN+RBV)

Direct-acting antivirals (DAAs)

Protease Inhibitors (PIs)
- Simeprevir
- Paritaprevir
- Grazoprevir
- Glecaprevir
- Voxilaprevir

Inhibits translation and polyprotein processing

NS3/4

Non-nucleoside PIs (NNPIs)

Nucleoside polymerase inhibitors (NPIs)

NS5A Inhibitors
- Daclatasvir
- Elbasvir
- Ledipasvir
- Ombitasvir
- Velpatasvir
- Pibrentasvir

Inhibits replication complex

NS5A

Translation and polyprotein processing

NS5B

(+)-RNA

Inhibits replication of viral RNA

Sofosbuvir

Dasabuvir

Receptor binding and endocytosis

Fusion and uncoating

α-glucosidase inhibitors
Cegasvir

Transport and release

Viral assembly

RNA replication
Newer DAAs

- Sofosbuvir
  - NS5B inhibitor
- Simeprevir
  - 2nd generation PI
SVR rates in G1

*SVR12 rate of 90% among GT 1 patients in the Phase 3 NEUTRINO trial (12 weeks of SOF+PEG-IFN+RBV)

Fixed dose combinations in the DAA era

• Ledipasvir-sofosbuvir
• Ombitasvir-paritaprevir-ritonavir-dasabuvir
• Glevaprevir-pibrentasvir
• Sofosbuvir-velpatasvir
• Elbasvir-grazoprevir
• Sofosbuvir-daclatasvir
• Sofosbuvir-velpatasvir-voxilaprevir

• All oral regimens
• SVR rates > 95% in non-cirrhotics
• Real-world efficacy in diverse populations (PWIDs, inmates)
• Well tolerated; minimal side effects
• Shorter durations (8-12 weeks in non-cirrhotics)
• Fewer drug-drug interactions
• Easier dosing (OD for the majority)
• Pan-genotypic regimens:
  • Sofosbuvir-velpatasvir
  • Glevaprevir-pibrentasvir
  • Sofosbuvir-velpatasvir-voxilaprevir
Global HCV elimination by 2030

• May 2016: WHO released 1st global strategy on viral hepatitis
  • “Elimination of HCV”: 90% reduction in incident HCV infections and a
    65% reduction in HCV mortality
• DAAs now make elimination of HCV possible!
• “Micro-elimination” approach encouraged
• Canada is NOT on track for elimination by 2030

Barriers to HCV elimination in Canada

**System**

- $$$$ → Restrictions on reimbursement of DAAs to:
  - Advanced liver disease (>F2)
  - HIV/HCV co-infection
  - Insulin-dependent diabetes, etc.
- March 1, 2018: Quebec and British Columbia became the first two provinces to remove restrictions

**Provider**

- Stigma and discrimination towards PWIDs
  - Concerns re. poor adherence and risk of re-infection
- Specialty care

Are there any patient-related barriers?
Canadian HIV-HCV Co-infection Cohort

Cohort Demographic Information
- Aboriginal Female
- Non-aboriginal Female
- Aboriginal Male
- Non-aboriginal Male

Risk Factors for HCV
- IDU ever
- MSM
- Blood
- Other

Map of Canada with regions and data points:
- British Columbia
- Alberta & Saskatchewan
- Ontario
- Quebec & Nova Scotia

Legend:

Details:
- British Columbia: A - Oak Tree (n=101), B - Pender (n=207), E - BCCFE (n=109), U - Native BC (n=63)
- Alberta & Saskatchewan: F - Regina (n=113), G - South Alberta Clinic (n=47), X - Saskatchewan (n=19)
- Ontario: J - Windsor (n=30), M - McMaster (n=59), K - Sunnybrook (n=19), T - Toronto General (n=112), W - Ottawa (n=63)
- Quebec & Nova Scotia: C - Montreal Chest Institute (n=189), K - Montreal General (n=52), H - Halifax (n=13)
Treatment uptake in the Canadian Co-infection Cohort

