CHRONIC HEPATITIS C ERADICATION MODEL THROUGH PRIMARY CARE: TREATING HCV IN PRISONS AND THE COMMUNITY CONTINUUM of care

Farley J[1], Jabar A[1], Farley J-R[1], Hakobyan V[1]
[1]Dr John Farley Inc, Vancouver, BC, Canada

Disclosures

- Dr. John Farley has received research grants and honoraria from Gilead Sciences Canada, Roche Canada, Abvie Canada and Merck Canada

National Incarceration System:

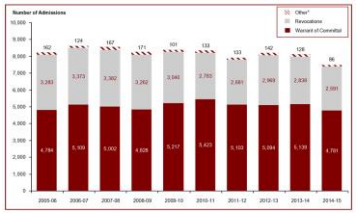
- Provincial / Territorial:
  - Sentences < 2 years
  - Offenders sentenced to probation
  - Young offenders
- Federal: (Correctional Service Canada)
  - Sentences > 2 years
  - 53 penitentiaries (5 for women only)
  - 17 community correctional centres (day parole, conditional release)
  - 175 community-based residential facilities (half-way houses)

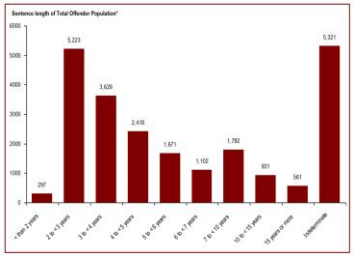
(PWGSC, 2001)

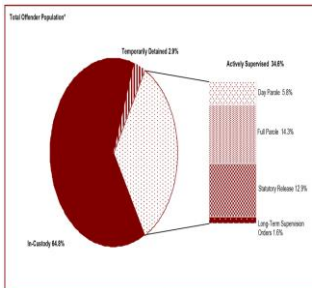
Incarcerated Population:

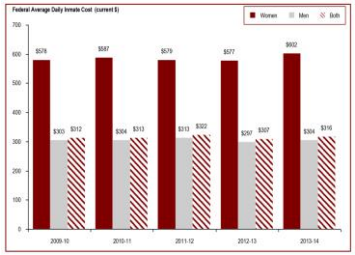
- **1999/00:**
  - **Total average combined incarcerated population (FPT) 31,600**
  - **285,000 convictions (adults):**
    - **2/3 no term sentence**
    - **1/3 term sentence – 5% of which are Federal (> 2 yrs)**
- **2001:**
  - **Federal population: 14,984 (average)**
    - **97% men**
    - **15% aboriginal**
  - **Approximately 7000 new admissions per year**

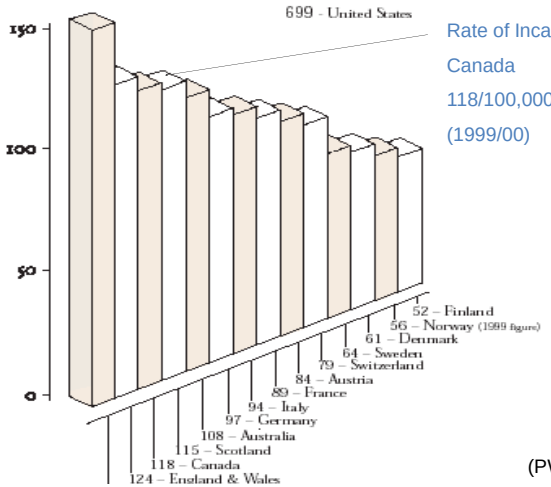
(PWGSC, 2001)







