Statistical Analysis Plan
Cover Page

Study Title:
Clinical utility and feasibility of a one-step HCV testing algorithm for syringe services program clients

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Administrative Information

1.1 Study Title: Clinical utility and feasibility of a one-step HCV testing algorithm for syringe services program clients

1.2 Staff Roles:

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- **Nurse Tester (PHSKC):** Kristen Wilson-Weiberg, RN
- **Additional Tester (PHSKC):** Gardenia Vivas Jimenez
- **HCV Epidemiologist (PHSKC):** Leilani Schwarcz, MPH

2. Introduction

2.1 Background and Rationale: The prevalence of HCV is high among people who use drugs (PWUD), many of whom receive harm reduction services at SSPs. While many SSPs provide rapid HCV antibody screening, the need for laboratory-based HCV RNA testing has presented a significant barrier to engagement in treatment. Results are typically not available for days, and due to high levels of poverty and housing instability, it can be difficult to reconnect and reengage with PWUD. It is critical to understand how the new Cepheid Xpert HCV VL Fingerstick point-of-care test will function in SSPs with PWUD to minimize this barrier.

2.2 Objectives: The HOT Study is a single-site, observational prospective study to demonstrate the clinical utility of a one-step HCV RNA testing algorithm at an SSP using the Xpert HCV RNA point-of-care (POC) test. The study aims are:

Aim 1: To evaluate the receipt of test results, linkage to care, and treatment initiation among PWUD who receive one-step HCV RNA POC testing in an SSP.

Aim 2: To develop best practices for utilizing a one-step HCV RNA POC testing algorithm in SSPs.

We hypothesize that PWUD who receive one-step HCV RNA POC testing at SSPs will be more likely to receive their HCV test results and begin treatment.

3. Study Methods

3.1 Study Setting: The study will be conducted at the PHSKC SSP, known as the Robert Clewis Center, which is located in the Belltown neighborhood of Seattle, WA.

3.2 Study Population

Inclusion criteria:

- Interested in and seeking HCV testing at the PHSKC RCC
- Age 22 years or older (the HCV test that will be used is FDA-approved for adults, defined by the FDA as 22+ years)
- Qualitative study: Prior participant in HCV testing component *or* SSP staff or stakeholder

Exclusion criteria:

- Already know that they have HCV (based on self-report)
- Currently receiving HCV treatment
- Already participated in testing during the study period

3.3 Data Sources: Two-hundred (200) participants will be recruited from the PHSKC SSP for HCV RNA POC testing. All testing and study data will be entered into the PHSKC REDCap program for HCV testing.

3.4 Data Collection Processes: SSP participants will be recruited during routine visits. SSP staff will refer potential participants to the study coordinator or HCV testing nurse. The HCV testing nurse will determine final eligibility. If a person provides informed consent, the HCV testing nurse or other tester will collect a fingerstick blood sample and test it using the Xpert system. While the test is running, the tester will ask the participant questions about their demographics, HCV risk, and current health care. The participant will have the option of staying until the test result is ready or returning. Once the result is ready, the HCV testing nurse or other tester will tell the participant their result and provide appropriate counseling and referrals. Once the participant has received their result, they will receive a $15 gift card incentive. Participants who have HCV will have the option of enrolling in onsite HCV treatment at any time.

For qualitative interviews, we will recruit a subsample of 12-15 participants who completed the testing component of the study: 4-5 participants who tested HCV-negative, 4-5 participants who tested positive and initiated HCV treatment, and 4-5 participants who tested positive but did not return for treatment. The goal of these interviews will be to understand the participants' previous testing experiences and interest in HCV care, present testing experiences and interest in care, and overall impressions of the one-step testing algorithm. The study coordinator and HCV testing nurse will recruit a purposive sample of these participants. Participants will complete a separate informed consent process for the qualitative interview. UW research staff will then conduct private interviews using a semi-structured interview guide. No names will be collected during the interviews. These interviews will be audio-recorded and transcribed for analysis. Participants will receive a $40 gift card for completing an in-depth interview.