## DAA treatment uptake among people in prison

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incarceration status (time-updated)</strong></td>
<td>0.71 (0.53, 0.95)</td>
</tr>
<tr>
<td>Age</td>
<td>1.01 (0.99, 1.02)</td>
</tr>
<tr>
<td>Female</td>
<td>0.90 (0.66, 1.21)</td>
</tr>
<tr>
<td>Indigenous ethnicity</td>
<td>0.73 (0.48, 1.13)</td>
</tr>
<tr>
<td>Monthly income &lt; $1500 CAD</td>
<td>0.62 (0.46, 0.85)</td>
</tr>
<tr>
<td>History of IDU</td>
<td>0.90 (0.63, 1.28)</td>
</tr>
<tr>
<td>Active IDU</td>
<td>0.66 (0.43, 1.01)</td>
</tr>
<tr>
<td>Binge drinking at least monthly</td>
<td>0.92 (0.67, 1.27)</td>
</tr>
<tr>
<td>Undetectable HIV RNA (≤ 50 copies)</td>
<td>2.33 (1.63, 3.34)</td>
</tr>
<tr>
<td>APRI &gt; 1.5</td>
<td>1.57 (1.21, 2.05)</td>
</tr>
<tr>
<td>HCV G3</td>
<td>0.77 (0.53, 1.11)</td>
</tr>
<tr>
<td>Psychiatric comorbidities</td>
<td>0.91 (0.71, 1.17)</td>
</tr>
<tr>
<td>British Columbia</td>
<td>1</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>0.24 (0.10, 0.59)</td>
</tr>
<tr>
<td>Quebec</td>
<td>1.83 (1.3, 2.57)</td>
</tr>
<tr>
<td>Other province (ON, AB, NS)</td>
<td>1.08 (0.76, 1.53)</td>
</tr>
</tbody>
</table>

Multiple choice

1. Which groups of people in Canada have NOT failed to access hepatitis C treatment in recent years?
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Multiple choice

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   c. Indigenous people
   d. Active injection drug users

**Patient**-level barriers DO exist!
HIV and HCV prevalence in Canadian correctional facilities

• HIV prevalence (federal/provincial, 2011): ~2-8%\(^1\)
  • 10-fold higher than general population

• HCV prevalence (federal/provincial, 2011): ~25%\(^2\)
  • 40-fold higher than general population

\(^1\)http://www.catie.ca/en/hiv-canada/2/2-3/2-3-8
\approx 84,000 \text{ Canadians living with HIV} \quad \cap \quad \approx 250,000 \text{ Canadians living with HCV} \\
\downarrow \\
\approx 17,000 \text{ Canadians are co-infected}
Canadian adult correctional statistics

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Custody number</th>
<th>Custody rate</th>
<th>Community supervision number</th>
<th>Community supervision rate</th>
<th>Total correctional services number</th>
<th>Total correctional services rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newfoundland and Labrador</td>
<td>359</td>
<td>82</td>
<td>1,610</td>
<td>369</td>
<td>1,968</td>
<td>452</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>84</td>
<td>71</td>
<td>824</td>
<td>698</td>
<td>907</td>
<td>769</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>483</td>
<td>62</td>
<td>13,581</td>
<td>632</td>
<td>14,798</td>
<td>385</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>442</td>
<td>71</td>
<td>7,202</td>
<td>960</td>
<td>14,411</td>
<td>379</td>
</tr>
<tr>
<td>Quebec</td>
<td>5,097</td>
<td>76</td>
<td>6,495</td>
<td>316</td>
<td>14,798</td>
<td>385</td>
</tr>
<tr>
<td>Ontario</td>
<td>7,960</td>
<td>72</td>
<td>43,977</td>
<td>937</td>
<td>49,944</td>
<td>1,445</td>
</tr>
<tr>
<td>Manitoba</td>
<td>2,424</td>
<td>242</td>
<td>722</td>
<td>960</td>
<td>827</td>
<td>277</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>1,812</td>
<td>207</td>
<td>6,495</td>
<td>316</td>
<td>14,798</td>
<td>385</td>
</tr>
<tr>
<td>Alberta</td>
<td>3,673</td>
<td>112</td>
<td>8,877</td>
<td>379</td>
<td>14,411</td>
<td>379</td>
</tr>
<tr>
<td>British Columbia</td>
<td>2,653</td>
<td>69</td>
<td>13,146</td>
<td>318</td>
<td>14,798</td>
<td>385</td>
</tr>
<tr>
<td>Yukon</td>
<td>94</td>
<td>317</td>
<td>895</td>
<td>2,377</td>
<td>120,568</td>
<td>438</td>
</tr>
<tr>
<td>Northwest Territories</td>
<td>189</td>
<td>570</td>
<td>136</td>
<td>575</td>
<td>120,568</td>
<td>438</td>
</tr>
<tr>
<td>Nunavut</td>
<td>136</td>
<td>575</td>
<td>136</td>
<td>575</td>
<td>120,568</td>
<td>438</td>
</tr>
<tr>
<td>Provinces and territories-total</td>
<td>25,405</td>
<td>88</td>
<td>96,087</td>
<td>349</td>
<td>120,568</td>
<td>438</td>
</tr>
<tr>
<td>Federal</td>
<td>14,742</td>
<td>51</td>
<td>8,215</td>
<td>28</td>
<td>22,956</td>
<td>79</td>
</tr>
<tr>
<td>Total</td>
<td>40,147</td>
<td>139</td>
<td>104,298</td>
<td>442</td>
<td>120,568</td>
<td>438</td>
</tr>
</tbody>
</table>

