The Cedar Project: Evaluating a culturally safe case management approach to support hepatitis C treatment among Indigenous Peoples who use(d) drugs in BC.

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THE CEDAR PROJECT

BACKGROUND

Settler colonialism drives the HCV epidemic among Indigenous Peoples who use drugs while imposing barriers to HCV treatment.

Cedar Project's Indigenous governance developed the Blanket Program to support Hep C treatment access and care.

The Blanket Program is a two-site pilot study nested in an Indigenous governed cohort on the traditional lands of Musqueam, Squamish, and Tsleil-Waututh (Vancouver) and Lheidli T'enneh (Prince George) Peoples.

HEP C BLANKET PROGRAM

- Blanket Program provides coordinated access to Hep C specialists with one-to-one support before, during & after treatment (9 months).
- Support is participant-led & wholistic – supporting connections to physical, emotional, mental & spiritual resources/services.
- Care is relationship-centered, honoring participant agency & strengths, and is responsive in mitigating colonial harms across systems (e.g., advocacy, transportation, & attending appointments).

STUDY AIM

Examine program's impact on adherence, treatment outcomes, & reinfection.

METHOD

Enrollment

- 60 participants enrolled between 2017-2019.
- 53% women, 32 % HIV co-infected & 78% used injection drugs in past month.

Main outcomes

- Sustained virologic response (SVR-12) at 12 weeks post-treatment.
- HCV RNA within 9 months post-treatment.
- Near perfect adherence ($\geq$ 95%) measured through self-report scale.

Analytic approach

- *A priori* non-inferiority margins, based on HCV specialists' recommendations, were set at: >80% SVR12 and <20% HCV RNA.
- Logistic regression was used to assess factors associated with imperfect adherence (>5% missed doses). Results were adjusted for city, age, and sex.

MAIN FINDINGS

Treatment outcomes: SVR-12 and reinfection

- 98% (59/60) completed treatment, with 97% clearing HCV at EOT
- 92% (55/60) cured HCV 12-weeks post-treatment (ITT proportion)
- 91% (50/55) remained HCV-free at end of study (~ 9 months) (ITT proportion)

Loss to follow-up:

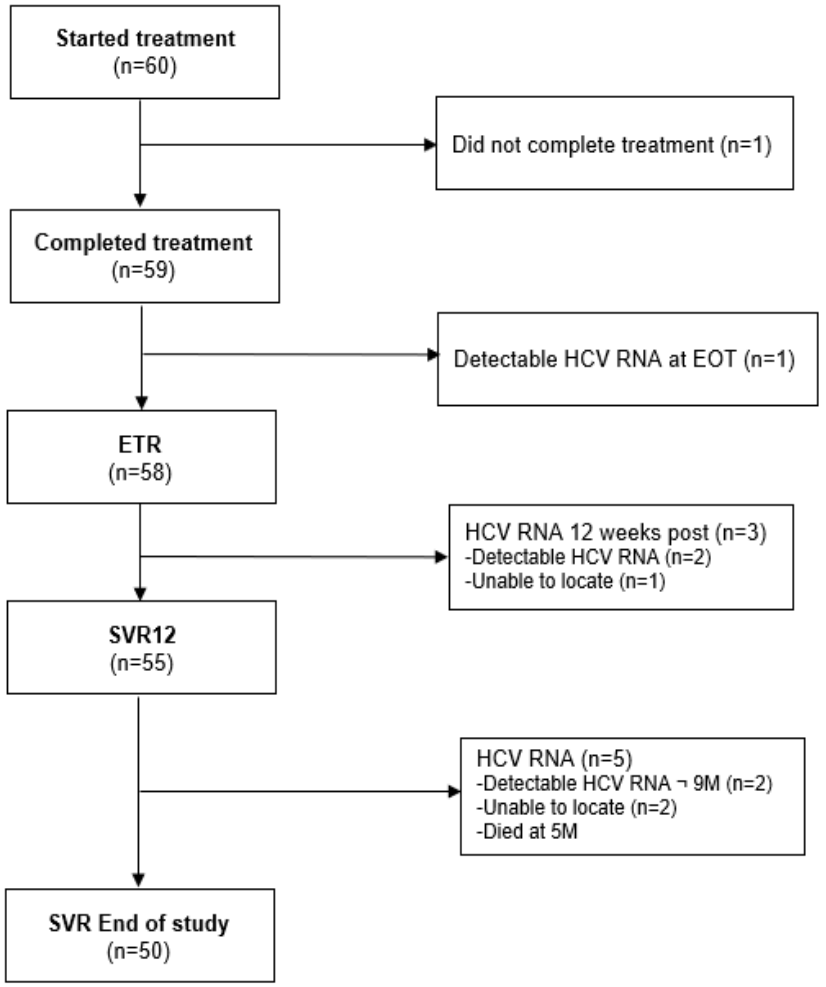
- 1 at SVR-12 and 3 at end of study -- 1 participant died of potential drug poisoning