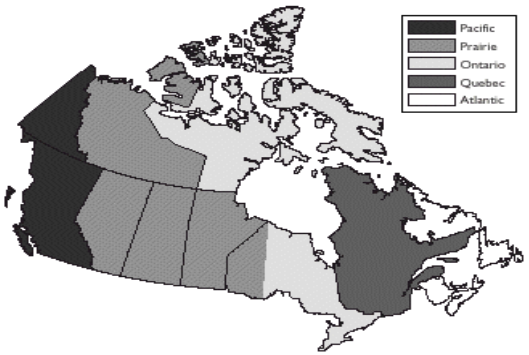


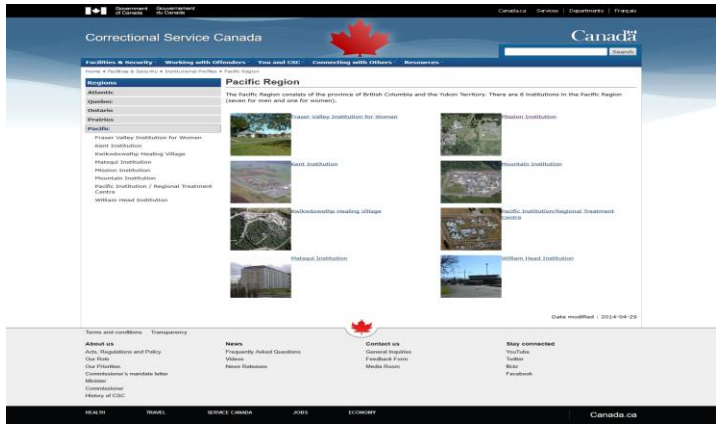


Rate of Incarceration:
Canada
118/100,000 population
(1999/00)

(PWGSC, 2001)

Figure 1. Regions administered by the Correctional Service of Canada





Legislation

- **THE CORRECTIONAL SERVICE OF CANADA**
  Corrections and Conditional Release Act
  Section 86 – Inmate Health
- ***The Service shall provide every inmate with***
  (a) essential health care; and
  (b) reasonable access to non-essential mental health care that will contribute to the inmate's rehabilitation and successful reintegration into the community.
- ***The provision of health care under subsection (1) shall conform to professionally accepted standards.***
- **Services provided by CSC Health Services Branch**

- **Screening for HCV/ HIV/ HBV etc offered to inmates at intake (and any time after)**
- **Inmates may request evaluation for treatment**

Infectious Diseases Program (continued)

- Based on surveillance system (2001, in general inmate population)
- HIV:
  - 223 cases (1.8%)
  - ~50% on HAART
- HCV:
  - 2993 cases (23.6%)
  - Rates of reported infection Much higher in women (41.2% vs 23.2%)
  - Treatment largely non existent: Logistical nightmare - Sent to community specialists
- HBV: 43 new cases (0.3%)
- STI: poor testing uptake

(CSC, 2003)

HCV Epidemiology: Canada

- Prevalence[1]
  - .8% anti HCV positive
- Incidence[3]
  - 8,000 new cases per year
  - 2,000 of these recognized as acute

1. **Zou S et al. Canada Communicable Disease Report. Sept 2001;2753.**.

3. Health Canada - About Hepatitis C; 2003 05 01

Infectious Diseases Consultant Contract Services

HCV Treatment in Institutions

- **Organized**
  - **Nurse – centered program including mentorship**
  - **Protocols for treatment**
  - **Contracted Liver Biopsies to local Radiology Clinic**
  - **Advocated for and Started HCV Treatment in institutions (with Interferon/ Ribavirin- based regimens**
  - **Set up electronic database**

Review based on database

- **Retrospective review (Nov 2000- February 2004)**
- **558 inmates of which 454 were anti-HCV+**
- **233 inmates on treatment**
- **Of the 233 inmates on treatment,**
  - **114 were on Rebetron®**
  - **118 were on Pegetron®**
  - **1 was on Pegasys®**

This publication focuses on the 114 inmates on Pegylated Interferon & Ribavirin combination

Hepatitis C treatment in a Canadian federal correctional population: Preliminary feasibility and outcomes

Author(s):
John Farley (Dr. John Farley Inc., Vancouver and Department of Health Care and Epidemiology, The University of British Columbia, Vancouver, BC, Canada)

Abstract:
Hepatitis C virus (HCV) infection is a major public health concern in Canada, which now mostly affects marginalized populations, including correctional inmates. These populations - until recently - have largely been excluded from HCV pharmacotherapy. We report preliminary data on HCV treatment in a federal correctional population sample in British Columbia (BC), using Pegetron combination therapy. HCV RNA results are presented at week 12 of treatment, a strong predictor of treatment outcome. Just over four-fifths (80.8%) of inmate patients had no detectable HCV RNA at week 12; inmates with genotype 2 and 3 fared better than those with genotype These preliminary results suggest that HCV treatment is feasible and promises to be efficacious in correctional populations.