2,700
4,400
Focusing on prison populations is key

• Modelling studies have shown:
  1. Negative impact of incarceration on perpetuating the HCV epidemic\(^1\)
  2. Scaling-up prison-based HCV treatment to 80% of chronically-infected PWID with sentences >16 weeks could reduce HCV incidence and prevalence among all PWID by ~ 45%, suggesting both an individual and population-level impact\(^2\)
  3. HCV treatment in prisons could be cost-effective if continuity of care is ensured at the time of release\(^3\)

** Unique opportunity to engage high-risk individuals in care

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Dramatic budget increase for Hepatitis treatment in federal prisons

Paul Webster | Toronto | July 27, 2017

All federal inmates with HCV eligible for treatment
Percentage of releases from adult provincial/territorial custody, by time served, 2015/2016

Note: Excludes Alberta due to the unavailability of data.
Provincial prisons – what makes them unique?

1. High turnover rates due to short incarcerations
2. Prison transfers are not uncommon
3. High cost of DAAs that must be defrayed by prison budgets
4. HCV treatment outcomes differ depending on sentence duration and possibility for transfer:
   • SVR rates were highest for inmates who remained in prison during treatment (74%) when compared to those who were transferred (59%) or those who were released during treatment (45%)

LINKAGE/CONTINUITY OF CARE AT TIME OF RELEASE SHOULD BE PRIORITIZED
COMMENTARY  VULNERABLE POPULATIONS

Care for people with hepatitis C in provincial and territorial prisons

Nadine Kronfli MD MPH, Joseph Cox MD MSc

HCV cascade of care

- Identification of high-risk individuals
- Testing & diagnosis
- Linkage to care
- Treatment
- Sustained virologic response (SVR)
- Long-term f/u (re-infection)
What can be learned from HIV care in prisons?

• **Testing**
  - *Universal screening* (opt-out > opt-in) >> Risk-based screening >> On-demand
  - *Early* (within 24 h of incarceration) > Immediate to entry > 1-week delay
    - 53% vs. 45% vs. 33%
  - *POC* testing (finger prick or salivary) is acceptable to people in prison

• **Linkage**
  - *Pre-discharge planning* with scheduling of specialist appointment at the time of release
  - *Appointment escort* post-release transportation
Interventions to increase testing, linkage to care and treatment of HCV infection among people in prison: A systematic review