Finally, we will conduct in-depth interviews will PHSKC SSP staff who were involved with the HCV testing study. The goal of these interviews will be to understand the experiences of staff who conducted the one-step testing algorithm compared to previous testing algorithms (e.g., HCV rapid screening and/or laboratory-based HCV RNA testing). Specific questions in the semi-structured interview guide will assess facilitators and barriers to providing one-step HCV testing in SSPs, as well as recommendations for implementing similar protocols in other

SSPs. These interviews will be conducted in-person and recorded and transcribed for analysis.

4. Study Outcomes and Other Variables

4.1 Primary Outcomes: The primary outcomes for this study are:

- Receipt of HCV RNA POC test results
- Linkage to HCV care, if HCV+ (i.e., attends at least one appointment related to HCV treatment)
- HCV cure, if HCV+ (i.e., sustained viral response at 4 weeks [SVR4])

These variables will all be measured using data collected during the study encounter and any subsequent encounters with the HCV nurse who also provides HCV treatment at the SSP. All data will be entered into the routine PHSKC HCV REDCap program.

4.2 Secondary Outcomes: The secondary outcomes for this study are:

- Willingness to receive HCV RNA POC test
- HCV test positivity

4.3 Other Variables: The PHSKC HCV REDCap collects additional data, some of which will be extracted for research analyses. These variables include:

- Demographics
- Medical care
- Prior testing history
- HCV risk assessment and substance use behaviors
- Medication tracking

5. Analysis Methods

5.1 Primary Outcomes: We will use descriptive statistics to analyze the primary outcomes. We will not conduct any statistical testing.

- Receipt of HCV RNA POC test results: We will calculate the proportion of all people who receive the HCV RNA POC test who receive their final result.
- Linkage to HCV care, if HCV+: We will calculate the proportion of all participants who test positive for HCV that attend at least one appointment related to HCV treatment within 6 months of their test.
- HCV cure, if HCV: We will calculate the proportion of all participants who test positive for HCV that have evidence of SVR4 within 6 months of their test.

5.2 Secondary Outcomes

- Willingness to receive HCV RNA POC test: We will calculate the proportion of all people approached for the study who agree to complete the HCV RNA POC test.
- HCV test positivity: We will calculate the proportion of test results that are positive for HCV.

5.3 Sample Size and Power: We will test 200 participants, which is determined by budget and staffing capacity.

6. Data Management Plan

6.1 Data Access: All HCV RNA POC testing data will be directly entered into the PHSKC HCV database, which is hosted by REDCap. Only PHSKC staff who work on the HCV team have access to those data. To create a dataset that can be analyzed by the UW research team, the PHSKC epidemiologist will extract a deidentified analytic dataset from the REDCap database. The PHSKC HCV epidemiologist will extract the list of study participants from REDCap, including any subsequent treatment appointments, prescriptions, or SVR4 tests in the 6 months following their testing. She will also search the PHSKC HCV surveillance database to determine whether participants have evidence of SVR4 from another provider. No other information will be requested or recorded from health care providers.

6.2 Data Storage: The PHSKC HCV testing data are stored on secure servers maintained by King County. The deidentified dataset that will be shared with UW researchers will be stored on a secure OneDrive file maintained by UW.

6.3 Data Standards. The PHSKC epidemiologist will create a .csv file to share the deidentified dataset with the UW research team. The UW team will analyze the data in Stata or R.

6.4 Confidentiality and Dissemination. The dataset provided to the UW research team will not include any identifiers, and there will not be a linking code that connects the research dataset back to the PHSKC REDCap database. The PHSKC HCV epidemiologist who will be responsible for extracting the deidentified dataset that will be used for UW research purposes does not have any other role on this project. Outside researchers interested in these data will need to receive approval for use of the dataset from the study PI and PHSKC.

7. IRB Approval and Modifications.

7.1 IRB ID: STUDY00021203 by the UW Human Subjects Division

7.2 Initial Approval: 09/11/2024

7.3 Modification #1: 09/26/2024