Keywords:
HCV, Treatment, Canadian correctional populations
Type:
General review
Publisher:
Emerald Group Publishing Limited

Citation:
John Farley, Shawn Vasdev, Benedikt Fischer, Jürgen Rehm, Emma Haydon, (2005) "Hepatitis C treatment in a Canadian federal correctional population: Preliminary feasibility and outcomes", International Journal of Prisoner Health, Vol. 1 Issue: 1, pp.13-18, https://doi.org/10.1080/17449200500157044

HCV RNA+ Inmates treated with Rebetron®: Treatment Outcome

	Overall		By Genotype						
			1		2		3		Total
SVR	52/80	65%	17/38	45%	12/12	100%	23/30	77%	52
Failure	28/80	35%	21/38	55%	0/12	0%	7/30	23%	28
Total	80/80	100%	38/38	100%	12/12	100%	30/30	100%	80

Conclusions: Available Evidence (Proof of concept)

- Canadian federal correctional settings offer a very important opportunity to reach a marginalized (& motivated) population.
- Effective treatment and adherence to a complex regimen can be satisfactorily achieved.
- Every effort should be made to use this opportunity for an important public health intervention.
- A team comprising of a specialist and nurses can be very cost effective in delivering treatment and care to those with chronic Hep C.

Barriers to Treating Hepatitis C in Canadian prison populations

- The major barrier for initiating the HCV and HIV treatment in correctional facility: capability for continuing the treatment and follow up on discharge to the community.

Continuation of Treatment of Inmates with Hepatitis C Infection on Discharge to the Community

2004: The Inmate Community Health Reintegration Services Project (InCoHRS)

Why InCoHRS?

- Transition for prisoners from custody to community often chaotic and difficult.
- Health-care concerns often take a lower priority than the search for jobs and housing, rebuilding personal relationships, and other chores.
- InCoHRS provides an accessible health-care service for prisoners during transition from custody to community.

What are InCoHRS services?

Post-Release Services

- **Health services including education**
- **Counseling and group support**
- **Assist in applying for support services (eg welfare)**
- **Health clinics and methadone clinics**
- **Communicate with family members on support issue**
- **Referral to other services (HIV/AIDS, metal health, transition houses, outreach workers, employment)**
- **Assistance with ensuring that medications available on release eg NAVIGATING THE HEALTH CARE / PHARMACARE SYSTEM MAZE**

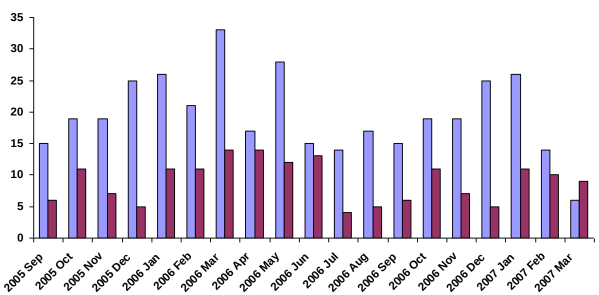
Importance of INCOHRS

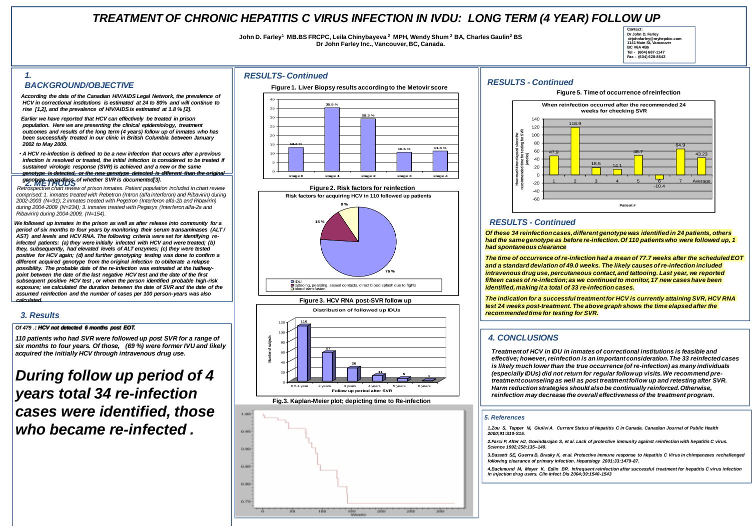
- A link between CSC and community to assist in their reestablishment in the community

INCOHRS services

- As of March 31, 2007,
  - 373 CSC Inmates received services

Number of inmates who access InCoHRS services monthly





TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION IN IVDU: LONG TERM (4 YEAR) FOLLOW UP

John D. Farley[1] MB.BS FRCPC, Leila Chinybayeva[2] MPH, Wendy Shum[2] BA, Charles Gaulin[2] BS
Dr John Farley Inc., Vancouver, BC, Canada.