## Interventions to increase testing

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Study Design</th>
<th>Location</th>
<th>Setting</th>
<th>Population</th>
<th>Intervention description</th>
<th>Comparator description</th>
<th>Outcome description</th>
<th>Outcome in intervention arm</th>
<th>Outcome in comparator arm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On-site HCV testing with education and counselling</strong>&lt;br&gt;Winter (2017)³</td>
<td>Two-arm, (pre-post) controlled</td>
<td>Australia</td>
<td>3 adult prisons (2 male, 1 female)</td>
<td>100% prisoners; 67% male</td>
<td>Opt-in blood-borne virus and sexually transmitted infection (BBV/STI) testing through a once-weekly clinic operated by specialist public health nurses</td>
<td>Standard of care</td>
<td>HCV testing uptake</td>
<td>25.4% (95% CI: 20.3-30.5%)</td>
<td>13.0% (95% CI: 9.1-16.9%)</td>
</tr>
<tr>
<td><strong>Combination birth-cohort and risk-based testing</strong>&lt;br&gt;Stockman (2016)⁴</td>
<td>Single arm</td>
<td>USA</td>
<td>2 adult state prisons (1 male, 1 female)</td>
<td>965 prisoners</td>
<td>Risk-based HCV testing. (Any one of: history of injection drug use; elevated liver enzymes; anti-HCV Ab+; HIV+; or history of liver disease)</td>
<td>Risk-based HCV testing. (Any one of: history of injection drug use; elevated liver enzymes; anti-HCV Ab+; HIV+; or history of liver disease)</td>
<td>HCV testing uptake</td>
<td>36.9% tested (95% CI 88, 96)</td>
<td>28.3% tested (95% CI 83, 93)</td>
</tr>
<tr>
<td><strong>Dried blood spot (DBS) testing</strong>&lt;br&gt;Craine (2015)²</td>
<td>Step-wedged RCT</td>
<td>United Kingdom</td>
<td>5 prisons (4 male, 1 female)</td>
<td>14 sites (3 prisons; 11 drug specialty clinics)</td>
<td>Standard of care: on-demand venipuncture</td>
<td>Standard of care: on-demand venipuncture</td>
<td>HCV testing uptake</td>
<td>No arm-specific outcome information provided.</td>
<td>No arm-specific outcome information provided.</td>
</tr>
<tr>
<td>Hickman (2008)⁵</td>
<td>Cluster RCT</td>
<td>United Kingdom</td>
<td>14 sites (3 prisons; 11 drug specialty clinics)</td>
<td>348 tested (all participants)</td>
<td>HCV testing uptake</td>
<td>HCV testing uptake</td>
<td>348 tested (all participants)</td>
<td>122 tested (all participants)</td>
<td></td>
</tr>
<tr>
<td>McLeod (2014)⁶</td>
<td>Two-arm, (pre-post) controlled</td>
<td>United Kingdom</td>
<td>Multiple settings including prison</td>
<td>429 tested (all participants)</td>
<td>HCV testing uptake</td>
<td>HCV testing uptake</td>
<td>429 tested (all participants)</td>
<td>257 tested (all participants)</td>
<td></td>
</tr>
</tbody>
</table>
## Interventions to increase linkage to care

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Study Design</th>
<th>Location</th>
<th>Setting</th>
<th>Population</th>
<th>Intervention description</th>
<th>Comparator description</th>
<th>Outcome description</th>
<th>Outcome in intervention arm</th>
<th>Outcome in comparator arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tait (2010)</td>
<td>Cohort study (pre-post)</td>
<td>United Kingdom</td>
<td>Multiple settings including prison</td>
<td>No prison-specific demographic information provided</td>
<td>Non-medical and outreach nurse-led facilitated referral to hepatitis specialist</td>
<td>Medical-led referral only (usual care)</td>
<td>Hepatitis specialist appointment attendance</td>
<td>75 inmates linked to care</td>
<td>4 inmates linked to care</td>
</tr>
</tbody>
</table>

### A. Risk of bias assessment for included randomised studies using the Cochrane Collaboration’s risk of bias tool3

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Selection bias (random sequence)</th>
<th>Selection bias (allocation concealment)</th>
<th>Performance bias</th>
<th>Detection bias</th>
<th>Attrition bias</th>
<th>Reporting bias</th>
<th>Other bias</th>
<th>Number of domains of high risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craine (2015)</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>Unclear</td>
<td>2</td>
</tr>
<tr>
<td>Hickman (2008)</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>4</td>
</tr>
</tbody>
</table>

