Point-of-Care HCV RNA Compared to Laboratory-Based HCV RNA in a Tribal Health Setting

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BACKGROUND

Study Objective: To assess how point-of-care (PoC) versus laboratory-based standard-of-care (SoC) hepatitis C virus (HCV) RNA screening protocols affect time to treatment initiation.

Purpose:

- American Indian/Alaska Native (AI/AN) people experience disproportionately high rates of HCV infection[1]. In 2024, an FDA-approved PoC HCV RNA test[2] was integrated into community-based and clinic screening efforts within Cherokee Nation to expand access and improve HCV treatment initiation for underserved individuals.
- Persons who inject drugs (PWID), those experiencing housing instability, have current or prior justice system involvement, and/or belong to a minority racial or ethnic group are disproportionately affected by HCV, yet are often less likely to receive treatment. Thus, initiating treatment on same day or shortly after diagnosis can support engagement in care and reduce loss to follow up[3].

METHODS

- **Design:** Retrospective cohort study analyzing electronic medical record data from a tribal health system to evaluate the impact of PoC testing with incentives versus SoC HCV RNA testing on time to treatment initiation.
- SoC testing was conducted in a clinic or Emergency Department, with RNA results returned within 2-3 days. PoC testing was conducted in community settings or Infectious Disease clinic, with RNA results available in approximately one hour.
- **Study Population**: HCV positive AI/AN adults aged 22 years or older who underwent HCV RNA testing between October 30, 2024, and August 31, 2025.
- **Primary Outcome**: Time from RNA-positive test to initiation of HCV treatment.
- **Analysis:** Baseline characteristics were compared between groups using Wilcoxon rank-sum test for continuous variables and chi-square or Fisher's exact tests for categorical variables. Time to treatment was analyzed using Wilcoxon rank-sum tests and Kaplan-Meier methods. Multivariable Cox proportional hazards models adjusted for age groups, sex, substance use disorder (SUD), PWID status, and incarceration history.

Point-of-Care Hepatitis C RNA testing may decrease time to treatment initiation for underserved individuals, supporting HCV elimination efforts.

RESULTS

- A total of 24 active HCV cases were diagnosed via PoC HCV RNA testing and 125 through SoC HCV RNA testing.
- Treatment was initiated in most patients in both groups: 70.8% (17 of 24) in the PoC group and 63.2% (79 of 125) in the SoC group (p = 0.5).
- Mean time to treatment initiation was significantly shorter in the PoC group (18.2 days, median 1 day) compared with the SoC group (92.4 days, median 25 days; p < .0001). (**Figure 1**)
- Among treated patients, there were no significant differences in mean age (p = 0.35), sex (p=0.62), history of SUD (p=0.08), history of PWID (p=0.14), or incarceration history (p=0.42) (**Figure 2**)
- In adjusted Cox proportional hazards models, PoC participation was associated with a more than fourfold decrease in time to treatment initiation compared with SoC (HR 4.22, p<.0001).
- Overall, age 55-64 years was independently associated with longer time to treatment initiation (HR 0.42, p=0.03), while sex, history of SUD, PWID status, and incarceration history were not significantly associated with time to treatment.

Figure 1. Time to HCV Treatment by POC and SOC

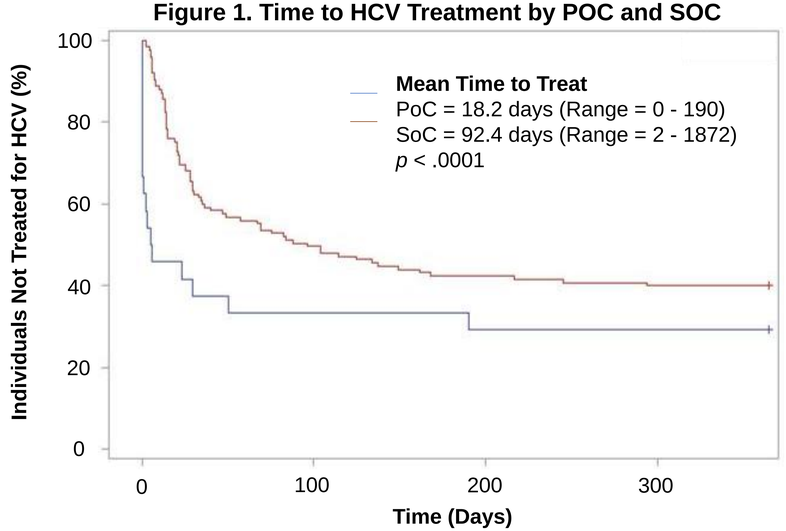
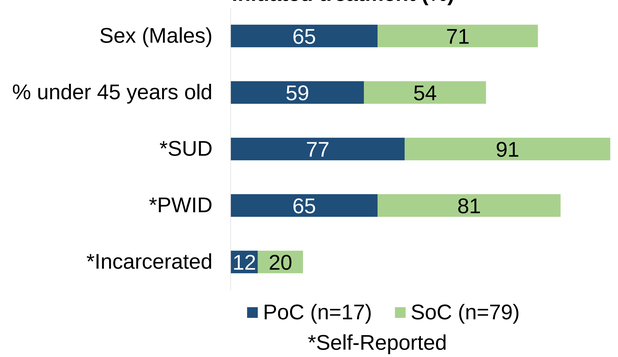


Figure 2. Characteristics of those who initiated treatment (%)



CONCLUSIONS

- PoC and SoC HCV RNA testing yielded comparable treatment initiation in our program, however, PoC HCV RNA testing significantly reduced time to treatment.
- These results highlight PoC HCV RNA testing as a promising strategy to expedite access to HCV care and improve treatment engagement, particularly among those with a history of PWID and SUD.
- Rapid treatment initiation in these populations may be critical to reducing HCV transmission and advancing HCV elimination efforts.

LIMITATIONS

- Unmeasured confounding is possible due to the observational design.
- The smaller PoC group limited statistical power, and site populations may have differed.
- Self-reported SUD, PWID and incarceration status are subject to misclassification.
- Incentives were provided only to the PoC group and may have contributed to shorter time to treatment.

PLAIN LANGUAGE SUMMARY

People diagnosed with hepatitis C using rapid, point-of-care RNA testing started treatment over four times faster than those tested through standard-of-care methods. Rapid point-of-care RNA testing and subsequent rapid treatment initiation has the potential to improve hepatitis C health outcomes.

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