Contact:
Dr John D. Farley
drjohnfarley@myhepdoc.com
1141 Main St, Vancouver
BC V6A 4B6
Tel - (604) 687-1147
Fax - (604) 628-8642

1. BACKGROUND/OBJECTIVE

According the data of the Canadian HIV/AIDS Legal Network, the prevalence of HCV in correctional institutions is estimated at 24 to 80% and will continue to rise [1,2], and the prevalence of HIV/AIDS is estimated at 1.8 % [2].

Earlier we have reported that HCV can effectively be treated in prison population. Here we are presenting the clinical epidemiology, treatment outcomes and results of the long term (4 years) follow up of inmates who has been successfully treated in our clinic in British Columbia between January 2002 to May 2009.

- A HCV re-infection is defined to be a new infection that occurs after a previous infection is resolved or treated, the initial infection is considered to be treated if sustained virologic response (SVR) is achieved and a new or the same genotype is detected, or the new genotype detected is different than the original genotype regardless of whether SVR is documented[3].

2. METHODS

Retrospective chart review of prison inmates. Patient population included in chart review comprised: 1. inmates treated with Rebetron (Intron (alfa interferon) and Ribavirin) during 2002-2003 (N=91); 2.inmates treated with Pegetron (Interferon alfa-2b and Ribavirin) during 2004-2009 (N=234); 3. inmates treated with Pegasys (Interferon alfa-2a and Ribavirin) during 2004-2009, (N=154).

We followed up inmates in the prison as well as after release into community for a period of six months to four years by monitoring their serum transaminases (ALT / AST) and levels and HCV RNA. The following criteria were set for identifying re-infected patients: (a) they were initially infected with HCV and were treated; (b) they, subsequently, had elevated levels of ALT enzymes; (c) they were tested positive for HCV again; (d) and further genotyping testing was done to confirm a different acquired genotype from the original infection to obliterate a relapse possibility. The probable date of the re-infection was estimated at the halfway-point between the date of the last negative HCV test and the date of the first subsequent positive HCV test , or when the person identified probable high-risk exposure; we calculated the duration between the date of SVR and the date of the assumed reinfection and the number of cases per 100 person-years was also calculated.

3. Results

Of 479 .: HCV not detected 6 months post EOT.

110 patients who had SVR were followed up post SVR for a range of six months to four years. Of those, (69 %) were former IVU and likely acquired the initially HCV through intravenous drug use.

During follow up period of 4 years total 34 re-infection cases were identified, those who became re-infected .

RESULTS- Continued

Figure 1. Liver Biopsy results according to the Metovir score

Figure 2. Risk factors for reinfection

Figure 3. HCV RNA post-SVR follow up

Fig.3. Kaplan-Meier plot; depicting time to Re-infection

RESULTS - Continued

Figure 5. Time of occurrence of reinfection

RESULTS - Continued

Of these 34 reinfection cases, different genotype was identified in 24 patients, others had the same genotype as before re-infection. Of 110 patients who were followed up, 1 had spontaneous clearance

The time of occurrence of re-infection had a mean of 77.7 weeks after the scheduled EOT and a standard deviation of 49.0 weeks. The likely causes of re-infection included intravenous drug use, percutaneous contact, and tattooing. Last year, we reported fifteen cases of re-infection; as we continued to monitor, 17 new cases have been identified, making it a total of 33 re-infection cases.

The indication for a successful treatment for HCV is currently attaining SVR, HCV RNA test 24 weeks post-treatment. The above graph shows the time elapsed after the recommended time for testing for SVR.

4. CONCLUSIONS

Treatment of HCV in IDU in inmates of correctional institutions is feasible and effective; however, reinfection is an important consideration. The 33 reinfected cases is likely much lower than the true occurrence (of re-infection) as many individuals (especially IDUs) did not return for regular follow up visits. We recommend pre-treatment counseling as well as post treatment follow up and retesting after SVR. Harm reduction strategies should also be continually reinforced. Otherwise, reinfection may decrease the overall effectiveness of the treatment program.