### B. Risk of bias assessment for included non-randomised studies using the ROBINS-I assessment tool4

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Bias due to confounding</th>
<th>Bias in selection of participants into the study</th>
<th>Bias in classification of interventions</th>
<th>Bias due to deviations from intended interventions</th>
<th>Bias due to missing data</th>
<th>Bias in measurement of outcomes</th>
<th>Bias in selection of the reported result</th>
<th>Risk of bias judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stockman (2016)</td>
<td>Moderate</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
<tr>
<td>McLeod (2014)</td>
<td>Serious</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Serious</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Serious</td>
</tr>
<tr>
<td>Winter (2016)</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

| Tait (2010)   | Critical                | Moderate                                       | Moderate                                | Serious                                       | Moderate                 | Moderate                            | Moderate                        | Critical                |
Conclusions

• Dearth of studies focused on enhancing engagement along the HCV care cascade for people in prison

• With the introduction of DAAs, rigorous controlled studies evaluating interventions to improve testing, linkage and treatment uptake for people in prison are necessary to eliminate HCV
Multiple choice

2. What evidence-based intervention has increased linkage to HCV care following release for people in prison?
   a. Escort to first appointment
   b. Scheduling of first appointment
   c. Peer navigator-based intervention
   d. Dried blood spot (DBS) testing
Multiple choice

2. What evidence-based intervention has increased linkage to HCV care following release for people in prison?

a. Escort to first appointment
b. Scheduling of first appointment
c. Peer navigator-based intervention
d. Dried blood spot (DBS) testing
HCV models of care

• Australian prisons: Nurse-led care packages including testing, liver disease assessments (transient elastography), HCV education and disease management → Increased treatment initiation and completion

• Transient elastography resulted in increased linkage to HCV care for PWID

• ASCEND study: Similar SVR rates whether patients treated by NPs, primary care physicians or ID specialists
  • Important cost implications

1 McDonald L et al. EASL 2017
Study site: Bordeaux prison
Bordeaux Prison inmates (Sentence ≥ 2 weeks)

Incarceration

HCV Ab- n=1600

POC HCV screen by prison nurses n=2000+

24 hours

Excluded

HCV Ab+ n=400

Confirmatory HCV serology and other bloodwork

Bloods sent for analysis

HCV RNA- (Cleared) n=100

Nurse-led HCV education

Nurse-led:
1. Liver health assessment via transient elastography (TE);
2. HCV education;
3. Disease management session; and
4. Preliminary treatment plan.

HCV RNA+ (Chronic) n=300

2-4 weeks**

Social worker-led:
1. Harm reduction needs assessment and community referral; and
2. Pre-release discharge plan.

Release

Patient navigator-led:
1. Pre-release meeting;
2. Post-release transport and/or support to first HCV care appointment.

HCV care appointment:
1. Satisfaction questionnaire; and
2. HCV treatment initiation.
Study objectives

• Objective 1:
  • To improve HCV care along the cascade of care to people in prison – from screening, access and linkage to care – using a multidisciplinary allied health care model.

• Objective 2:
  • To examine the implementation of the multidisciplinary allied health care intervention in a provincial prison in order to inform future scalability and sustainability.
Specialist advice

- Parameters requiring specialist advice (via telephone or electronic communication) include:
  - Total bilirubin > 1.5x UNL
  - Platelet count <150,000/μl
  - AST:Platelet Ratio Index (APRI) > 1.5
  - Known cirrhosis
  - Liver stiffness > 12.5kPA
  - HIV or HBV co-infection
  - Non-alcoholic steatohepatitis (NASH)
  - Previous or known malignancy
  - Chronic renal or cardiac disease
Outcome measures: objective 1