Removing LTFU (mITT)

- 93% (55/59) cured HCV 12 weeks post-treatment
- 96% (50/52) remained HCV-free ~ 9 months after treatment

Non-inferiority Margins Results (*ITT proportion)*

- SVR-12: 92% (55/60), above the non-inferiority margin of 80% (*p*=0.012, 95% CI: 0.833, 1.000)
- HCV RNA End of study: 9% (5/55), falling below the non-inferiority margin of 20% (*p*=0.025; 95% CI: 0.000, 0.116)



Sustained virologic response (12 weeks post-tx) and reinfection at end of study (~ 9M)

ADHERENCE OUTCOMES

- 72%(43/60) adherend to ≥ 10% medication, with 28% (17/6) missing more than 10%
- 58% (35/60) adhered to ≥ 95%, with 42% missing more than 5% of medication
- 28% (24/60) of participants requested more than weekly medication support by Cedar case managers

Factors impacting imperfect adherence (> 5%)

Characteristics	Adj. β	95% CI	*p-value*
Age (Years)	0.90	0.83, 0.99	0.03
Location (Vancouver)	5.30	1.39, 20.25	0.02
Recent housing instability	11.01	2.22, 54.57	<0.01
Recent overdose	4.04	0.91, 17.99	0.07
Recent access to traditional food	0.32	0.09, 1.10	0.07

Logistic regression analysis (baseline variables)
Recent (past 6 months)

Extending Hep C Treatment: Supportive strategy

- 37% (23/60) required extended treatment, ranging from 1-5 weeks beyond 12-week regime
- Majority of participants lived in Vancouver (20/23)
- Extending treatment did not negatively impact HCV cure (SVR-12) (p =0.2)

COLONIAL VIOLENCE AND HCV RNA

Colonial harms contributing to HCV RNA

- 66% (4/6) of participants HCV RNA positive were based in Vancouver.
- Majority of participants who remained HCV positive were Indigenous women.
- Many experienced colonial violence in forms of gender-based violence; forced removal of children (past/present), unsafe living conditions and periods of living on street during study –*source: case management documentation and field observations.*
- Lack of therapies/safe supply for those using stimulates/polysubstance use may contribute to reinfection.

Timeframe	Sex	Unstable Housing	OAT	ID Type	Frequency
EOT	Female	Yes	No	Opioid	≥daily
EOT	Male	Yes	No	Polysubstance	≥daily
3 months	Female	Yes	No	Polysubstance	≥daily
3 months	Female	Yes	No	Polysubstance	≥daily
9 months	Female	Yes	Yes	Opioid	≥daily
10 months	Male	Yes	No	Polysubstance	<daily

CONCLUSION

- A culturally safe case management approach yields a high cure rate and mitigates reinfection risk among Indigenous Peoples who use(d) drugs.
- Delivery discrepancies existed between sites and limited staffing resources impacted culturally-safe care in Vancouver, likely contributing to lower adherence & higher HCV RNA.
- Indigenous women continue to bear the highest burden of colonial violence. Federal/ provincial governments must fully implement MMIW recommendations, child welfare reforms, and decriminalize substance use/provide safe supply.