5. References

1.Zou S, Tepper M, Giulivi A. Current Status of Hepatitis C in Canada. Canadian Journal of Public Health 2000;91:S10-S15.

2.Farci P, Alter HJ, Govindarajan S, et al. Lack of protective immunity against reinfection with hepatitis C virus. Science 1992;258:135–140.

3.Bassett SE, Guerra B, Brasky K, et al. Protective immune response to Hepatitis C Virus in chimpanzees rechallenged following clearance of primary infection. Hepatology 2001;33:1479-87.

4.Backmund M, Meyer K, Edlin BR. Infrequent reinfection after successful treatment for hepatitis C virus infection in injection drug users. Clin Infect Dis 2004;39:1540-1543

Differences in HCV Treatment Outcomes Between Prison and Community Populations: 8 year follow-up

John D. Farley MD[1]; MBBS, MPH[1], Gary Horvath, MD[2]; Andy Truong, M.D[1]; Esad Paripovic, CRC[1]; Trang Nguyen[1]; Wendy Shum, BA[1].
[1]1141 Main Street, Vancouver, British Columbia, Canada, [2] Doc-Side Clinic, Vancouver, British Columbia, Canada

BACKGROUND

•An estimated 270-300 million people worldwide are infected with hepatitis C virus (HCV).

•HCV is mainly transmitted through intravenous drug use (IDU), but can occur via other routes of blood-to-blood contact.

•In 2007, Corrections Services of Canada (CSC) reported that 31% of inmates have HCV (prevalence of general Canadian public is 0.8%).

•Inmates are at greater risk for HCV infection due to higher prevalence of needle sharing in penitentiaries.

OBJECTIVE

•To evaluate the differences in HCV treatment outcomes between inmates and individuals in the community.

METHODS

•Retrospective chart review of 619 individuals living in the community and in the Pacific Region Correctional Institutions of Greater Vancouver who received HCV treatment between December 1999 and July 2010.

•All virologic studies were performed at either: British Columbia Centre for Disease Control (BCCDC), or University of British Columbia Virology Department at St. Paul's Hospital.

•Treatment was based on current standard guidelines and protocols. Regimens included Interferon alfa-2b (before 2003) or pegylated interferon alpha 2a/2b with Ribavirin for 24-48 weeks depending on genotype.

•Post treatment follow ups were recommended every 6-12 months.

•Statistical analysis: Predictive Analytics Software, PASW (SPSS version 18). Univariate analysis on baseline demographic characteristics using X^2 test. P-Value of 0.05 was considered statistically significant.

RESULTS

Table 1: **Baseline Characteristics**

	Community (N=234)	CSC (N=385)	P-value
Male	149 (63.7%)	363 (94.3%)	0.00
Female	85 (36.3%)	22 (5.7%)	0.00
Mean age (years±S.D)	52.6±10.4	44.2±9.1	0.00
Geno 1	130 (55.6%)	236 (61.3%)	0.18
Geno 2	35 (15.0%)	36(9.4%)	0.04
Geno 3	64 (27.4%)	110 (28.6%)	0.78
Other Geno	5 (2.1%)	3(0.8%)	0.16

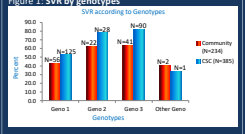
More male than female inmates were seen and treated because treating physician only started treating female inmates after 2006.

Table 2: **HCV Associated Risk Factors**

	Community (N=234)	CSC (N=385)	P-value
Admitted IDU	143 (61.1%)	369 (95.8%)	0.00
Tattoos	33 (14.1%)	239 (62.1%)	0.00
Blood transfusion	5 (2.1%)	5 (1.3%)	0.52
HIV co-infection	11 (4.7%)	53 (13.8%)	0.00

CSC population had significantly increase risks compared to individuals in the community

Figure 1: **SVR by genotypes**



P-Values: Geno 1[0.00] Geno 2[0.01] Geno 3[0.00] Other Geno [0.236]

Table 3:**Treatment Outcome**

	Community (N=234)	CSC (N=385)	P-value
Discontinued Tx	9 (3.8%)	28 (7.3%)	0.11
Lost to follow up	39 (16.7%)	44 (11.4%)	0.07
Null response	42 (17.9%)	47 (12.2%)	0.06
Relapse	23 (9.8%)	19 (4.9%)	0.02
SVR	121 (51.7%)	244 (63.4%)	0.00
Other (*partial response*)	0 (0%)	3 (0.8%)	0.29

Inmates had higher SVR and lower relapse rates possible due to more availability and earlier initiation of treatment.