- **Primary endpoints** - To assess the proportion of prison inmates who are:
  - Screened for HCV: That is, who agree to HCV diagnostic testing.
  - Evaluated for liver disease: That is, who agree to transient elastography.
  - Scheduled for a follow-up HCV care appointment: That is, who are provided with a pre-release discharge plan.
  - Linked to HCV care: That is, who present for their first HCV care appointment outside the provincial prison setting within 30 ("early linkage") or 90 days ("delayed linkage") from the time of release.
Outcome measures: objective 1

- **Secondary endpoints** - To examine:
  - Treatment uptake: That is, the proportion of released inmates who are initiated on Health Canada approved DAAs; and
  - Correlates of retention and attrition along the HCV care cascade.
Outcome measures: objective 2

• Primary endpoints:
  • Acceptability: That is, to what extent is the multidisciplinary allied health care intervention satisfactory to prison inmates?
  • Costs: That is, how do costs associated with the multidisciplinary allied health care intervention compare to those for individuals receiving usual care? Is the intervention cost-effective compared to usual care?
Patient Flow

Bordeaux Prison inmates (Sentence ≥ 2 weeks)

Questionnaire re. previous HCV testing and status n=1000

Yes

POC HCV screen

HCV Ab+

Confirmatory HCV serology

HCV RNA+ (Chronic)

Healthcare utilization questionnaire (q3 months)

Standard of care

HCV Ab−

HCV RNA− (Cleared)

Healthcare utilization questionnaire

No

Do not know

Incarceration

24 hours

Release

2-4 weeks

90 days

180 days

Healthcare utilization questionnaire
Study design

- Quasi-experimental (pre-post) study design over 3 years
- **Preparatory phase**: January – June 2018
- **Pre-intervention phase**: July 2018 – December 2018
- **Intervention phase**: January 2019 – December 2019
- **Follow-up period**: January 2020 – December 2020
- **Data analysis**: January 2021 – June 2021
Ethical recommendations of research with prisoners

- A steering committee consisting of:
  - The research team
  - Representative(s) for health programs in the prison setting
  - Representative(s) from the Ministry of Public Security
  - Inmate(s) with chronic HCV to help guide project plans
Challenges of conducting research in correctional facilities

• Research in prison settings has yet to gain traction → Limited knowledge base/resources in Canada
  • F. Kouyoumdjian (CMAJ 2017): 2010-2014, 21 grants
    • During the 5-year study period, 21 grants were awarded that included a focus on prison health research, for a total of $2,289,948. Six of these grants were operating grants and 6 supported graduate or fellowship training.
    • In total, **0.13% of all grants and 0.05% of all funding was for prison health research.**

• Numerous anticipated challenges:
  • **System-level:** Gaining access to the research setting, obtaining research review and approval, navigating the research settings’ policies and procedures, and managing interruptions and delays due to the research setting\(^1\)
  • **Patient-level:** Maintaining privacy and confidentiality\(^2\)

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Successes to date...

- Funded!

- Stakeholder relationships one year old!

- Team has unique skill-set
  - Joseph Cox (co-PI)
  - Marina B. Klein
  - Bertrand Lebouche
  - Giada Sebastiani
  - Eric Latimer
  - Mathieu Maheu-Giroux
  - Jacques Fallu
Let’s end on a high note...

Demonstration of near-elimination of hepatitis C virus among a prison population: the Lotus Glen Correctional Centre hepatitis C treatment project 📚

Sofia R Bartlett, Penny Fox, Harris Cabatingan, Anissa Jaros, Carla Gorton ...

*Clinical Infectious Diseases, ciy210, https://doi-org.libaccess.lib.mcmaster.ca/10.1093/cid/ciy210*

**Published:** 12 March 2018

<table>
<thead>
<tr>
<th>Intention to Treat population (n=98)</th>
<th>Per protocol population (n=66)</th>
<th>Lost to follow up*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n = 119)</td>
<td>SVR12**§ (n = 64)</td>
<td>HCV viral relapse (n = 2)</td>
</tr>
<tr>
<td>Primary endpoint not yet reached (n=21)</td>
<td>Treatment not yet complete (n = 12)</td>
<td>SVR12 not yet reached (n = 9)</td>
</tr>
</tbody>
</table>
Acknowledgments

Marina B. Klein

Joseph Cox
Thank you!