Table 4: **Long Term Follow Up**

	Community(N=234)	CSC (N=385)	P-value
Admitted IDU after Tx	1 (0.4%)	22(45.7%)	0.00
Re-infections identified	1 (0.4%)	52 (13.5%)	0.00
Death	15 (6.4%)	15 (3.9%)	0.18

IDU after treatment is highly associated with re-infection.

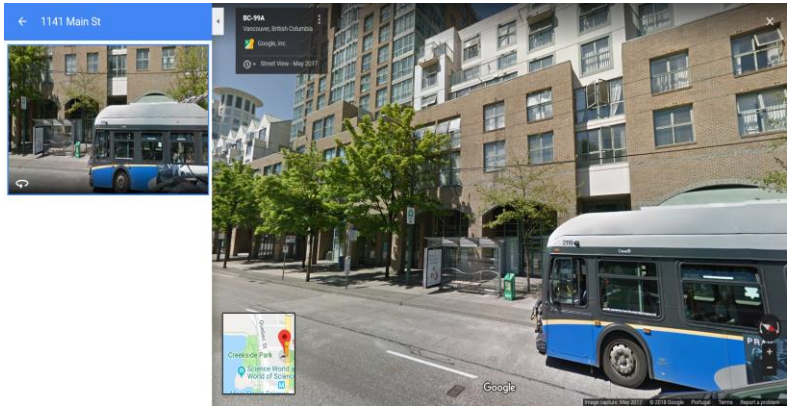
CONCLUSIONS

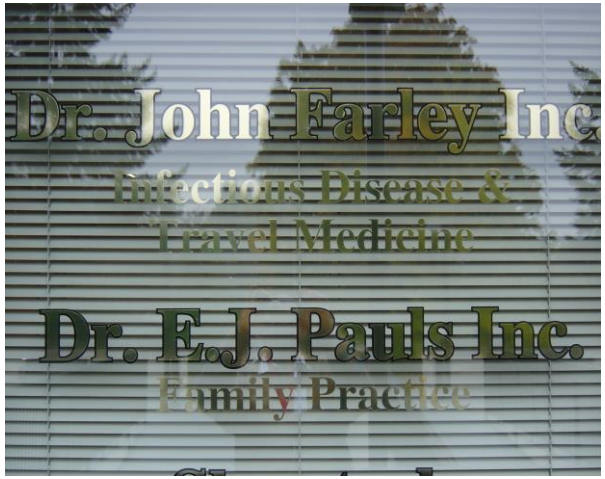
•Providing HCV therapy for inmates was effective as shown by comparable SVR rates to community population.

•HCV re-infection rate was higher among inmate population; possibly due to the higher rate of IDU after HCV therapy.

•More harm reduction programs, follow up programs after release and community engagement programs are needed to make current HCV treatment programs in correctional institutions more effective.

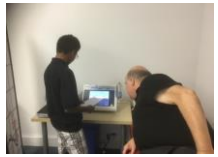
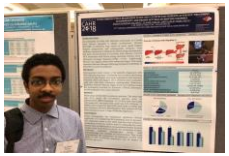
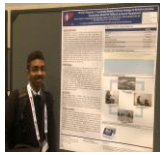
"Dr Farley is My Family Doctor"
About 20% of Main street Vancouver clinic: Inmates (& Former Inmates)
Getting Primary care – A challenge

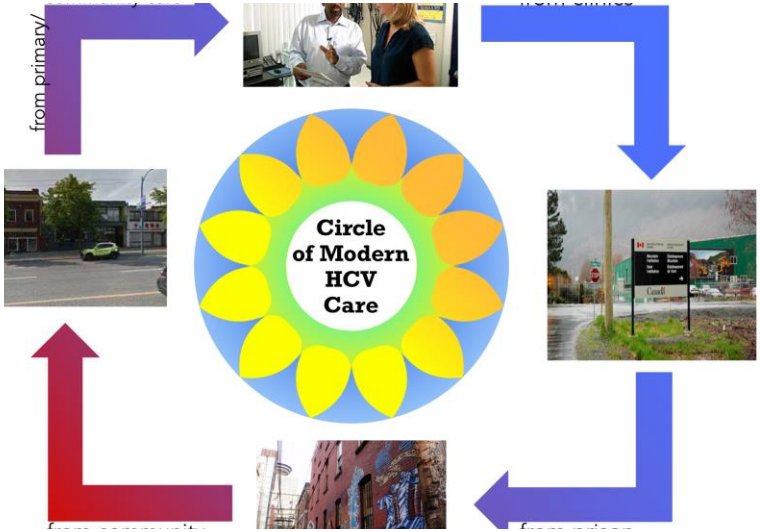




COMMUNITY PARTICIPATION





Review 2018 Patients on DAAs

- Eight Federal Canadian prisons and two community-based clinics in Vancouver.
- 439 HCV-infected patients treated with DAAs in 10 centers by a healthcare team under the supervision of one infectious diseases specialist from March 2015 to December 2017
- Most were treated for 12 weeks;
- seen by the nurses on average 4-5 times and by the specialist 2 times during treatment course.
- Post-treatment HCV RNA determination was available for 389 cases;
- SVR (12 week post): achieved 381 (98 %).

Conclusion

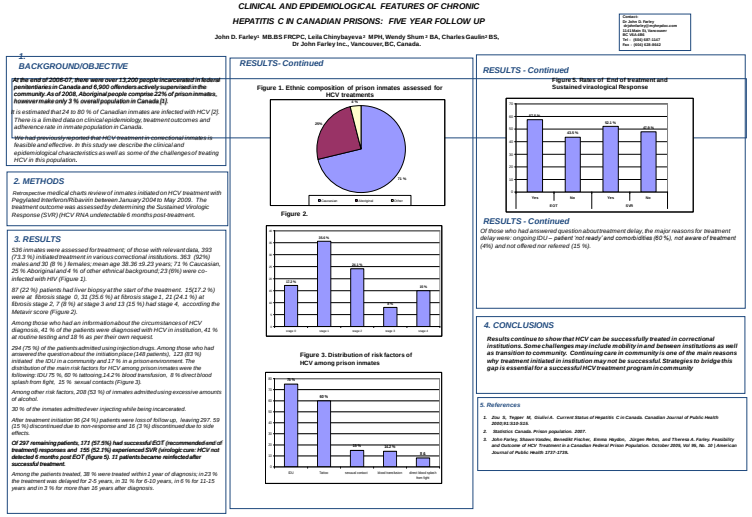
- Our HCV care model demonstrated that treatment in multiple centers can be successfully achieved by trained primary healthcare professionals **with input from specialists**.
- This model of HCV treatment can be adopted in diverse settings and can address most cases (~90%).
- This will reduce wait times for HCV treatment and reduce specialist service strain.
- It will contribute to the goal of elimination of HCV while helping address the epidemic.
- .

THANK YOU

THANK YOU ☺

InCoHRS Summary (Jun – Dec 2004)

Month	#Referred to InCoHRS	#On Tx	#Referred (by InCoHRS) to G.P
June	9	2	5
July	15	8	3
August	15	1	6
September	6	5	5
October	5	3	3
November	7	5	5
December	10	5	7
Total	***67***	***29***	***34***



CLINICAL AND EPIDEMIOLOGICAL FEATURES OF CHRONIC HEPATITIS C IN CANADIAN PRISONS: FIVE YEAR FOLLOW UP

John D. Farley[a] MB,BS FRCPC, Leila Chinybayeva [a] MPH, Wendy Shum [a] BA, Charles Gaulin[a] BS, Dr John Farley Inc., Vancouver, BC, Canada.

1. BACKGROUND/OBJECTIVE

At the end of 2006-07, there were over 13,200 people incarcerated in federal penitentiaries in Canada and 6,900 offenders actively supervised in the community. As of 2008, Aboriginal people comprise 22% of prison inmates, however make only 3 % overall population in Canada.[1]

It is estimated that 24 to 80 % of Canadian inmates are infected with HCV.[2]. There is a limited data on clinical epidemiology, treatment outcomes and adherence rate in inmate population in Canada.

We had previously reported that HCV treatment in correctional inmates is feasible and effective. In this study we describe the clinical and epidemiological characteristics as well as some of the challenges of treating HCV in this population.

2. METHODS

Retrospective medical charts review of inmates initiated on HCV treatment with Pegylated Interferon/Ribavirin between January 2004 to May 2009. The treatment outcome was assessed by determining the Sustained Virologic Response (SVR) (HCV RNA undetectable 6 months post-treatment.

3. RESULTS

536 inmates were assessed for treatment; of those with relevant data, 393 (73.3 %) initiated treatment in various correctional institutions. 363 (92%) males and 30 (8 %) females; mean age 38.36 ±9.23 years; 71 % Caucasian, 25 % Aboriginal and 4 % of other ethnical background.23 (6%) were co-infected with HIV (Figure 1).

87 (22 %) patients had liver biopsy at the start of the treatment. 15(27.2 %) were at fibrosis stage 0, 31 (35.6 %) at fibrosis stage 1, 21 (24.1 %) at fibrosis stage 2, 7 (8 %) at stage 3 and 13 (15 %) had stage 4, according the Metavir score (Figure 2).

Among those who had an information about the circumstances of HCV diagnosis, 41 % of the patients were diagnosed with HCV in institution, 41 % at routine testing and 18 % as per their own request.

294 (75 %) of the patients admitted using injection drugs. Among those who had answered the question about the initiation place (148 patients), 123 (82 %) initiated the IDU in a community and 17 % in a prison environment. The distribution of the main risk factors for HCV among prison inmates were the following: IDU 75 %, 60 % tattooing,14.2 % blood transfusion, 8 % direct blood splash from fight, 15 % sexual contacts (Figure 3).

Among other risk factors, 208 (53 %) of inmates admitted using excessive amounts of alcohol.

30 % of the inmates admitted ever injecting while being incarcerated.

After treatment initiation 96 (24 %) patients were loss of follow up, leaving 297. 59 (15 %) discontinued due to non-response and 16 (3 %) discontinued due to side effects.

Of 297 remaining patients, 171 (57.5%) had successful EOT (recommended end of treatment) responses and 155 (52.1%) experienced SVR (virologic cure: HCV not detected 6 months post EOT (figure 5). 11 patients became reinfected after successful treatment.

Among the patients treated, 38 % were treated within 1 year of diagnosis; in 23 % the treatment was delayed for 2-5 years, in 31 % for 6-10 years, in 6 % for 11-15 years and in 3 % for more than 16 years after diagnosis.

RESULTS- Continued

Figure 1. Ethnic composition of prison inmates assessed for HCV treatments

Figure 2.

Figure 3. Distribution of risk factors of HCV among prison inmates

RESULTS - Continued

Figure 5. Rates of End of Treatment and Sustained virological Response

RESULTS - Continued

Of those who had answered question about treatment delay, the major reasons for treatment delay were: ongoing IDU – patient 'not ready' and comorbidities (60 %), not aware of treatment (4%) and not offered nor referred (15 %).

4. CONCLUSIONS

Results continue to show that HCV can be successfully treated in correctional institutions. Some challenges may include mobility in and between institutions as well as transition to community. Continuing care in community is one of the main reasons why treatment initiated in institution may not be successful. Strategies to bridge this gap is essential for a successful HCV treatment program in community

5. References

1. Zou, S., Tepper, M., Giulivi, A. Current Status of Hepatitis C in Canada. Canadian Journal of Public Health 2000;91:313-316.
2. Statistics Canada. Prison population. 2007.
3. John Farley, Shawn Hankin, Benedikt Fischer, Emma Hayden, Jürgen Rehm, and Theresa A. Farley. Feasibility and Outcome of HCV Treatment in a Canadian Federal Prison Population. October 2009, Vol 99, No. 10 | American Journal of Public Health 1737-1739.

INMATE COMMUNITY HEALTH REINTEGRATION SERVICES (InCoHRS)

Chronic Hepatitis C Eradication Model Through Primary Care in British Columbia, Canada

Authors:
Farley J[1], Jabar A[1], Farley J-R[1], Hakobyan V[1]
[1]Dr John Farley Inc, Vancouver, BC, Canada

Offenders under the responsibility of Correctional Service of Canada